EXECUTIVE SUMMARY

Introduction

Falls are a major health problem among older adults in the United States. One of every three people over the age of 65 years living in the community falls each year, and this proportion increases to one in two by the age of 80 years.[1-3]

Fall-related injuries in older adults often reduce mobility and independence, and are often serious enough to result in a hospitalization and an increased risk of premature death.[4] Studies among older persons in the community have found that about 10 percent of the fallers have a serious fall-related injury, including fractures, joint dislocations, or severe head injuries.[5-7] Falling has also been found to be associated with subsequent admission to a nursing home.[8]

The costs of health care associated with fall-related injuries and fractures, including hip fractures, are staggering. The total direct cost of all fall injuries in older adults in 1994 was $20.2 billion and is estimated to reach $32.4 billion by 2020.[9] Medicare costs for hip fractures were estimated in 1991 to be $2.9 billion.[10] With an aging population and a growing number of hip fractures, these cost estimates are projected to rise to as high as $240 billion by the year 2040.[11]

Clearly, the prevention of falls is an important issue if it can prevent significant declines in function and independence, and the associated increase in costs of complications. 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.[3] However, the interventions designed to address these risk factors share the same diversity. Likewise, the evidence for the effectiveness of a single intervention in preventing falls has been inadequate.[12] Since the risk of falling appears to increase with the number of risk factors,[3] multifactorial interventions have been suggested as the most effective strategy to reduce falling.

Heretofore, numerous interventions have been studied in the prevention of falls. Results have been mixed, yielding uncertainty as to which interventions are most clinically effective or cost-effective, or what kind or combination of interventions should be included in a program to prevent falls.

To gain a better understanding of which interventions may be beneficial in the Medicare population, the Centers for Medicare and Medicaid Services (CMS), as part of its Healthy Aging Project, commissioned an evidence-based systematic review of interventions in the prevention of falls, the results of which are detailed in this report. For this report, CMS asked us to provide evidence in response to the following questions:

1. Are falls prevention programs effective? What are the key components that should be included in a falls prevention intervention? Are multifactorial approaches more effective than single intervention approaches?

2. Are public information or education campaigns alone effective in reducing or preventing falls?
3. Which care settings/approaches have been more effective than others for the delivery of falls prevention interventions? Which providers should deliver this service?
4. What are the key issues in sustaining falls prevention programs?
5. Cost effectiveness or cost savings—Do falls prevention interventions appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
6. Should falls prevention programs be targeted toward high-risk individuals? Are there a few basic questions to identify these individuals? Can this be done through self-identification?
7. Are there specific falls prevention exercises recommended for seniors?
8. Are falls prevention programs acceptable to seniors?

Methods

For our systematic review, we classified intervention components that can be used to prevent falls among persons age 65 or older into the following broad categories:

Exercise:

General Physical Activity. Includes non-physiotherapy activity -- for example walking, cycling, aerobic movements, and other endurance exercises.
Specific Physical Activity. Includes training geared specifically towards balance, strength, or gait.

Multifactorial falls risk assessment and management program. This can include a focused post-fall assessment or a systematic risk-factor screening among at-risk individuals tied to interventions and follow-up for the risks uncovered. A multifactorial falls risk assessment and management program consists of three components: 1) a questionnaire to identify risk factors for falls, which can be self-administered or administered by a professional; 2) a thorough medical evaluation (including examination of vision, gait, balance, strength, postural vital signs, medication review, cognitive and functional status); and 3) follow-up interventions, that may include a tailored exercise program, environmental modifications, and assistive devices.

Education. Educational efforts can be directed toward an individual, group, or entire community. Pamphlets and posters can raise awareness among older adults or staff members at senior centers and nursing homes. More intense interventions include one-to-one counseling about risk factors.

Assistive Devices. These include canes and walkers.

Medication / Medication Review. This category includes two approaches. First, physicians can review patient records to evaluate whether side effects of any medication may contribute to falls. Second, hormone replacement therapy, calcium, and vitamin D can be used to increase muscle or bone strength in an effort to prevent falls.

Environmental Modification. Environmental modification often includes home visits to older adults living in the community. Professionals examine the environment for hazards such as poor lighting, sliding carpets, and slippery floors. Recommended modifications include installing grab bars, placing bath mats in the shower, and keeping a working flashlight at home.

Staff / Organization Related. These interventions most often take place in hospitals and nursing homes. A falls-prevention specialist may visit a facility and make recommendations, including patient-reminder bracelets, bed alarms, and restraints.

In addition to conducting an extensive library search, we used literature from RAND's Assessing the Care of Vulnerable Elders (ACOVE) project, the Cochrane Collaboration, the American Physical Therapy Association (APTA), CMS, and the American Geriatrics Society (AGS) Falls Guidelines Taskforce. When articles arrived, we reviewed each reference list in order to find additional relevant literature.

We reviewed the articles retrieved from the literature searches against exclusion criteria to determine whether to include articles in the evidence synthesis. To be accepted for inclusion, a study had to be either a randomized controlled trial (RCT) or a controlled clinical trial (CCT).

We abstracted data from the articles on a specialized Quality Review Form (QRF). The form contained questions about the study design; the number and characteristics of the patients; the setting, location, and target of the intervention; the intensity of the intervention; the types of outcome measures; the time from intervention until outcome measurement; and the results. We selected the variables for abstraction with input from Dr. Laurence Rubenstein, an expert on falls prevention and Principal Investigator of the Healthy Aging Project. Two physicians, working independently, extracted data in duplicate and resolved disagreements by consensus.

We entered all data on outcomes and interventions into the statistical programs SAS[13] and Stata.[14] Our summary of the evidence is both qualitative and quantitative. For questions on effectiveness, we conducted two meta-analyses using statistical pooling and meta-regression. The first analysis was on the outcome “falling at least once” during a specified follow-up period and was measured using a risk ratio. The second analysis was of the outcome “monthly rate of falling,” which was calculated from the mean number of falls per person and the follow-up time, and which was measured with an incidence rate ratio. Our approach is described in detail in the Methods Section of the main report.

Results

In total, the above mentioned sources yielded 851 articles, of which we were able to obtain 826 for the screening process.

Of the 826 articles screened, 73 did not discuss falls prevention. Six hundred twenty-eight were rejected because they were not RCTs or CCTs. Another 16 articles were duplicates of articles already on file. Thirteen others did not include outcomes; i.e. they were simply descriptions of a falls prevention program. One did not report on a study population of the appropriate age. Eliminating these articles left 95 articles for quality review.

On detailed review of these 95 articles, we rejected 38 that did not have falls outcomes or reported falls as a secondary outcome of an intervention whose primary goal was something else (such as hormone replacement therapy). Thus 57 articles were considered for meta-regression analysis. Three of the 57 studies were excluded either because they presented the data in aggregate or did not provide data on outcomes by intervention or control group. Additionally, seven of the 65 studies were rejected as duplicate publications from the same study population (only one report of a particular intervention and study population could be included in the meta-analyses). Another 6 studies were rejected as being of the wrong intervention type for our conceptual model. Studies were included in the meta-analyses if the study reported data on either "subjects who fell at least once during the study period" and the study included follow-up data at a time point between six and 18 months after the baseline; or "mean number falls per subject." These last criteria excluded two studies.

Question 1. Are falls prevention programs effective? What are the key components that should be included in a falls prevention intervention? Are multifactorial approaches more effective than single intervention approaches?

Our meta-analyses support the effectiveness of falls prevention programs at reducing both the number of older adults who fell and the monthly rate of falling per person. The pooled risk ratio from 20 randomized clinical trials was 0.89, 95% CI [0.81, 0.98], indicating the interventions in these studies are significantly associated with a reduced risk of falling. We also pooled data in 26 randomized clinical trials and determined the incidence rate ratio was 0.77, 95% CI [0.68, 0.87], indicating these interventions are significantly associated with a reduced number of falls per person.

We did not find any clinical trials that directly compared the effectiveness of single component falls intervention programs (for example, a trial comparing environmental modification with exercise.) To assess the relative effectiveness of intervention components, we entered all studies in meta-regression models to assess the effect of individual intervention components while controlling for other intervention components and study level differences. While there were no statistically significant differences among components, there was a clear trend that a multifactorial falls risk assessment and management program was highly effective and appeared to be the most effective intervention. The most commonly assessed risks in such programs were medication review, vision, environmental hazards, and orthostatic blood pressure. Exercise was the next most effective intervention component. There was no evidence that environmental modification or education were effective as independent components, but the paucity of studies precludes firm conclusions. There were no data regarding the independent effects of other components in our conceptual model (assistive devices, medication review, and staff/organizational changes). As nearly all interventions were to some extent multifactorial, it was not possible to directly test the relative effectiveness of multifactorial versus single component approaches.

QUESTION 2. ARE PUBLIC INFORMATION OR EDUCATION CAMPAIGNS ALONE EFFECTIVE IN REDUCING OR PREVENTING FALLS?

We found no specific studies about the effectiveness of public information or mass education campaigns. In the meta-regression analyses, patient education given as part of multifactorial falls prevention programs did not show a significant independent effect.

QUESTION 3. WHICH CARE SETTINGS/APPROACHES HAVE BEEN MORE EFFECTIVE FOR THE DELIVERY OF FALLS PREVENTION INTERVENTIONS? WHICH PROVIDERS SHOULD DELIVER THIS SERVICE?

Successful interventions have been conducted in physician offices, patient homes, hospitals, nursing homes, community centers and specialized research centers. No evidence currently exists to advocate for increased effectiveness based on care setting. Successful falls-prevention interventions have been provided by exercise leaders, nurses, physical therapists, social workers, and teams of multiple providers. Insufficient evidence currently exists to conclude that one provider type is preferable over another.

QUESTION 4. WHAT ARE THE KEY ISSUES IN SUSTAINING FALLS PREVENTION PROGRAMS?

There are two key issues in sustaining falls prevention programs – insufficient funding and lack of available programs. The interventions reviewed in this report were performed through the use of special funding from research grants or demonstration projects, and none of them were continued as regular programs. Funding seems to be needed to sustain falls prevention programs and would be required to bring about the widespread use of such effective interventions as supervised exercise programs and multifactorial fall risk assessments and management.

QUESTION 5. COST EFFECTIVENESS OR COST SAVINGS: DO FALLS PREVENTION INTERVENTIONS APPEAR TO REDUCE HEALTH CARE COSTS BY REDUCING DISEASE, PHYSICIAN OFFICE VISITS, HOSPITALIZATIONS, NURSING HOME ADMISSIONS, ETC.?

Whether a falls prevention intervention is cost effective or cost saving is a function of many parameters including the targeted population, the environment where the targeted population resides, the effectiveness of the intervention due to design and implementation, the effect of time, the account of benefits and costs, the perspective of costing, and the selection of comparator. We found 15 studies of cost-effectiveness with substantial heterogeneity in these parameters. Thus, we were unable to compare the relative cost-effectiveness by type of intervention or draw definitive conclusions about the economic impact of falls prevention interventions. Common threats to the validity of cost-effectiveness analyses in the studies included 1) the highly selective trial population (which results in “cost-efficacy” instead of “cost-effectiveness” findings and unknown generalizability); 2) lack of a clear perspective in accounting costs and benefits; and 3) inadequate sample size (which causes the health care cost and utilization outcomes to be substantially influenced by a few outliers).

Overall, the evidence is not conclusive but suggests that an effective intervention provided to people with a high risk of falling has the potential to be cost-effective or even cost saving compared with current practice. Further research is needed before informing policy-makers about which intervention is effective for what population, and such research should use sound methodology to provide more solid evidence of the cost-effectiveness.

We made estimates of the potential cost-effectiveness of a new Medicare benefit, a falls prevention rehabilitation program, that combines multifactorial assessment of falls risk with individually tailored recommendations and a supervised exercise program. We assumed that Medicare would pay $95 for the initial multifactorial assessment, and that 60% of these people would subsequently be eligible for an eight session, six week supervised exercise program reimbursed at $280. All patients would also need one follow-up visit dedicated to assuring that recommendations were being implemented, reimbursed at $40. We used existing data regarding the number of people aged 65 and over, the annual number of falls with injury in this population, the mean cost of a fall with injury, and our pooled estimate of the effectiveness of a multifactorial falls risk assessment and management program. This analysis was not sophisticated, yet still instructive. Under these assumptions, a falls prevention rehabilitation program would have a net cost to Medicare of $272 million annually, and would avert 542,000 falls with injury, or about $500 per fall averted. This supports the hypothesis that falls prevention programs may be cost-effective by reducing health care costs due to injuries.

QUESTION 6. SHOULD FALLS PREVENTION PROGRAMS BE TARGETED TOWARD HIGH RISK INDIVIDUALS? ARE THERE A FEW BASIC QUESTIONS TO IDENTIFY THESE INDIVIDUALS? CAN THIS BE DONE THROUGH SELF-IDENTIFICATION?

Existing data support that identifiable risk factors exist for falls. These risk factors can be identified using basic questions and a physical examination. However, we assessed the effectiveness of what had proven to be the two most effective interventions, exercise and a multifactorial falls risk assessment and management program, in high-risk and non-high-risk populations. Estimates of efficacy were not statistically or clinically different from each other, which prevents us from concluding whether falls prevention programs are more effective in high risk compared to non-high risk populations.

That being said, interventions targeted to high and low risk populations have been different in most studies. For example, post-fall assessments and low-intensity exercise programs have been mostly targeted to frail and high-risk populations, while high intensity exercise programs have been targeted to broader populations (often excluding high-risk participants because of poor endurance). Therefore, comparing trials that focused on either high or low risk populations is not possible without some confounding by intervention variation.

Though not proven, it makes clinical and scientific sense that comprehensive post-fall assessments and fall risk assessments should be targeted to persons at higher risk.

Because of their increased fall risk, they have the most to gain and would tend to have the largest effect size. In terms of identifying individuals at high risk for falls, there are a number of instruments, of varying length and complexity, with greater and lesser degrees of sensitivity and overall accuracy. From a practical standpoint, a simple identifier or set of questions is better, as long as it is reasonably accurate. With this in mind, the American Geriatrics Society evidence-based clinical guideline for prevention of falls recommended the following persons to have a comprehensive fall evaluation (risk assessment): 1) older persons presenting for medical attention with one or more falls, 2) older persons who report recurrent falls (2 or more in a 6 month period), or 3) older persons with abnormalities of gait and/or balance.

QUESTION 7. ARE THERE SPECIFIC FALLS PREVENTION EXERCISES RECOMMENDED FOR SENIORS?

Exercise is effective in falls prevention programs. Our meta-analyses showed that exercise interventions reduced the risk of falls by 12% (pooled risk ratio: 0.88, 95% CI [0.78, 1.00]), and the number of falls by 19% (pooled incidence rate ratio: 0.81, 95% CI [0.72, 0.92]). Falls prevention programs using exercise typically included one or more of the following: cardiovascular endurance, muscular strength, flexibility, and balance.

While both the FICSIT meta-analysis and our meta-analysis showed some trends in differing effectiveness among exercises, these differences were not consistent and not statistically significant. Therefore, while there are compelling data to recommend exercise in general, there are no conclusive data to recommend particular falls prevention exercises.

QUESTION 8. ARE FALLS PREVENTION PROGRAMS ACCEPTABLE TO SENIORS?

We did not find any direct evidence that answered this question, either in the form of surveys, focus groups, or other methods that directly assess the general acceptability of falls prevention interventions among seniors. Some indirect evidence can be obtained from the clinical trials of falls prevention interventions. About half of the studies reported the "refusal rate" of those contacted and eligible for the intervention. These figures represent a mix of studies that attempted to enroll subjects from large populations or small specialty clinics, and hence variation in the "refusal rates" may represent differences in the stages of "readiness to change" of various populations. Furthermore, this refusal rate includes people who refuse for reasons other than the acceptability of the intervention; for example, people may refuse to participate in any clinical trial because they equate this with "experimentation." With these caveats in mind, we calculated an average "refusal rate" of 30.5 percent. Furthermore, among the studies that reported both the number of persons beginning the study and those completing the study, the average "dropout" rate was 16 percent. Taken together, these data suggest that the proportion of seniors for whom falls prevention programs are acceptable, while not precisely known, is likely substantial.

Limitations

The primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. Heterogeneity is another major issue. Even more so than in reviews of single therapies (e.g., coronary revascularization for coronary artery disease, pharmaceutical therapy for rheumatoid arthritis), the studies presented here are heterogeneous in terms of the interventions tested and populations included.

Furthermore, many of the study-level variables are highly idiosyncratic and inter-correlated (e.g., all studies of restraints take place in institutions). Many interventions have multiple components, making the assessment of the effect of the individual components challenging. Furthermore, the populations studied were heterogeneous in that some enrolled population-based samples of patients, while others enrolled attendees at a special clinic or even respondents to advertisements. Also, our assessment of the relative effectiveness of individual components was made using indirect methods, as we did not find any direct comparisons of individual components. Such indirect comparisons are not as powerful as direct comparisons. However, the convergent results of our two meta-analyses lend validity to our conclusions.

We gave equal importance to all studies that met our minimum criteria (RCTs that measured the percent of a group with at least one fall or the number of falls per person). We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in falls prevention trials (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and bias, we did not attempt to use other criteria.

Our results regarding exercise need to be interpreted in light of the results of the pre-planned meta-analysis of the FICSIT trials. One of the original eight FICSIT studies was excluded from this pre-planned meta-analysis as it did not have a relevant treatment arm and we also excluded it from our analysis. The FICSIT meta-analysis[15] included seven RCTs that assessed a variety of exercise interventions, including endurance, flexibility, platform balance, Tai Chi, and resistance. This meta-analysis used individual patient-level data. We could include only two of the individual FICSIT trials in one of our meta-analyses ("subjects who fell at least once").[16, 17] Six of the FICSIT studies did contribute data to our second meta-analysis, one was excluded due to insufficient statistics. Our results are in general agreement with the central FICSIT meta-analysis result: exercise programs help prevent falls (FICSIT pooled effect: 0.9, 95% CI [0.81 – 0.99]; our pooled effect for percent with at least one fall: 0.89, 95% CI [0.81 – 0.98] and for monthly rate of falling: 0.77, 95% CI [0.68, 0.87]). FICSIT also reported pooled effects for balance that were greater than (but not statistically different from) the overall effect. Our analysis assessing monthly rate of falling also found this result, however our analysis assessing number of subjects who fell at least once did not.

Regarding study populations, few studies of falls prevention stratified results by gender or ethnicity. Most studies either did not report the ethnic composition of the sample or used predominantly Caucasian samples. Thus, without further evidence, it should not be assumed such interventions will be similarly effective among all ethnic groups.

Conclusions

1. Falls prevention programs, as a group, have been shown to reduce the risk of experiencing a fall by 11% and monthly rate of falling by 23%.
2. Because few studies of single falls prevention interventions exist, statistical models were used to examine the independent effects of the four interventions with sufficient evidence to synthesize – multifactorial falls risk assessment and management; exercise; environmental modification; and education. Evidence supports a multifactorial falls risk assessment and management program as the most effective intervention. Exercise is the next most effective independent intervention. Thus, the evidence suggests that to be successful, falls prevention interventions should either use a multifactorial falls risk assessment and management program or exercise. However, the best approach to preventing falls is likely to use both a multifactorial falls risk assessment and management program along with exercise.
3. Falls risk assessments must be coupled with individually-tailored follow-up interventions to be effective.
4. Risk factor identification, which is one component of a multifactorial falls risk assessment and management program, may be self administered or administered by a professional. Both population-based public health approaches and medical model approaches are effective.
5. Our meta-analyses showed that exercise interventions reduce the risk of falls by 12% and the number of falls by 19%. While numerous exercise programs have been recommended to help prevent falls, there are insufficient data to identify the most effective exercises.
6. Successful falls prevention interventions have been delivered by a variety of providers, including exercise instructors, nurses, physical therapists, social workers, and teams of multiple providers. There is currently insufficient evidence to conclude that one provider type is preferable over another.
7. While not conclusive, the evidence suggests that falls prevention programs provided to seniors have the potential to be highly cost-effective compared with current practice. We estimate that a falls prevention rehabilitation program as a new Medicare benefit would be highly cost effective (even cost-saving in persons older than age 75) by preventing Medicare costs from injuries due to falls.
8. In the absence of new resources, it seems unlikely that much progress will be made in getting seniors to receive the benefits of falls prevention activities.

Recommendations

1. There is strong evidence that falls prevention programs are effective at preventing falls, and therefore ways are needed to better integrate these programs into the current care received by seniors.
2. There is strong evidence to support adding a falls prevention rehabilitation program as a new Medicare benefit. Such a program would be eligible to beneficiaries who have fallen, and would encompass a multifactorial risk assessment with a supervised exercise program.