Abt Associates Inc.

CENTER FOR HEALTH AND long term care research

The Effect of Reducing Falls on Acute and Long-Term Care Expenses

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A. Justification

The Assistant Secretary for Planning and Evaluation (ASPE) is requesting clearance to conduct a demonstration and evaluation of a newly designed state of the art multi-factorial fall prevention program. Falls constitute one of the most significant and common causes of injury and disability for the elderly. It has been estimated that one in every three people age 65 and older living in the community fall in any given year and that the rate increases to one in two by age 80.[1] Fall-related injuries in older adults—fractures, joint dislocations and severe head injuries—affect mobility, independence and can even result in premature death. Falling also has been found to be associated with admissions to a nursing home and use of home health care services. As the population ages, cost-effective interventions that reduce the risk of falls can have important and positive financial and quality of life implications.

The goal of this project is to contribute to the knowledge base regarding fall prevention strategies that are cost effective, and to operationalize, implement and evaluate a comprehensive fall prevention program. This will be accomplished by obtaining a sample of individuals with private long-term care insurance who are age 75 and over and deploying an innovative fall prevention program; as well, we will employ a multi-tiered random experimental research design to evaluate the effectiveness of the proposed fall prevention intervention program.

To date, ASPE has commissioned two previous task orders whose goals were to review existing fall prevention literature; interview and appraise existing fall prevention programs around the country; develop a model fall prevention program based on this knowledge; and develop a study design to measure the impact of the fall prevention intervention on a variety of outcome measures including acute and long-term care use and costs. The proposed fall

prevention model is the culmination of extensive research and contributions from nationally recognized fall prevention experts and is designed to be effective, replicable, adoptable and affordable on a national basis.

A.1 Circumstances that necessitate the data collection

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.[2] 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 services such as nursing home and home health care. While accounting for roughly 12 percent of the U.S. 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.[3] Over one-third of the population aged 65 and older falls annually, although most falls do not lead to deaths.[4] 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.

Most falls occur in the home. In fact, 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 long-term care facility for a year or longer.[7]

Thus, fall prevention is crucial if we are to be successful in reducing one of the leading causes of excess morbidity and premature mortality in older adults and in avoiding the concomitant high costs. The major risk factors for falling are diverse, and many of them—such as balance impairment, muscle weakness, polypharmacy, and environmental hazards—are potentially modifiable. The interventions that are designed to address these various risk factors are diverse as well. However, the evidence for the effectiveness of an intervention in preventing falls has been inadequate. Even when interventions take into account the multi-factorial nature of fall risk, the results have been mixed, leading to uncertainty about which interventions are most effective for specific populations.

To gain a better understanding of which interventions may be beneficial in the Medicare population, CMS, as part of its Healthy Aging Initiative, commissioned an evidence-based systematic review of interventions in the prevention of falls. The meta-analysis did not find any clinical trials that directly compared the effectiveness of single components of falls prevention programs (e.g., a trial comparing environmental modification with exercise). For example, while there was no evidence that environmental modification or education was effective as independent components, the lack of well-designed studies precluded firm conclusions. The meta-analysis

concluded that falls risk assessment must be coupled with individually tailored follow-up interventions to be successful. While not conclusive, the evidence suggests that well-designed fall prevention programs provided to older adults can be highly cost-effective compared with current practice.

An American Geriatric Society (AGS) panel issued evidence-based guidelines for the prevention of falls in older persons. The panel specifically recommended multi-factorial interventions for community-dwelling older persons and for nursing home and assisted living residents. It recommended that multi-factorial interventions for community-dwelling older people address: gait training and advice on use of assistive technology, medication and polypharmacy review, exercise and balance training, treatment of postural hypotension, environmental modification, and treatment of cardiovascular disorders.

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 falls.[8] [9] [10] 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 long-term care and certain acute care services.

The limitations in the literature suggest that a study that focuses on a specific group of individuals, along with a set of homogeneous assessment and ongoing intervention strategies, outcomes measurements, and an analysis of the cost-effectiveness of the implemented strategies,

would make a significant contribution to the knowledge base. As part of the effort to construct such an intervention, we analyzed existing fall prevention literature and interviewed individuals currently operating nine fall prevention programs that are considered by the CDC to be among the best in the U.S. (see Appendix A for the complete Literature Review document and transcripts of the site interviews). As well, we convened a national panel of recognized experts in the field of fall prevention to obtain consensus around particular elements of a "best-practices" strategy (see section A.8 for a complete list of our Technical Advisory Group [TAG]). Based on this pre-work, we concluded that 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 and a reduction in related medical and long term care expenditures. Moreover, most of the consulted experts believed that the benefits of a well-crafted program would more than outweigh the associated costs of operating the program. A key to success was deemed to be effective targeting and tailored strategies based on individuals' assessed risks and needs.

A.1.1 Study Summary

The current study will employ an experimental and control group research design to test the effectiveness of a targeted falls prevention program. Focused on individuals age 75 and over who have long-term care insurance policies, the intervention and subsequent evaluation are comprised of the following elements: (1) detailed assessments to determine the presence of fall risk factors; (2) development of an Action Plan designed to eliminate or reduce these risk factors; (3) presentation of the Action Plan to program participants and their physicians so that the latter is armed with objective information to help assure buy-in to the action plan; (4) follow-up with the participant to encourage *"buy-in"* and compliance with recommended action steps and

assistance in securing needed services; (5) ongoing quarterly follow-ups for a two year period; and, (6) a repeat of the detailed assessments at the end of a two year period. Items 1-4 relate to the proposed intervention program, while items 5 and 6 relate specifically to the evaluation of the program. The project is unique in that it employs a targeted multi-factorial approach to the intervention and assures that the physician plays a central role in working with the participant to assure implementation of the Action Plan. Moreover, by employing an experimental design with ongoing cataloguing of program benefits and costs, we will be able to determine the cost-effectiveness of the program.

A.1.1.1. Fall Prevention Program Components

The proposed fall prevention program consists of the following elements:

1. Telephonic risk assessment
2. In-person assessment
3. Clinical review of assessment findings
4. Targeted intervention developed
5. Presentation of recommendations to participant and physician in an individualized action plan
6. Follow-up phone call to participant to "jump start" recommended action plan and answer any questions

As noted, these key outline features are based on two years of prior-research and consultation with falls prevention experts around the country. What follows is a discussion of each program component in detail, followed by an explanation of the study methodology that will be used to evaluate the effectiveness of the proposed program.

Telephonic Risk Assessment

The use of a telephonic screening mechanism in a fall prevention intervention is prudent because it allows a more effective targeting of intervention resources. It allows for the relatively quick and inexpensive identification of 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.

The purpose of the telephonic risk assessment is to (1) introduce the participant to the fall prevention program, (2) secure their interest in participating, (3) gather key background information, and (4) classify the participant into broad risk categories. Nurses experienced in long-term care risk assessment will conduct the telephone interview. The telephone interview takes approximately 20 minutes; this is based on our own experience with similar surveys in previous work as well as on the results of the pre-test. We have found in previous studies with older adults that any telephone contact over this amount of time is not conducive to retaining participants; moreover, the quality of information diminishes after an individual is on the phone for more than one-half an hour (at most).

The telephonic assessment protocol collects information necessary to stratify people into broad risk categories that inform the development of our targeted intervention strategies. The telephone survey is administered to everyone recruited to the study and is used to randomize the sample into control and experimental groups. It provides important baseline data to enable analysis of changes over time in variables of interest and it assures that the control and experimental groups are indeed similar in relevant respects. The key areas to be probed include information related to *intrinsic* falls risk factors like the medical, functional, and cognitive status of the individual along with falls history, and *extrinsic* factors, which are issues related to the home environment. To assure information accuracy and consistency, the protocol includes a number of scales measuring elements of similar domains. Also, because we are interviewing older adults age 75 and over, we have included a telephonic cognitive screen, so that we may

automatically contact a proxy if cognitive issues are detected; this screen has been used extensively in the gerontology field.

The full telephone instrument can be found in Appendix B. We have done extensive work to incorporate all of the necessary components recommended by our panel of experts and those items that we know from previous study experience assure validity and reliability and can be implemented so that the interview is not too long, difficult or burdensome. The phone screen is sensitive enough to be able to classify participants into fall risk categories that will inform the targeted intervention, and concise enough so as not to burden them. Pre-tests of this instrument have borne this out. Finally, we have replicated questions from a number of national surveys such as the National Long-Term Care Survey and the Women's Health and Aging Survey. Many of the questions have been administered to well over one million elders over the past decade in the context of insurers' risk assessment process.

In-person Assessment

The in-person assessment, which is administered to everyone in the experimental group, builds upon the data collected during the telephone interview. 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 the telephone. 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 interview, except in those instances where information might have changed since the time of the telephonic interview. We briefly review those answers and ask if there were changes, and document those accordingly.

Aside from the importance of visual observation of the individual functioning in their home environment, the nurse will also focus on issues related to medication management. Medication screening is very important, in part because the presence of multiple medications has been shown to be a major risk factors for falls.[11] At the time of the in-home assessment we will obtain a list of every medication the individual is taking, including over-the-counter (OTC) drugs. There are broad classifications of medications that can increase the risk of a fall. These will be noted on the assessment and summarized on the action plan that is sent to the physician for review.

Nurses experienced in long-term care risk assessment will conduct the in-person assessment; each has a minimum of two years of geriatric experience. The complete in-person interview instrument can be found in Appendix C. Note that some of the elements from the telephone interview are included here so that any possible changes or discrepancies from the phone interview can be noted and important information validated.

The in-person assessment takes approximately one hour and 15 minutes to administer. During our pre-testing of this instrument, the interview time ran from 45 minutes to one hour and 15 minutes. The length of the interview depends largely upon the extensiveness of the participant's medical history and number of medications. We have found from previous research with this population that an interview of up to two hours is not an excessive amount of time to spend gathering information; nevertheless, the current instrument is expected to take much less time. Taken together, the telephonic and in-person assessments are the first element in assuring a successful intervention: both are designed to obtain a very clear picture of the individual, their risk factors, and the potential strategies for ameliorating those risk factors. Again, many of the questions on the in-person interview have been used extensively by the long-term care insurance

industry on more than one million elderly applicants and can be found in many national studies of elderly and disabled populations.

Clinical Review of Assessment Findings

A clinical team will review the findings from both the telephonic risk assessment and the in-person evaluation for consistency, accuracy and completeness. A registered nurse who will serve as a case manger for a particular participant will conduct this review. Based on the findings of the assessment, the nurse will make clinical recommendations and develop an *"Action Plan"*, that is, a specific cataloguing of the recommended targeted intervention components, given the individual's needs. The activities involved in this clinical review and Action Plan development are summarized in Table 1.

Table 1: Summary of Clinical Review

1. Review for completeness and internal consistency;
2. Review medications for interactions and number ≥ 10;
3. Review for balance problems, gait problems, or muscle weakness;
4. Review Medical History for new or unstable concerns, including cognitive deficits, requiring primary Physician Assessment;
5. Review for recurrent falls;
6. Review for functional loss requiring supportive services or assistive devices in the home (or the suggestion of changing living environment);
7. Review for necessary home hazard modifications;
8. Make Intervention Recommendations;
9. Prepare Action Plan to be delivered to participant.

Targeted Intervention Components

The multi-factorial assessment strategy 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 any or all of the following:

1. Health promotion and fall prevention education materials
2. Home modification(s)

3. Physician visit (with medication review)
4. Exercise program
5. Supportive home care services

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. However, we will first discuss the issue of targeting, an important component in assuring a cost-effective program.

Targeting Criteria

Gillespie et al. (2003) point out that interventions which target known fallers 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.[12] 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. If someone has experienced a prior fall, they are more likely to receive a more comprehensive Action Plan. With that said, the goal is to individually tailor the intervention strategies to meet the specific risk factors identified for each individual.

Health Promotion and Fall Prevention Education Materials

A Health Promotion and Fall Prevention Education Packet will be provided to everyone who receives a telephone assessment. It will include the following necessary components: Fall

awareness and home safety information; Wipe-off medication management planner; a National Institute on Aging (NIA) developed exercise video; Fall calendar; Exercise Diary, including functional goals; and a Pedometer. See Appendix D for the materials that will be included in the Health Promotion and Fall Prevention Education Packet.

Exercise

The challenge is to implement exercise interventions that are practical, yet efficacious. The fall experts we consulted agreed that the appropriate focus is on 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 would be evaluated with an eye toward determining the need for a referral to a Physical Therapist (PT). The Physical Therapist's 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, and flexibility), frequency and duration of treatment.

The TAG agreed 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 National Institute on Aging (NIA) exercise video will be the "default" exercise program with an exercise diary to encourage participants to keep track of their level of exercise. In addition, people will be encouraged to walk and to accumulate as many as 10,000 steps every day. Pedometers will be part of the Health Promotion and Fall Prevention Education Packet, and can be worn to count steps and motivate people to do more walking.

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 are 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 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 felt that getting physician buy-in would be critically important. Therefore, the way this intervention component is positioned to physicians is important in gaining their acceptance to do what we are recommending for the participant. In order to accomplish this, we designed a Physician referral form (see Appendix E), which provides (in summary format) critical information found during the assessment and educates the physician about certain risk factors. 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 input. If we do not receive the information back from the physician, or if the physician is resistant to consider our recommendations, then follow-up will be necessary to try to gain compliance. We anticipate that part of the efforts of the care managers will be to educate the physician about the relationship between certain identified risk factors (e.g. multiple medications) and falls.

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 required and the frequency and duration of needed care. Taken into account is also the availability and capabilities of family caregivers to support the participant. These caregivers are typically spouses or adult children who provide assistance at no charge; they are also the first-line providers of care with supportive home care services typically required when family support cannot alone sustain the individual in the community. Table 2 lists the types of supportive home care services that may be suggested to assist the person to remain safely and independently in their home. These services are typically recommended to individuals who have limitations in activities of daily living (ADLs) or in instrumental activities of daily living (IADLs).

Table 2: 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

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. Many modifications are relatively simple to do and will be done by the assessor while at the home. These "small modifications" include installing night-lights and bath mats, taping down loose scatter rugs, and installing extension cords in a safe manner. Many of the other possible recommendations for home modifications or durable medical equipment (DME) that would be included on the Action Plan are shown in Table 3. In many cases, assistive

devices such as a walker, or other therapeutic devices, will need to be ordered by the physician and part of the intervention strategy is to assure that the appropriate need is well documented (through the assessment process). The clinical team will also make arrangements with a DME vendor to assist the individual in obtaining any needed pieces of equipment and allay concerns about installation.

If additional items not previously mentioned are discovered during the home safety review (for example, broken stairs or missing stairway handrails), the participant will 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 participant is responsible for making the decision to proceed with modifications and would be responsible for all of the costs associated with these modifications to the extent that they are not reimbursed by other sources (such as Medicare or long-term care insurance).

Table 3: 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

Action Plan Recommendations and Delivery

The results of the Assessments and the recommended Interventions are delivered to the participant in the form of an Action Plan (see Appendix F). The Action Plan includes a summary of the findings and recommended "Action Steps." It lays out for the participant all of the details of the recommended Intervention tailored to meet the deficits identified in the

Assessment. It is a written document, with specific prescriptive services for Intervention, as described above. It include goals for the participant to achieve (for example, as with exercise), and provides specific directions for how to implement the recommended Interventions. The primary Action Plan components are as follows:

1. Assessment Summary
2. Action Steps
3. Referral to Primary Physician – including reason
4. Referral Recommendation for Home Health Care Services – including reason and recommendation (may also need to involve physician)
5. Referral Recommendation for Physical Therapy – including reason and recommendation (may also need to involve physician)
6. List of Equipment needed
7. List of Home Repairs needed
8. Specific home exercise program given to participant

Jump Start Phone Call

Our panel of experts agreed that giving participants the names or places where they might be able to find services would not necessarily be effective, because individuals would not follow through on their own. Therefore, as part of the Intervention, a care manager will call the participant and review both the assessment results a well as the specific Action Plan components. The purpose is to gain the participant's acceptance of the Intervention and to assist the individual by helping to "jump start" the implementation of the recommendations.

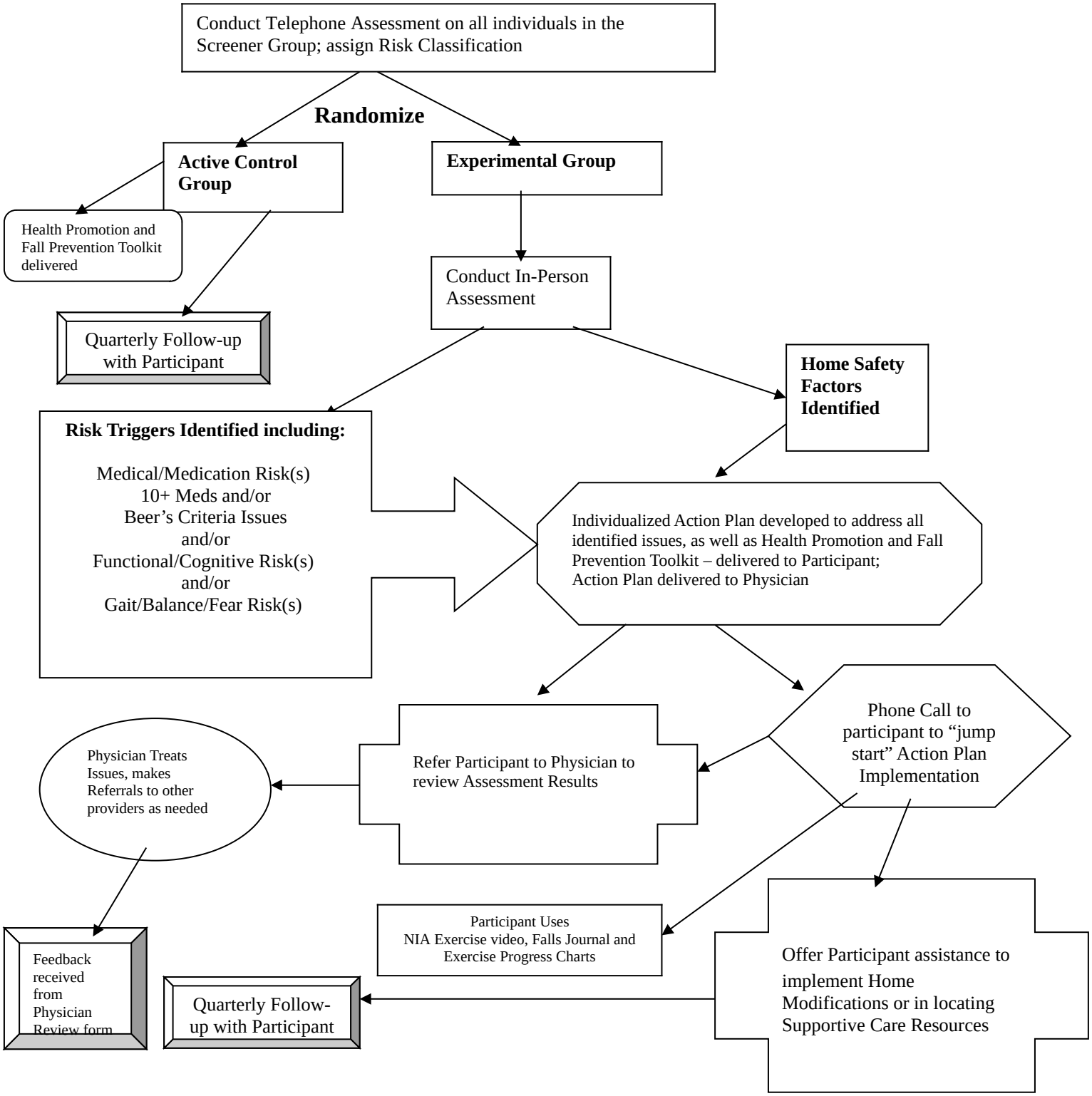
A.1.1.2. Evaluation Components

It is important to distinguish between those items that are part of the proposed fall prevention intervention (which are detailed above) and items that relates strictly to the evaluation of the program. There are two datasets that will be used for evaluating the cost-effectiveness of the program. These include: (1) data from Medicare on the acute care costs of a random sample of beneficiaries; and (2) data from Medicare and participating long-term care insurance companies on the acute and long-term care costs of policyholders who participate in the study.

In addition to this data, we will be making quarterly telephone calls to study participants to determine if there has been any change in their health status, medication use or hospital use, and to record any falls they may have had and the circumstances surrounding them. Additionally, we will collect information on any fall prevention activities they have been involved in and their compliance with the recommended action plan that they received as part of the fall prevention program. See Appendix G for the full quarterly telephone instrument.

The schematic that follows in Figure 1 summarizes the process flow for both the intervention and evaluation components of the study.

Figure 1: Process Flow for Fall Prevention Study



A.1.2 Sample

For this project we will collect 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 long-term care insurance policyholders from one or two insurance carriers.

We will draw a sample of 8,000 individuals aged 75 and over that have private long-term care insurance policies and are not currently residing in nursing homes or assisted living facilities and are not currently on claim. 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.[13] There are a number of reasons for drawing a sample of policyholders with long-term care 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 as a control sample. Thus, setting up the experimental design can be done in a very cost-effective manner.

Second, we can easily track service utilization during the study period; the insurers' administrative systems will enable us to track the frequency, intensity, and duration of any long-term care 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 can 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. Put another way, it will greatly enhance our ability to recruit sample because we will have the "backing" or seal-of-approval from the

individual's insurance company. We have already secured the commitment from one and possibly a second company to participate in such a demonstration project. See Appendix H for the commitment letter.

All potential participants will receive the same explanatory letter and informed consent introducing the study. This letter will come from the insurance company in order to lend weight and credibility to the study and boost participation. It 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 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. See Appendix I for a sample of the introductory letter and HIPAA release form.

The participating sample will then be randomized in equal numbers to a screener group (those who will receive a telephone screen) and to an administrative control group (ADCG) (those who will not receive a telephone screen). Those in the screener group will then receive the telephonic risk assessment to classify their fall risk into specific categories and be further randomized into two equally sized groups: an active control group (ACG) and an experimental group (EG).

Our ultimate goal is to have a final sample of at least 1,200 individuals in the Active Control Group and 1,200 individuals in the Experimental Group. 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 80% participation rate and will lose roughly 4% a year to attrition[14].

By focusing on a sample of long-term care insurance policyholders over age 75 and employing a multi-tiered random experimental design to implement and evaluate the proposed fall prevention program, we hope to answer the following major research questions:

1. Is the proposed intervention more likely to prevent falls and reduce fall risk factors than no planned intervention?
2. Does the proposed intervention affect aggregate acute and long-term care use and costs, and if so, by how much?
3. Is the proposed intervention cost-effective in reducing long-term care and acute care utilization relative to no intervention at all?

Obtaining answers to these questions is an important step toward understanding whether the proposed fall prevention program is effective in both reducing falls and reducing the cost of acute and long-term care. Data collected from this study will enable policymakers to determine the efficacy of supporting and implementing a program on a national level.

A.2 Use of the Information and Consequences if Data Collection is not Completed

Obtaining answers to the questions posed by this research is important from both a public policy and private program development perspective. First, the rapid increase in health care expenditures -- due in part to the aging of the population -- has policymakers reexamining ways to effectively support cost-effective prevention programs. Heretofore, there has been limited empirical evidence that demonstrates definitively that a well conceived falls prevention strategy leads to meaningful reductions in acute and long-term care costs. The proposed study is designed to do just that. In the absence of the information that will be available from this study,

it would be difficult for policymakers to seriously consider, let alone debate, the merits of supporting fall prevention efforts through Medicare or Medicaid initiatives.

Second, there are many local programs around the United States that are designed to reduce falls among older adults. Yet, few of the program components have ever been evaluated to see if they are effective. Therefore, although significant time, energy, and resources are being allocated to these efforts, it is unclear what impact they are having on reducing falls or reducing the risk of falls. The current study would provide extremely useful information to such programs and highlight what strategies do and do not meet the overall objective of reducing falls; this would likely lead to implementation of more effective strategies and fewer wasted resources nationwide.

Third, an increasing share of state Medicaid budgets is allocated to nursing home care and this is leading to tremendous fiscal strain across the states. In an attempt to correct the institutional bias of Medicaid, a growing number of states are applying for waiver programs to expand home and community-based care programs. Others are beginning to focus efforts on prevention programs as a way to reduce reliance on formal (paid) support systems. Empirical evidence for a particular direction in fall prevention program development can assist states in expanding policies and strategies that will lead to a more effective deployment of prevention resources. In the absence of such data, additional opportunities may be lost and resources wasted as more individuals enter the long-term care or acute care system as a consequence of avoidable falls.

Finally, private organizations responsible for managing and delivering health care to the elderly are also struggling with the challenge of providing high quality care in a cost-effective manner. HMOs, commercial insurers, retirement communities, adult day care centers, and even

fraternal organizations all have an interest in assuring that their members/insured's can live independently and safely in their own homes for as long as possible. Falls prevention is an important component in any comprehensive program designed to do this. The current study will therefore provide insight into how to develop such a program, how to target prevention resources on the appropriate individuals, and how to implement a program in a way that leads to benefits outweighing costs. In the absence of the information provided by this study, there will likely remain an underinvestment in prevention.

A.3 Use of Technological Collection Techniques and Information Technology to Reduce Burden

The data collected in this study will be obtained from telephonic and in-person interviews; follow-up telephone interviews to collect information recorded by individuals on their exercise regimen and fall experience during the quarter; from the administrative system of the participating Long-term care insurance company; and from the Centers for Medicare and Medicaid Services. For a number of reasons, these interviews, as well as the follow-up phone interviews, should not prove to be burdensome to respondents.

First, the individual interviewers are part of the Family Caring Network[15] and are all highly trained and experienced nurses and social workers with a minimum of two years of experience in geriatric assessment. All have previous experience in assessing the functional (e.g. Activities of Daily Living (ADLS) and Instrumental Activities of Daily Living (IADLS)) and cognitive (e.g. TICS cognitive screen)) status of disabled elders. Many have also had experience administering survey instruments in previous national studies sponsored by ASPE and approved by OMB. They will receive training in the use of new elements of the survey instruments that they have not yet seen. Most of the questions used in the interviews are very straightforward and easy to answer and are standard to the geriatric assessment field.

Second, many of the questions have already been tested and have been used in the assessment process of about 1,500,000 elders applying for long-term care insurance or making claims on their policies. Therefore, the interviewers have substantial experience collecting information on medical, functional and cognitive abilities similar to that which they will be collecting in this study. Finally, in cases where a respondent cannot answer questions due to cognitive impairment, interviewers have been trained to identify and work with proxy respondents. This has worked well in the past (in insurance assessments and other ASPE sponsored studies) and should help to assure the collection of accurate and reliable information.

Third, the telephonic interviews will be conducted using a Computer Assisted Telephone Interview (CATI) system, which allows the interviewer to move quickly through questions and reduce the amount of time spent on the phone. The interview questionnaire is programmed into a computer in such a way that the questions being viewed by the interviewer are generated based on a respondent's previous answers. This will serve to reduce the burden on the respondent and increase the accuracy and efficiency of the interviewer each time a quarterly follow-up is conducted.

In addition to the initial phone interview and in-person interviews, follow-up phone interviews will be conducted on a quarterly basis as part of the evaluation of the demonstration. These quarterly calls are designed to obtain information on compliance with the exercise program and track falls and changes in health status. Individuals who have had extensive training in administering telephone interviews will conduct these phone interviews. They will also have had significant experience in interviewing elders. These interviews will also be conducted using a Computer Assisted Telephone Interview (CATI) system. We expect the quarterly follow-up phone calls to take between 10 to 15 minutes to complete. Given the nature

of this survey and the relatively small number of open questions, such calls should not prove burdensome to respondents; since respondents will be able to consult with the exercise and falls diary provided to them at the outset of the study, the follow-up phone interview will be completed expeditiously and accurately.

The insurer that is contributing sample to the study will provide administrative data on long-term care (LTC) policy designs and on claims payments. We have worked with this company on a common format and the computer programs have already been developed so that data transfer can occur either electronically or on diskette. Finally, a data use agreement with CMS will enable an analysis of Medicare claims data; this provides no burden whatsoever to respondents.

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[5] Gibson, JF, Andres, RO, Isaac, B. The prevention of falls in later life. Danish Medical Bulletin. 1987; 34(4): 1-24.
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[9] RAND Evidence Report and Evidence-Based Recommendations, op cit.
[10] Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, 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.
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[7] Liu, Barbara. The relationship between antidepressants and the risk of falls. Geriatrics and Aging. 2003; 6(7): 45-47.
[12] Gillespie et al, op cit.
[13] 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.
[14] Attrition is defined as participants who are no longer able to participate (different from those who refuse to participate). For instance, they may have moved and we are unable to locate them or they may have died during the study period.
[15] The Family Caring Network is a national network of nurses and care managers that conducts in-person assessments with elders who are applying for long-term care insurance or are applying for benefits under their long-term care insurance policies. In its 15th year of operation, the network of locally contracted individuals has provided services to more than 1,500,000 individuals, conducted a previous study for the federal government, and works with more than 45 insurance companies.

A.4 Description of Efforts to Avoid Duplication

To date, no other Federal agency, private consulting firm, or trade association has conducted a study or data collection effort comparable to what is proposed in this study. No program with a longitudinal study and data collection approach based on a sample of individuals age 75 and over -- who have had long-term care insurance policies for more than five years and therefore more closely resemble a general population in terms of health status and fall risk -- exists. The project's Technical Advisory Group is comprised of policymakers, practitioners, academics, and generally recognized national experts on falls prevention. These individuals have all verified that the proposed study does not duplicate other studies or efforts of which they are aware. We conducted an extensive review of fall related literature and currently operating fall prevention programs around the country and every effort has been made to avoid unnecessary duplication and to ensure that the research team is abreast of any related studies on falls prevention and efforts to measure the cost-effectiveness of approaches.

A.5 Minimization of Burden on Small Businesses

Does Not Apply

A.6 Consequences to Federal Program if Collection is not Conducted

As noted in section A.2, the information collected here will assist policy related activities designed to support cost effective fall prevention activities and reduce both the financial and system delivery burden caused by the problem of falls in older Americans. We believe we have designed an intervention and data collection method that will accurately and effectively address the outstanding questions and gaps in existing fall prevention work that will enable policymakers to make informed decisions when considering the issue of falls. Each contact with participants is

designed to be brief, yet effective and we believe it does not cause undue burden. We are not aware of any legal or technical obstacles to reducing burden for the proposed study.

A.7 Special Circumstances

Does Not Apply

A.8 Public Comments and Consultation with Outside Experts

A 60-day Federal Register Notice was published in the *Federal Register* on March 17, 2006, vol. 71, No. 52; pp. 13850. There were/were no public comments. There are a number of individuals outside of ASPE and their contractors (Abt, Associates –who has responsibility for conducting the evaluation -- and the Center for Health and Long-Term Care Research – who has responsibility for implementing the demonstration) that have been consulted on the design of the study, as well as on the development of all of the survey instruments and clinical protocols. The most prominent include members of the Technical Advisory Group and individuals involved in implementing exemplary Fall Prevention Programs around the United States. Members of the TAG include:

Experts		Address/Phone
1	Rein Tideiksaar, Ph.D. Senior Vice President	ElderCare Company Blackwood, NJ 08012 Email: lvrein@aol.com Cell: 856-374-2790
2	Lewis Lipsitz , MD Vice President for Academic Medicine and Irving and Edyth S. Usen Director of Medical Research	Hebrew Rehabilitation Center Department of Medicine 1200 Centre St Boston, MA 02131 lipsitz@mail.hrca.harvard.edu Llipsitz@bidmc.harvard.edu Ph:617-363-8318 Fax: 617-363-8929
3	Laurence Rubenstein, MD Director, Geriatric Research Education and Clinical Center	Sepulveda VA Medical Center 16111 Plumber Street Sepulveda, CA 91343 Attn: GRECC Mail Code 11E Laurence.rubenstein@med.va.gov 1-818-895-9311 x9066
4	Judy A. Stevens, PhD Epidemiologist, Division of Unintentional Injury Prevention	Centers for Disease Control and Prevention 4770 Buford Highway NE MS K-63 Atlanta, GA 30341 jas2@cdc.gov (770) 488-4649
5	(Bonita) Lynn Beattie, MPT, MHA Assistant Vice President, Research and Demonstration	The National Council on Aging 300 D Street, SW Suite 801 Washington, DC 20024 bonita.beattie@ncoa.org 202-479-6698
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7	David. C. Stapleton, Ph.D. Director	Cornell University Institute for Policy Research 1342 22nd St., NW Washington, DC 20037-3010 V: 202 223-7670 Ext. 101 Fax: 866-371-1633 dcs28@cornell.edu
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9	Pauline Lapin, MHS Director, Healthy Aging Project	DHHS/CMS/OA/CBC/QMHAG/DHPDP South S3-02-01 Baltimore, MD PLapin@cms.hhs.gov 410-786-6883
10	Susan Coronel Long Term Care Director	America's Health Insurance Plans (AHIP) 601 Pennsylvania Avenue, NW South Building Suite 500 Washington, DC 20004 (202) 778-3202 Scoronel@HIAA.org
11	Vicki A. Freedman, Ph.D. Professor Department of Health Systems and Policy	UMDNJ-School of Public Health 335 George Street, Suite 2200 New Brunswick, NJ 08903 Tel: (732) 235-9061 Fax: (732) 235-9780 vfreedman@umdnj.edu
12	Rosemary Yancick, PhD. Health Scientist Administrator	Geriatrics and Clinical Gerontology Program National Institute on Aging, NIH 7201 Wisconsin Avenue, Suite 3C307 Gateway Building, MSC 9205 Bethesda, MD 20892 Phone: (301) 496-5278 Fax: (301) 402-1784 email: yancikr@nia.nih.gov

In July of 2004 we held a two-day meeting in Washington, D.C. with the TAG to review the findings of the comprehensive review of the literature and our recommendations for the key elements of an effective falls prevention program. At that time, we also discussed the evaluation strategy. Along with additional telephone consultations, these interactions addressed study objectives and design, research hypotheses, methods for sample recruitment and retention, and sources and methods of data collection. As a result of these meetings, the broad parameters of the prevention and evaluation strategy were delineated and agreed to by the Technical Advisory Group.

In July 2005, after the project team had developed a detailed work plan laying out how the program was to be operationalized and implemented, the TAG met again for a two-day

meeting. At this time, clinical protocols were reviewed as well as all of the assessment instruments, communication documents to participants and their physicians, and the implementation plan and strategy. Based on the input of the TAG, we made additional revisions to the project plan and instruments and shortly thereafter conducted a pretest. We also utilized whenever possible survey questions that had been used in other national studies and had been verified for validity and reliability.

A.9 Payment to Respondents

There will be no payments to respondents

A.10 Assurance of 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 identifying information. All data file transfers will be encrypted and paper data will be kept in locked file cabinets until it is scanned and entered into a database. At this point, the originals will be shredded.

A.11 Justification for Questions of a Sensitive Nature

There may be certain questions that may be viewed as sensitive by respondents, particularly those related to cognitive ability, and certain activities of daily living. It is important to note that at the beginning of each assessment (both telephonic and in-person), the assessor gives a brief introduction to put the individual at ease and let them know that the interview focuses on general health history. In other parts of the questionnaire the nature of the

question is explained, as is the purpose for obtaining the information. For example, the introduction to the telephonic assessment reads as follows:

> **"Hi, my name is _____ and I am calling on behalf of *(Name of Insurance Company)*, your long-term care insurance company. A few weeks ago, you agreed to participate in a national study about falls prevention that your LTC insurance company is participating in. First, we want to thank you for your willingness to contribute to helping us understand such an important issue. As part of the study, we need to ask you some questions related to your general health history. It will take about 20 minutes. Do you have time to do that now or would you like to schedule a time that is more convenient for you?"**

Regarding cognitive ability, all participants will be asked to answer questions from the TICS, a widely used telephonic geriatric assessment test that has been shown to be an accurate and reliable measure of current cognitive ability. It asks questions about orientation and memory, as well as tests certain computational abilities. In some cases the answers seem so obvious that an individual may wonder why they are being asked to answer them. The interviewers, who have been trained to administer the test, preface it with the following statement:

> **"For this next exercise I am gong to ask you some questions to test your memory. Some of these are likely to be easy for you, but some may be difficult. Please bear with me and try to answer all the questions as best you can. If you can't answer a question don't worry, just try your best. If there is a television, radio on, please turn it off so that you are not distracted for this part of the interview."**

Our experience with insurance assessments suggests that respondents do answer these questions and that the test does not encumber completion of the entire survey.

Another sensitive area of the surveys may be the assessment questions related to certain functional abilities like toileting and continence. Again, these are standard questions derived from the Katz Activities of Daily Living (ADL) scale and have been used by geriatricians for over 30 years, as well as in all national studies of functional status among the elderly. The information is necessary to characterize the elderly person and every effort is made to assure that the respondent is not made uncomfortable by the question. For example, this can include a

conscious choice by the interviewer not to use the word "continence" but instead to speak to the level of understanding of the respondent her/himself.

Finally, the issue of falls can in and of itself be sensitive. Many people might feel a sense of embarrassment if they have experienced a fall. Therefore, the question is asked in a way that minimizes this. It has been used in other national surveys and reads as follows:

> **"How many times in the past 6 months have you had an episode of fainting, falling or dropping to the ground or lost your balance, slipped or tripped over something that resulted in falling or dropping to the ground?"**

Information from these and other questions will be used to characterize study participants over time and determine whether and how the intervention influences the incidence of falls among the control and experimental groups.

A.12 Estimated Annual Hour and Cost Burdens

Versions of the in-person and telephonic surveys have undergone pre-testing. Many of the questions are used in phone history interviews and assessment instruments that are administered on behalf of insurance companies and/or are used in geriatric assessment. Other sections have been extensively tested and used in other studies and settings and are related to home safety, physical performance (gait and balance), falls and demographics (race, education, income status, etc.). The estimates for total interview time is based on our pre-test, the evaluation of field staff and internal clinical staff, and the experience of insurers with implementing the functional, cognitive and medical assessment as part of the underwriting and claim processes.

The pre-test suggests that the administration of the telephonic risk assessment requires about 15 to 20 minutes to complete. The calls are made only to those who have agreed to

participate in the study and are not "cold calls." This helps shorten the amount of time that would otherwise be spent introducing the study or interviewer. The interview times vary in part because in many cases, respondents like to talk about the survey or other issues that may be on their mind. The pre-test of the in-person interview suggests that it takes between 1.0 to 1.25 hours to complete. Again, the variation was due to the fact that certain questions generated discussions with respondents and their desire to provide more information than what was requested by the interviewer.

Based on our experience with assisting disabled elders implement care plans in the insurance environment, we estimate that the phone call necessary to "jump-start" the Action Plan will take roughly 30 minutes to complete. This call occurs only one time approximately one week after the insured received his or her individualized action plan. There is a great deal of variation around the length of this call because each participant's action plan is tailored to his or her specific needs. There may be some who wish to discuss the recommendations at greater length than others. During this call, we will also be able to provide referrals to a variety of home care providers, durable medical equipment providers and community resources if requested by the participant.

There will be seven quarterly telephone calls that are not part of the intervention, but associated with the evaluation of the intervention. The purpose of these phone calls is to simply collect information about any falls that the participant has had over the past three months, any changes to their medical history and any exercise they may have engaged in. We estimate that these phone calls will vary in length from 5 minutes (for those with no falls, exercise or changes in their medical history) to 15 minutes for those who may have fallen or have medical changes to

report. Given this potential variation, we estimate an average of 10 minutes per phone call for our burden estimate.

Given our 18 years of experience in interviewing and assessing the elderly in the insurance environment, we are confident that none of these interviews or phone calls presents an undue burden on respondents. Each is within an acceptable time range and we have found that in many cases, elderly respondents desire that the interview process continue, rather than stop.

Table 4 summarizes the parameters used in making an estimate of annual and total burden hours. Although we know from previous experience that there will be attrition and drop-off (due to death, illness and refusal, etc.), we have kept the sample size (number of respondents) constant for the purposes of the table. Table 4 includes an annual burden column (which represents the total project burden divided by the 2 years over which the fieldwork will take place), as well as a project total burden column.

Our intention is to do a more comprehensive and extensive field test, focusing mainly on the intervention processes and the response rates as part of the third phase of this project. Once OMB clearance has been obtained, we will undertake a field test of all the instruments and processes involved in the intervention with a sample of 30 individuals drawn from one of the participating insurance companies. This field test will include an initial phone call, initial in-person interview, jump start phone call and two quarterly follow-up calls. The burden hours associated with this field test are shown separately in Table 4a.

As shown, the total number of burden hours is estimated to be 6,060, which includes the project total and the field test burden.

We do not anticipate any cost burden to the respondents associated with their participation in the study. The individuals who participate in this study will be long-term care

insurance policy holders over the age of 75. The vast majority are likely to be retired, and those that are still working will be able to schedule the interviews and phone calls at their convenience (during non-work hours) as our trained clinicians doing the interviews work nights and weekends in addition to daytime hours. Therefore, there are no costs to respondents associated with the hours presented here.

Table 4: Estimated Annualized and Total Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hrs)	Total Annual Burden Hours
LTC Policyholders	Telephone screen	**1,200**	1	20/60	400
LTC Policyholders	In person interview	**1,200**	2	1	2400
LTC Policyholders	Jump start phone call	**1,200**	1	30/60	600
LTC Policyholders	Quarterly telephone calls	**1,200**	4	10/60	800
Total					**4,200**

Table 4a: Estimated Field Test Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hrs)	Total Burden Hours
Field Test	Telephone screen	**30**	1	20/60	10
Field Test	In person interview	**30**	2	1	60
Field Test	Jump start phone call	**30**	1	30/60	15
Field Test	Quarterly telephone calls	**30**	4	10/60	20
Total					**105**

A.13 Total Annual Cost Burden to Respondents

Other than their time, there are no additional costs to respondents.

A.14 Estimates of Annual Cost to the Federal Government

The costs of the project can be classified as those related to the program implementation (demonstration project), and those related to the evaluation. The total costs of the demonstration are estimated at $4,000,000 over a four year period. Thus, the annual costs are $1,000,000, although these costs will likely not be divided equally among the four years. This includes the costs associated with coordinating sample recruitment; operationalizing and computerizing all of the clinical protocols; implementing the intervention in all its phases (including assessment, action plan development and coordination and final assessment), preparing all data for the evaluation phase of the project, analysis, report writing, and public and private briefings.

The evaluation related phase of the project is expected to cost $500,000. This includes activities related to data collection, data cleaning, development of all analytic files, analysis plan, quantitative analysis, report-writing, and public and private briefings.

A.15 Program Changes

This project represents a new data collection effort resulting in a single time program increase reported in Item 13 of the OMB Form 83-I.

A.16 Project Schedule and Tabulation Plan

A.16.1 Project Schedule

Table 5 summarizes the timeline for tasks associate with the implementation and evaluation of the fall prevention program. As shown, we anticipate that the project will be completed by August 2010, provided it starts in October 2006. The key project tasks include (1) sample recruitment; (2) initial telephone interview and randomization into control and experimental groups; (3) in-person baseline assessments; (4) deployment of the prevention protocols and intervention strategy; (5) quarterly follow-ups; (6) final interviews; (7) completion of evaluation and final report on outcomes of demonstration. We anticipate that the major operational development work necessary to support the implementation (CATI programming, systems development, assessor training, etc.) will commence after receipt of OMB clearance and procurement of funding. We expect that we will be able to do all of the administrative development in about 5 months, at which time, we will begin sample recruitment. Assuming that can begin the project on October 1, 2006, then we expect sample recruitment to be completed by March 2007 and the telephonic interviews to be completed by June 2007.

For individuals in the experimental group, baseline interviews will commence shortly after the telephonic-assessment has been completed. We anticipate that all in-person interviews will be completed roughly 7 months after the completion of telephonic assessments. Individuals will be monitored quarterly for just under two years after their in-person assessment. Thus, we expect to complete all data collection, deployment of Action Plans, and monitoring by January 2010.

As information is returned, it will be entered into a database for use by the evaluation team. Analysis will begin immediately once the initial assessment data is collected. Every

quarter additional data will be appended to each case so that we can track changes in health and functional status, falls history, risk factors, and compliance with the Action Plan over time. We anticipate interim reports after the baseline interview has been completed and after one full year of follow-up interviews has been completed. The final report and briefings to policymakers and insurers will occur by August 2010.

Table 5: Projected Implementation and Evaluation Timeline and Project Milestones

Task	**Estimated Time Frame**
Sample recruitment	January 2007-March 2007
Initial telephone interview and randomization into control and experimental groups	February 2007-June 2007
In-person baseline assessments	June 2007-January 2008
Deployment of the prevention protocols and intervention strategy	June 2007-February 2008
Quarterly follow-ups	September 2007-October 2009
Final interviews	June 2009-January 2010
Completion of evaluation and final report on outcomes of demonstration.	June 2010
Briefings to policymakers and participating insurers	August 2010

A.16.2 Tabulations Plan

In the sections that follow, we present more detail on the data analysis techniques employed by the evaluation team. As mentioned, we will employ a rigorous evaluation of the falls prevention intervention that focuses on these study questions:

- ***How did the intervention affect the risk of falling?*** The initial and final telephone surveys include information on a number of factors that have been identified in the literature as contributing to the risk of falling, including medications (new medications, discontinued medications, medication dosage), general home safety, safety-related home modifications, medications (number of medications, use of medications for anxiety, depression, stress, memory loss), and physical activity. It is clear that the nature of falling is multifactorial – that is, there is not typically a single "cause" of falls, but rather, a combination of multiple

risk factors that put an elder at risk for falling. If the intervention is effective, we should see a decrease in the number of intervention group members at high-risk of falling relative to the baseline assessment and to the administrative control group.

- ***How did the intervention affect the incidence of falls?*** There are two potential sources of information on falls:
    - *Quarterly follow-up reports:* Information on falls will be collected from the intervention group and the ACG through the quarterly follow-up reports. The available data includes whether a fall occurred; for those with a fall, we also plan to collect information on the location and time of the fall, whether it resulted in injury, and whether medical attention was required.
    - *Medicare claims data:* We can use information on the primary and secondary diagnoses to identify potential fall-related encounters. Examples of potential fall-related diagnoses include fractures, head injuries, sprains, abrasions, concussions, and records in which "fall" was listed as a diagnosis. Because there are often multiple encounters associated with a given fall, we can measure whether there was a fall-related record in a given period, but not the number of falls that occurred. We can also examine the broader category of "accident and injury" outcomes that could capture spillover effects of the intervention on the incidence of injuries

  If the intervention is effective, then we should see a lower incidence of falls for those in the intervention group.
- ***How did the intervention affect use of physicians and other health professionals?*** 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 risks that are identified as part of the in-home assessment. Medicare claims data will be used for this analysis.

- ***How did the intervention affect hospitalizations and emergency department admissions?*** If the intervention is effective in reducing falls, then this should contribute to less overall utilization, although the exercise program that is part of the intervention may lead to some non-fall, exercise-related encounters. Medicare claims data will be used for this analysis.
- ***How did the intervention affect medication use? How did it affect use of psychotropic medications?*** If the medication review component of the intervention is effective, then physicians for some treatment group members at risk will prescribe fewer medications and fewer psychotropic medications[16]. Note that, since no claims data are available for medications, our only data source for these outcomes are the patient telephone interviews. As a result, we expect there to be significant limitations associated with self-reported medication information.
- ***How did the intervention affect nursing home admissions?*** Falls are a major source of nursing home admissions. If the intervention leads to a reduction in falls, then those in the intervention group should have fewer admissions for post-acute skilled nursing rehabilitation or for long-term placement due to fall-related injuries. Data from long-term care insurers will be used for this analysis, given that Medicare claims data would capture only a small portion of overall nursing home utilization.
- ***How did the intervention affect total (acute and long-term care) costs?*** The question of cost effectiveness is a key one for the evaluation. We can measure costs using a combination of Medicare claims and long-term care insurer data. If the intervention achieves its goals,

then reduced spending on "big ticket" items like hospital and nursing home admissions should outweigh increased spending for screening and prevention. Note that we expect that we will be somewhat limited in our ability to measure subject's out-of-pocket costs.

- ***How did the intervention affect rates of change in functional and cognitive status?*** Persons less likely to fall should also experience slower rates of physical and cognitive decline. We can measure the change in functional and cognitive status using the screening items on the baseline and follow-up survey.
- ***How did the intervention affect subject's fear of falling?*** 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. Our telephone surveys include information on whether subjects avoid certain activities because of a fear of falling.
- ***How did the intervention affect caregiver burden?*** For elderly persons living on their own, fewer falls should mean less need for both formal and family support. We expect to find lower average weekly hours required of informal caregivers, and less likelihood of caregivers quitting their paying jobs.

Properly implemented, random assignment of persons who are willing to join the study assures that the comparison 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. We estimate the effects of the intervention simply by comparing averages of

the outcome measures between the treatment and comparison groups. 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, so we plan to use multivariate models that adjust for differences between the intervention and comparison groups that were present at baseline.

Statistical Models

We plan to evaluate impacts based on the change relative to baseline and by comparing outcomes for intervention and comparison group members. Multivariate regression models will be used to evaluate differences between intervention and comparison group members adjusting for baseline medical conditions, medications and falls. Covariates in these models will likely include age, gender, race, measures of baseline health status/utilization, and other relevant measures. We propose to utilize available pre-intervention information that we have on both experimental and control groups to adjust effects estimates in a multivariate context using an equation such as:

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

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 intervention group, 0 for comparison group), ε is a measure of error; θ is a measure of the intervention's effect on y, adjusted for all the x characteristics.

Analyses Using the Silent Comparison Group

We will sample an external "silent control group" (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). The main purpose of these analyses will be to assess how our study population of long-term care insurance holders compares to the general Medicare population.

Internal Validity

If those in the comparison group stop participating in the study at a higher rate than those in the intervention group, then this selective, non-random attrition may threaten the intervention design. 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 comparison 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 administrative comparison group (ADCG) from long term care 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 (long term care insurance claims and Medicare claims) will be collected for the ADCG.

Reporting bias

Several key outcome measures, including self-reported incidence of falls and information on medications, rely on self-reported information, there will inevitably be some error due to poor memory or inconsistencies in how subjects count what should count as a fall or an active medication. There also may be bias in reporting (over-or under-reporting the actual falls subjects

experience) that will be associated with being an intervention or comparison 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 in health services utilization associated with injury to variations in reported falls incidence.

Statistical Power Analyses

Our goal is to have a final sample of at least 1,200 individuals in the intervention and active comparison groups. If we achieve an 80 percent response rate to follow-up survey, we should have survey data for approximately 800 individuals in both the intervention group and the ACG. We use baseline estimates from a recently completed study[17] that examined the impact of an intervention intended to reduce falls and inappropriate medication use in an elderly population at risk of falls because of their medication use. The findings from this study give a general indication as to the distribution of some of the key outcome measures that we will examine for this study.

We assessed the statistical power of the sample by examining the minimum detectable difference between the intervention and comparison groups that has an 80 percent chance of being statistically significant, using a one-tailed hypothesis test at the 10 percent level and given assumptions about the population distribution of outcome measures. In the study referenced above, 14 percent of respondents reported one or more falls during a six-month period; this rate is probably lower than what would be experienced given the population targeted by the current study – individuals age 75 and over. Even with this somewhat lower incidence rate, we can be reasonably confident of our ability to detect an impact on self-reported falls of 20 percent or

more but less confident in our ability to measure smaller effects (at this level of incidence). For example, if the intervention reduces the proportion reporting a fall from 18 to 14.4 percent (a 20 percent reduction), assuming a 28% annual incidence rate, the sample is sufficient so that we have an 80 percent chance of detecting a statistically significant difference (at the 10 percent level) between the two groups. Unless the incidence rate for falls is indeed higher, say in the range of 35%, it is less likely that we will be able to measure whether the intervention has had smaller differential impacts on falls for population subgroups, for example, based on age or gender. For example, assuming that 63 percent of the sample are female, at a 28% incidence rate, the intervention would need to be associated with a 25 percent difference in fall rates between male and female intervention group members in order for us to detect it with the power and statistical significance calculations above.

Combining the ACG and ADCG to analyze nursing home utilization, we have adequate statistical power to detect intervention impacts of around 20 percent (assuming a baseline nursing home utilization rate of around 15 percent). Finally, because there is often a large variance and skewed distribution of medical costs, it may be more difficult to detect small impacts of the intervention on costs. Assuming mean costs of $1,520 in the active comparison group and a standard deviation of $2,500, we would have an 80 percent chance of detecting a statistically significant difference in costs between the two groups if the experimental group costs were $1,250 or less (a difference of around 25 percent).

It is important to note that these power estimates are likely conservative since the analytic approach will not be limited to bi-variate comparisons but will also include multivariate regression models, which will enhance statistical power by eliminating variation that is attributable to potentially confounding covariates. Moreover, we anticipate a somewhat higher

incidence rate for falls given the population targeted for the study; as mentioned, national data suggests that one-in-three individuals age 65 and over fall at least once a year, and we are sampling older adults 75 years and older.

A.17 Expiration Date Display

Does Not Apply

A.18 Exceptions to Certification Statement

None.

B. Collection of Information Employing Statistical Methods

B.1 Respondent Universe

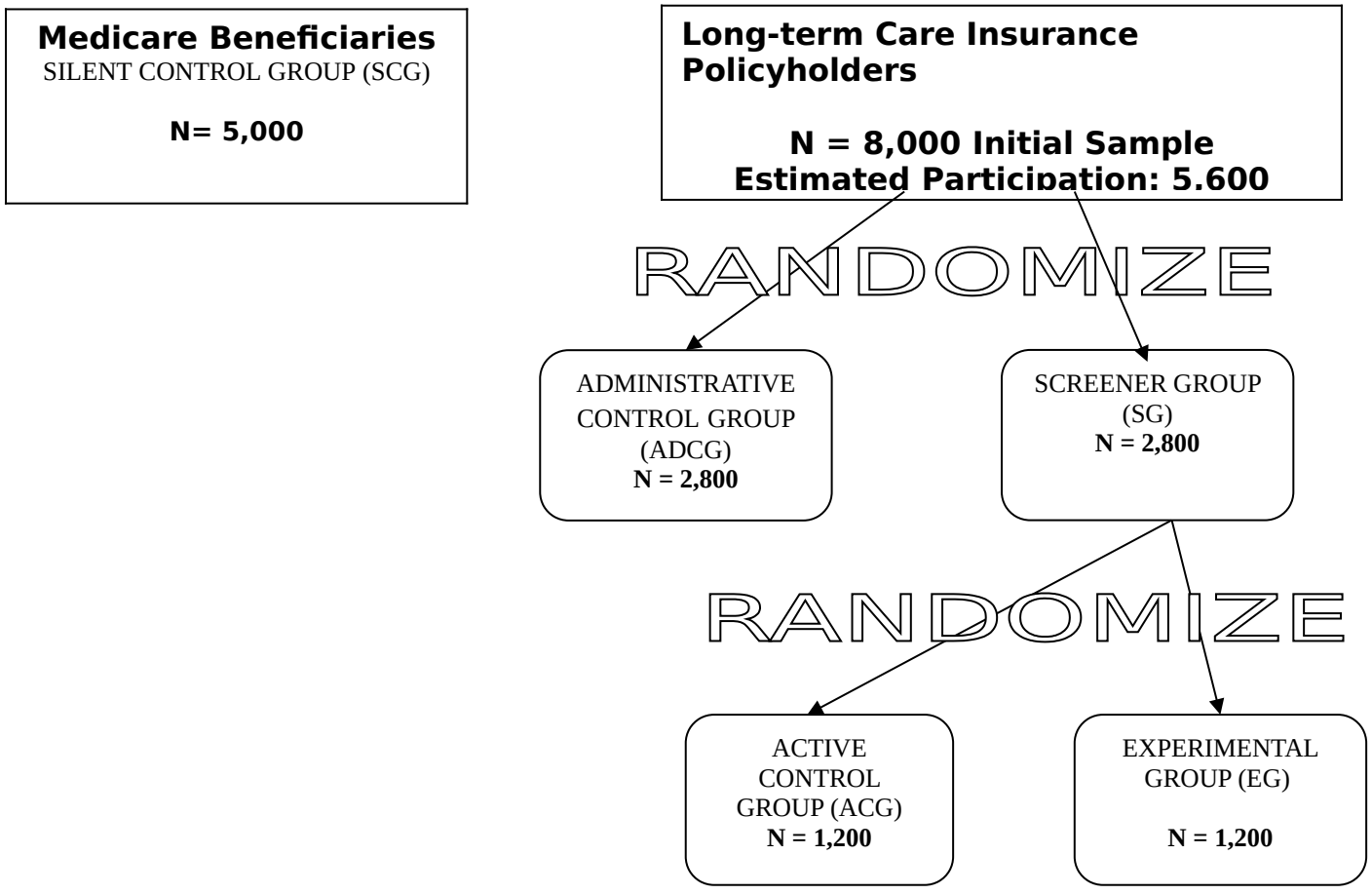
We plan to evaluate the intervention by comparing outcomes for those in the intervention group to three comparison groups. An active comparison group (ACG) that consists of private long-term care insurance policyholders who agree to participate in the study and receive the telephone screen but not the intervention. The active comparison group will include 1,200 individuals—the same number as in the intervention group. This equal assignment ratio minimizes the standard errors of our estimates of intervention impacts for any given sample size.

An administrative comparison group (ADCG) that consists of private long-term care insurance policyholders who agree to participate in the study and who receive no intervention. An external or silent comparison group (SCG) that consists of Medicare beneficiaries that is matched to study subjects based on characteristics such as age, gender, eligibility status and area of residence that are available in Medicare enrollment records. Note that it will not be possible to restrict the SCG to those with long-term care insurance policyholders. 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.

The same quarterly telephone calls will be conducted with both the intervention group and the ACG. The ADCG will allow us to explore whether there is evidence of a "placebo effect" (e.g., due to an increased awareness of fall risk factors that is triggered by the survey questions). For both the ACG and the ADCG, we will collect long-term care and Medicare claims data for three years beginning at the time of randomization from the long-term care insurance companies that are participating in the study.

Figure 2: Schematic of Sampling Plan



Note: Policyholders will have coverage for a minimum of five (5) years to assure that the effects of underwriting are eliminated.

B.2 Procedures for the Collection of Information

The data sources for the evaluation will include data from the baseline telephonic and in-person interviews, the quarterly telephone calls that we conduct with the intervention and active comparison groups, final in-person interviews, LTC claims, and Medicare claims data.

- ***Survey data:*** We will have baseline and follow-up data from the telephone interviews that we plan to conduct with members of the intervention and ACG. The intervention group will also receive in-person evaluations.
- ***Claims data from long-term care insurers:*** We will acquire long-term care insurer claims data for those in the intervention group, the ACG, and the ADCG. These data will allow us to track service utilization and costs for long-term care services.
- ***Medicare claims data*** We anticipate that Medicare claims data will be available for all study groups. We plan to able to link Medicare claims data to claims data from long-term care insurers (i.e., linking based on Medicare Patient ID) so that we can analyze outcomes based on utilization and health care expenditures.

B.3 Methods for Maximizing Response Rates

To meet our sampling objectives we will employ a number of techniques. First, all written communications with participants will be on their insurance company letterhead. This will ensure recognition, assist with study validation and legitimacy and take advantage of insurer affinity. Second, we are providing participants with free assessment and home safety evaluations, which are designed to promote healthy aging and independence. One of the goals of the program is to allow older adults to remain independent in their homes, which previous research has shown is of great importance to this population. Third, we will be providing

participants with a Health Promotion and Fall Prevention toolkit containing useful items such as a wipe off medication minder, pedometer and exercise video at no charge. Fourth, customer service representatives at the participating insurance companies are made aware that their company is participating in the study so that if phone calls are received form potential participants they can validate study participation. Finally, all potential study participants are provided with a toll-free phone number that they can call if they have any questions about the study.

It is important to note that on previous ASPE sponsored studies of LTC insurance claimants, we obtained an 80% response rate for participation. Participating companies are confident most potential study respondents will agree to take part in the survey process, in part, because the issues that are addressed in the survey are ones that they are dealing with in a very real way.

Company representatives also believe that because the industry is working together with the Federal government (i.e. the Department of Health and Human Services) potential respondents will be motivated to participate in the study. Finally, given the population characteristics of long-term care insurance policyholders, we expect almost everyone to have a telephone. We are cognizant of the fact that individuals have twelve opportunities to refuse to participate – at the time of the initial letter, the telephonic risk assessment, the in-person assessment, the jump-start phone cell, each of the seven quarterly telephone calls and the final assessment. Nevertheless, we believe that our 80% response rate estimate over the two year study period is reasonable.

[16] Psychotropic medications, used to treat neurological, psychological and emotional illness, are medications are medications that affect the mind or mood or mental processes. These medications may contribute to falls (either alone or in combination with other medications) by causing dizziness, unsteadiness, or perception issues. A number of previous studies have found a relationship between falling and the use of psychotropic medications.

[17] White A, Weber V. Utilizing the Electronic Medical Record and Case Management to Improve Patient Safety in the Rural Elderly, Final Report. Completed for the Agency for Healthcare Research and Quality, October 2004.

B.4 Testing Procedures and Methods

As noted previously, we have conducted a pretest of the survey instruments and have made changes based on the results. We have obtained feedback on the action plan and physician review form from physicians. Due to the nature of the evaluation strategy (quarterly follow-up phone calls over a two year period), we are only able to obtain limited feedback on the quarterly telephone follow-up instrument. Aspects of the planned fieldwork procedures have been implemented in a somewhat compressed timeline. As mentioned, many of the questions that are being asked have been field tested as part of insurance assessments and have been used extensively in national surveys.

B.5 Name of Contractor Responsible for Collection and Analysis and Other Individuals Consulted Regarding Method and Design

The contractors principally responsible for study design, data collection and analysis are:

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Additional consultation on the clinical aspect of falls and fall prevention, as well as on the sample selection, analytical and statistical methods of the design was provided and will continue to be provided by our technical advisory group. Each member is an expert in a specific area related to the study and has expressed interest in continuing there role throughout the process and willingness to offer additional expert input.

ENDNOTES