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Our Grandparents, Our Parents, Our Future Selves: Optimizing Function in Old Age.

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Policy Brief

Our Grandparents, Our Parents, Our Future Selves
Optimizing Function in Old Age

Thomas M. Gill

No. 42/2010

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He is also Director of the Yale Center on Disability and Disabling Disorders, Director of an NIA-funded postdoctoral training program in Geriatric Clinical Epidemiology, Co-Director of the Claude D. Pepper Older Americans Independence Center, and Director of the Research Career Development Core. His research accomplishments have been recognized through receipt of a MERIT Award from the National Institutes of Health and election to the American Society of Clinical Investigation.

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This publication and the lecture on which it is based are funded by the Finger Lakes Geriatric Education Center of Upstate New York, the Syracuse University Gerontology Center, and the Center for Policy Research.

The Policy Brief series is a collection of essays on current public policy issues in aging, health, income security, metropolitan studies, public finance, and related research done by or on behalf of the Center for Policy Research (CPR) at the Maxwell School of Syracuse University.

Single copies of this publication may be obtained at no cost from the CPR website at <http://www-cpr.maxwell.syr.edu> or from the Center for Policy Research, 426 Eggers Hall, Syracuse, New York 13244-1020.

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Policy Brief

Our Grandparents, Our Parents, Our Future Selves
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Among nondisabled, community-living persons aged 75 years or older, approximately 10 percent develop disability in their basic activities of daily living (ADLs) each year....Disability, in turn, is associated with increased mortality and leads to additional adverse outcomes such as hospitalization, nursing home placement, and greater use of formal and informal home services, all of which place a substantial burden on older persons, on informal caregivers, and on health care resources. (Gill et al. 2003)

Most of my research at Yale University School of Medicine over the past several years has focused on identifying older adults at risk of functional decline and disability, identifying events that may precipitate the transition from functional independence to disability, and developing strategies to postpone or reduce frailty and disability. As a result of the Precipitating Events Project (PEP) and other research conducted by the Yale Center on Aging/Pepper Center, we now realize that age is only a proxy for other factors that lead to disability, and that some of these factors can be modified to reduce the risk of disability. In fact, disability rates have been steadily declining among older adults for decades. Among our findings:

- Disability is not an inevitable outcome of physical and cognitive impairments, but often results when a precipitating event is superimposed upon a vulnerable host. The single most important

precipitating event for an older adult, even one with no diagnosed impairment, is hospitalization.

- Older persons at high risk for disability can be easily identified with what are called the “geriatric vital signs,” two simple tests of physical performance, namely rising from a chair and walking across a room.

- Functional decline and disability are dynamic processes, with high rates of recovery, although the rates of recovery are substantially higher among persons who are not physically frail. Many older adults experience temporary periods of disability mixed with periods of independence.

- Disability is often preventable through exercise and physical activity, through fall prevention, and perhaps in the future through pharmacologic treatment.

Chronic Disability Is Declining

Not only are Americans living longer than ever, but the prevalence of chronic disability (disability lasting 90 days or longer) among older Americans has been steadily declining since the 1980s. Data from the 1982-2004 National Long-Term Care Survey indicate that between 1982 and 1994 the absolute number of cases of chronic disability increased even as the prevalence of chronic disability decreased, reflecting the aging of the population. But around 1994 the number of cases began to decrease as well, a remarkable trend that continued through the end of the survey. As a result, the number of persons with chronic disability in 2004 (6.9 million) was nearly identical to that in 1982 (7.1 million), although the number of elderly people in the US grew over that same period by about one-third, from 26.9 to 36.2 million (Manton 2008).

David Cutler, a health economist at Harvard University, attributes most of the increase in life expectancy at age 65, and the concomitant decline in chronic disability, to improvements in treating cardiovascular disease (Cutler 2004). For example,

Kramarow and colleagues (2007) reported that coronary angioplasty procedures, which were introduced in the late 1970s for the treatment of coronary artery disease, tripled from 60 procedures per 100,000 elderly Americans in 1995 to 180 procedures per 100,000 by 2004. And several other modern therapies have similar trajectories.

But disease or impairment does not inevitably lead to disability. In PEP, we shifted our focus from the disease to the person and asked, what distinguishes people with chronic health conditions who progress to disability from those who do not? And what, if anything, can be done to slow or prevent that progression? Our research looks at the behaviors and circumstances of an older person at risk for disability to determine what kinds of events may push them into frank disability and how to intervene.

Disability Is Not an Inevitable Part of Old Age

Let us compare the World Health Organization's (WHO) early model of disability with our own to clarify the role of vulnerability and precipitating events.

The **WHO 1980 model of disability** is relatively simple:

disease leads to impairment;
and impairment leads to disability

For example, the disease might be diabetes, the impairment might be poor balance, and the disability might be inability to bathe in the tub or shower. Several diseases have been shown to be prominently associated with disability. In some cases—stroke, hip fracture—the disabling effect is immediate and direct. In others, the links are indirect and quite distant; hypertension and diabetes are two of the best examples. And then there are others that are somewhere in between: knee osteoarthritis, congestive heart failure, chronic

obstructive lung disease, dementia, peripheral vascular disease, and disorders of vision.

Our research, on the other hand, has been guided by what I call the **vulnerability model of disability**.

an older adult with impairment(s) is at risk for disability;
a precipitating event occurs,
which converts that risk to actual disability

We're interested in trying to understand what happens during the time between when an older person is assessed for impairment and when they become disabled. Although the impairment puts them at risk for disability, it does not lead directly to disability. Something happens in the interim, which we call a precipitating event. This model led us to start the Yale Precipitating Events Project (PEP), described below.

Identifying People at Risk for Disability

Physical Function

The gold standard for a performance-based measure of physical functioning is the Short Physical Performance Battery (SPPB), probably the most widely used performance-based test for quickly assessing lower-extremity physical functioning among older adults. It was developed by Jack Guralnik and colleagues at the National Institute on Aging and can be freely downloaded from the NIA website (Guralnik 2007). The SPPB consists of three timed tests, scored from 0 (unable to perform) to 4. The two components of the SPPB that are the strongest predictors of disability include the short distance walk, walking at the subject's usual pace, and the chair stand test, in which subjects fold their arms across their chests and stand up from a sitting position as quickly as possible three times. Summary scores on the SPPB range from 0 to 12.

The SPPB appears to identify individuals who have sarcopenia, or muscle loss. A CT cross-section scan of the thigh of a young active person shows bone in the center surrounded by muscle, with a bit of fat just under the skin. In the thigh of someone who's older and sedentary, much of the muscle has atrophied and been replaced by fat, which appears to lead to declines in physical functioning traditionally associated with old age. In our research, we have used components of the SPPB to identify at-risk individuals who may benefit from interventions to prevent future disability.

In 1995, Guralnik and his colleagues investigated whether the SPPB could be used to determine the risk of future disability in adults age 71 years or older living in the community who reported they had no ADL disabilities and could walk one-half mile and

Figure 1. Disability status at four years according to the baseline summary performance scores among 1121 subjects with no disability at baseline. Higher scores indicate better performance on the tests and thus better functional status. One person with a score of 3 has been excluded. $P < 0.001$ for the association between performance scores and disability status, by the chi-square test. ADL denotes activities of daily living. Source: Guralnik et al. 1995.

climb stairs without assistance. Subjects were assessed at baseline for physical functioning and again four years later for mobility-related and ADL disability status. The researchers concluded that there is a “clear gradient” in the risk of both ADL and mobility disability as the baseline scores increase from lowest to highest, indicating an apparent “preclinical stage of disability” among those with the lowest baseline scores (Figure 1).

Cognitive Function

Dementia or disorders of memory and thinking also play a prominent role in the disabling process. Using estimates of men and women with ADL disability in Tuscany, Italy, in 1999, divided by age and the presence or absence of dementia, Guralnik and Ferrucci (2003) observed that:

In both men and women, most ADL disability before age 75 years is not associated with dementia. From age 75 to 90 years about half of ADL disability is accompanied by dementia, and after age 90 years the majority of persons with ADL disability have dementia.

This doesn't mean that dementia causes disability, only that it's involved in those individuals who are disabled.

In 1997, there were 2.32 million people living with Alzheimer's disease (AD), the most common cause of dementia, in the United States, with about 360,000 new cases each year (Brookmeyer, Gray, and Kawas 1998). About 43 percent of them are between 75 and 85 years of age. As the population ages, the prevalence of AD may quadruple to about 8.64 million people in 2047, with about 1.14 million new cases per year. However, if interventions could delay the onset of Alzheimer's disease by just two years, it is estimated that there would be nearly 890,000 fewer cases fifty years after the intervention is introduced (Brookmeyer et al.

1998). Even a one-year delay would reduce the number of cases by 210,000.

Folstein, Folstein, and McHugh (1975) developed the Mini-Mental State Examination (MMSE) as a “simplified, scored form of the cognitive mental status examination, which includes eleven questions, requires only 5-10 minutes to administer, and is therefore practical to use routinely and serially.” The MMSE is widely used to assess cognitive function, and we have used it in our research for the same purpose.

Impact of Increasing Obesity on Disability Rates

There is a lot of concern about the obesity epidemic, particularly as individuals who are obese age into the Medicare population. I showed you earlier that disability rates have been declining over time. However, that is not the case among older obese adults (Alley and Chang 2007). Comparing the probability of functional impairment and disability between two groups of older adults, one with a normal BMI (18.5 to 24.99) the other group obese ($BMI \geq 30$) for two periods of time, 1988-1994 and 1999-2004, those who were normal weight appeared to have the expected temporal decline in functional impairments (walking one-quarter mile, walking up 10 steps, stooping, lifting 10 pounds, walking between rooms, and standing from an armless chair) and ADL disability (transferring, eating, and dressing). But those who were obese experienced significantly greater functional impairment and disability in both time periods, and their probability of functional impairment and disability actually increased between the first and second time periods. That, along with the dementia projections I showed you earlier, does not bode well for the future.

Other Predisposing Factors for Disability

Other researchers have identified a series of additional predisposing factors for disability: chronic conditions, depressive

symptoms, impairments in vision, low physical activity, poor nutritional parameters—whether it is weight loss or some deviation from normal weight—and cigarette smoking.

Delaying Disability

Compression of Morbidity

Nearly 30 years ago, Jim Fries at the Stanford University School of Medicine proposed the *compression of morbidity* hypothesis:

The amount of disability can decrease as morbidity is compressed into the shorter span between the increasing age at onset of disability and the fixed occurrence of death. (Fries 1980)

Fries and his colleagues hypothesized that adults with fewer “potentially modifiable health risks” would have less disability in later life (Vita et al. 1998). They defined three risk groups—low, moderate, and high—on the basis of habits: smoking, body mass index (BMI), and exercise patterns. Not only did they survive longer, but the low risk group, those with healthy habits in mid-life, postponed the onset of disability by about five years compared with those in the high risk group. They gained five years of disability-free time relative to those who were high risk on the basis of those three health risks.

Reserve Organ Capacity

Recently, Kuh described a life course approach to healthy aging, based on “[g]rowing evidence from life course and historical cohort studies that adult function and age-related chronic diseases have their origins in early life experience and share common risk factors and causative mechanisms” (2007). What might be happening is a kind of reserve capacity, or ““biological capital” acquired during growth” that, combined with varying rates of decline, determine the “potential for compression of morbidity.”

Rantanen and colleagues (1999) found that a simple test of grip strength, assessed at age 50, was a powerful predictor of disability 25 years later, including disability in a whole series of specific tasks people need to be able to perform to take care of themselves: housework, walking, lifting, dressing, and bathing. When divided into three groups, the group with the lowest grip strength experienced twice the risk of being unable to take care of themselves 25 years later than the highest grip strength group. The researchers suggested, “Good muscle strength in midlife may protect people from old age disability by providing a greater safety margin above the threshold of disability.”

Kuh et al. (2002) took this back a step further, linking birth weight to grip strength in middle age. They found that for every extra kilogram of weight at birth, men at age 53 demonstrated 83 percent greater grip strength and women 27 percent. They theorized that “birth weight is related to the number of muscle fibers established by birth and that...[a]s the inevitable loss of muscle fibers proceeds in old age, a deficit in the number of fibers could threaten quality of life and independence.” It’s almost as if what’s happening is predetermined. This is part of what scientists who are interested in the life course do, link what’s happening early in life to what’s happening later in life. This is a very interesting connection of birth weight to grip strength in midlife, playing out with disability in old age.

People follow different trajectories over a lifetime (Figure 2): the first trajectory, A, is just the effects of age. Superimposing something like chronic health conditions might get you on the trajectory of C. If you have a combination of bad health habits, such as smoking, lack of exercise, or bad diet, you might be on the trajectory of B. And if you have other misfortunes—perhaps you’re socioeconomically deprived, you’re not as highly educated, you don’t reach the most robust levels of physical capabilities—then you decline most rapidly (D) and cross the threshold below which

Figure 2. Physical capability across the life course. Source: Kuh et al. 2007.

you're going to have important functional limitations and disability as early as midlife.

We spend the first 30 years of our lives getting as strong and fit and smart as we can, trying to build our reserve capacity up to the highest possible level. After that we're making withdrawals.

Yale Precipitating Events Project (PEP)

As clinicians, my colleagues and I have long been interested in better understanding what drives disability. It is not just that older persons have impairments. Something else is happening to them that causes disability to happen, and we wanted to identify those factors, those intervening events.

PEP is a longitudinal study begun in 1997 to track the functional status of older adults living in the community. A sample of 754 nondisabled, community-living persons 70 years of age and older, was drawn from a computerized list of 3,157 age-eligible members of a large health plan in New Haven, Connecticut. Members

were eligible if they spoke English, lived in the community, and were nondisabled, that is, they required no personal assistance in four key activities of daily living (ADLs): bathing, walking, dressing, and transferring from a chair (Gill et al. 2001). Excluded were those who were diagnosed with a terminal illness and a life expectancy of less than one year, or who planned to move out of the area within the next year, and those with significant cognitive impairment and no available proxy. Each participant was given a comprehensive physical and cognitive baseline assessment by a trained research nurse.

To ensure that enough vulnerable older persons were included, participants were enrolled in a 4:2:1 ratio for low, intermediate, and high risk for disability, respectively, using a model developed in an earlier study (Gill, Williams, and Tinetti 1999). Risk for disability, or vulnerability, was determined by age (distinguishing young-old, less than 85 years of age, from old-old, age 85 or older), physical performance in the rapid gait test (walking back and forth over a 10-foot course as quickly as possible), and cognitive performance on the Mini-Mental State Examination (MMSE) or Folstein Test.

Participants have remained highly committed to the research; after more than 11 years, fewer than 5 percent of them have withdrawn from the study. Although the PEP study was originally envisioned as lasting only a couple of years, it has continued to the present day. As a result we have a much clearer picture of the disabling process among older Americans.

The unique aspect of this study, however, is that we have been interviewing participants every month over the phone for more than 11 years, asking a series of questions to document their functional status, focusing on four key activities of daily living: bathing, dressing, walking, and transferring. These are the big four. These are activities that older persons need to be able to complete in order to remain independent in their own home. We also inquire about events that could potentially precipitate functional decline

and disability, focusing primarily on admissions to the hospital and episodes of restricted activity.

Hospitalization and Restricted Activity

One of our early findings was that, indeed, hospitalization and other illnesses or injuries leading to restricted activity represent important sources of disability (Gill et al. 2004).

Table 1. Factors Associated with Development of Any Disability			
Factor	Multivariable Hazard Ratio	95% Confidence Interval	P Value
Age per each 5 years	1.34	1.20 to 1.50	<.001
Female sex	1.07	0.84 to 1.37	.59
Lives alone	0.66	0.53 to 0.83	<.001
Number of chronic conditions	1.09	1.00 to 1.17	.06
Cognitive impairment	1.29	0.95 to 1.74	.10
Depressive symptoms	1.32	1.03 to 1.68	.03
Physical frailty	2.09	1.67 to 2.62	<.001
New intervening events			
Hospitalization	59.8	46.6 to 76.8	<.001
Restricted activity only	5.11	3.84 to 6.79	<.001
Source: Gill et al. 2004.			

After accounting for all of the factors at the top of Table 1—age, sex, chronic conditions, cognitive status, depressive symptoms, physical frailty defined on the basis of the slow walk test—the hazard for disability in the event of a hospitalization is nearly 60-fold. And even if you take to bed or have to cut down on your usual activities but you are not actually hospitalized (i.e., have restricted activity only), the hazard is 5-fold. These hazard ratios dwarf those of any other factor that has previously been evaluated.

What is really driving disability are these episodes of illnesses or injuries.

Population attributable fractions illustrate how much of disability in the general population can be explained by these two types of intervening events (Table 2). For disability in one or more of four ADLs—bathing, dressing, walking inside the house, or transferring from a chair—hospitalization explained almost half, while

Table 2. Population Attributable Fractions		
New Intervening Event	Any Disability	Disability with Nursing Home Admission
Hospitalization	0.48	0.82
Restricted activity only	0.19	0.05
Source: Gill et al. 2004		

restricted activity explained almost 20 percent. And if the outcome is defined as disability that leads to a nursing home admission, hospitalization explains about 80 percent. Restricted activity by itself seldom leads to a nursing home admission. The pathway to a nursing home with disability is being hospitalized.

Bed rest during hospitalization leads to a substantial loss of lower extremity strength. Kortebein and colleagues (2008) studied the effects of 10 days of total bed rest on a small group of healthy older adults, age 60 to 85 years. Isokinetic muscle strength declined by about 13 percent, maximal aerobic capacity was 12 percent lower, and the percentage of time spent inactive increased by nearly 8 percent after the bed rest. These were healthy seniors who didn't have sarcopenia to start. If a frail older person is hospitalized and put to bed, that's a very potent source of sarcopenia and muscle weakness, largely through catabolism, or breakdown of muscle tissue.

Falls, Hospitalization, and Disability

My colleagues and I looked for the reasons why older adults were being hospitalized or were restricting their activity (Gill et al. 2004). Not surprisingly, the most common reason for hospitalization was a cardiac diagnosis, but the major driver of disability was an injurious fall that led to hospitalization. About half of these falls were hip fractures. For the restricted activity exposure, fatigue was the most common cause, but a fall was the one most strongly linked to disability. We know from my colleague Mary Tinetti's work that falls are preventable and probably should be high on our priority list if we want to reduce rates of disability.

Recovering from Disability

We also wanted to understand better what happens after an older person becomes disabled, so we looked at the PEP sample for 51 months from March 1998 to May 2003 (Hardy and Gill 2004). During that period, slightly more than half (420, or 56 percent) of participants experienced disability, that is, they became dependent on assistance for one of four key ADLs—bathing, dressing, walking, and transferring between bed and chair—for at least one month. Of these newly disabled participants, 81 percent recovered, that is, reported no ADL disability, within 12 months. This rate is much higher than the 30 percent rates of recovery that had been reported earlier, likely because we were monitoring our subjects every month, rather than annually or biannually. Even among those who reported persistent disability—two or more consecutive months, or chronic disability—three or more consecutive months, 68 percent and 60 percent, respectively, recovered independence within 12 months.

Predictors of Recovery

Then we looked at the predictors of recovery among newly disabled older persons, both in terms of how long it takes to recover and how long that recovery lasts (Hardy and Gill 2005).

Time to Recovery

- habitual physical activity
- mild disability (1-2 ADLs) at onset
- hospitalized in the month of disability onset

Duration of Recovery

- age
- habitual physical activity
- functional self-efficacy
- duration of prior disability episode

Physical activity is the one predictor that was significantly associated with both of these recovery outcomes.

Rehabilitation in Nursing Homes

The functional trajectories among hospitalized older persons admitted to a nursing home with disability are generally poor. Among the PEP participants, 296 (39 percent) were newly admitted to a nursing home with disability after an acute hospitalization over a 10-year period of follow-up (Gill et al. 2009).

In the month preceding hospitalization, 64 percent of those who were hospitalized and then admitted to a nursing home had no disability. Only 34 percent of those with no disability in the month prior to hospitalization were subsequently discharged home from the nursing home without disability. Another 40 percent were discharged home but with a disability. Twenty percent remained disabled and stayed in the nursing home. A very small percentage, 3 percent, stayed in the nursing home and bounced in and out of disability.

It’s even worse for the nearly 40 percent who had disability before they were hospitalized. A very small minority of them, less than 10 percent, went home nondisabled despite getting rehabilitation in a nursing home after their hospitalization.

The reasons underlying these poor functional outcomes are not clear. One possibility is that subacute, rehabilitative care may not be particularly effective in restoring independent function after a disabling event. Another possibility is that the prognosis after some disabling events is poor.

Figure 3: Trajectories of disability in the last year of life.
Source: Gill et al. forthcoming.

Trajectories of Disability

Over the last 10 years of PEP, an increasing number of participants have died, which has given us the opportunity to examine what happens at the end of life. Figure 3 shows 5 different trajectories of disability in the last 12 months of life based on our data. The top trajectory includes those who were severely disabled for the entire last year of life, about 25 percent of the decedents. At the

bottom is the nondisabled group who had no disability for the entire 12 months, a little less than 25 percent. Two of the other three groups start at the same place as the nondisabled group a year prior to death; the accelerated group starts developing disability about 9 months prior to death, and the catastrophic group is nondisabled until about 3 months prior to death. The progressive group has some disability a year prior to death, and their disability increases gradually. The three groups—progressive, accelerated, and catastrophic—converge in the month prior to death. These are each sizable groups, somewhere between 18 and 25 percent. Based on our data, about 80 percent of older persons are disabled in the month prior to death.

Figure 4: Trajectories and causes of death. Source: Gill et al. forthcoming.

We can also link these trajectories to causes of death: cancer, advanced dementia, organ failure, frailty, people who die suddenly (a very small group), and another category that didn't fit in any of the others (Figure 4). Nearly three-quarters of participants in the advanced dementia group were debilitated for the entire 12-month period of time. The functional trajectories for the five other causes

of death were quite varied; there's not a prominent trajectory for any of them. In the coming months, we hope to learn more about the factors that lead individuals who are dying of cancer, for example, to have one functional trajectory versus another.

Prevention of Disability

There are three different preventive strategies:

- **primary** prevention, which focuses primarily on early and midlife and is concerned with hypertension, smoking, cholesterol, vaccinations—and exercise. Over time the importance of these modes of prevention declines, and
- **secondary** prevention becomes more important when individuals develop impairments that put them at risk for disability, or early indicators of disability. Then the strategies are medical management, geriatric assessment, fall prevention—and exercise. Finally, there's what I call
- **tertiary** prevention for individuals who are already disabled, so the focus is on rehabilitation, medical management, geriatric assessment—and, again, exercise.

Exercise cuts across all three of these modes of prevention.

Yale PREHAB Study

Successful prevention strategies to prevent or delay disability in older adults have been developed and assessed in the last 15 years or so. They include **comprehensive geriatric assessment** (e.g., Stuck et al. 1995), which has been shown to delay development of disability and reduce permanent nursing home stays; **disease-specific strategies** (e.g., Ettinger et al. 1997) focusing on, for example, knee osteoarthritis, which are shown to modestly improve measures of disability, physical performance, and pain; and **center-based interventions** such as tai chi (Wolf et al. 1996) or resistive and aerobic training (Ades et al. 1996), which are

shown to reduce falls, increase muscle mass and strength, improve gait and balance, and enhance aerobic capacity.

The Yale PREHAB Study was a six-month, home-based **prehabilitation** intervention of physical therapy, including progressive balance and conditioning exercises, designed to prevent functional decline and disability in frail elderly persons (Gill et al. 2002). Participants included 188 community-living men and women aged 75 years or older (mean age was 83) who were ambulatory but physically frail. They were therefore at high risk for becoming either newly disabled or more severely disabled. To identify persons who were frail, we used two tests of physical performance; if they took more than 10 seconds to complete the rapid gait test or were unable to stand from a hard-back chair without using their arms, they were labeled moderately frail. If they met both of these criteria they were labeled severely frail. We recruited participants from doctors' offices in the adjacent county when they came in for their usual primary care visit.

Participants in the prehab group were assessed in their homes by physical therapists for specific impairments and then trained to perform exercises or adaptive strategies appropriate for each impairment. They were encouraged to perform the balance and conditioning exercises on their own at home. The areas targeted by the intervention included: muscle strength, balance and transfers gait both indoors and outdoors, assistive devices and footwear, an array of compensatory strategies to manage better in their own environment, and trying to remove obstacles or hazards or impediments in the home. The muscle strengthening was done using Theraband® elastic bands that were set up and left in place in the home. One of the compensatory strategies was, rather than walking down the basement stairs carrying a basket of dirty laundry, putting the clothes into a bag, tossing the bag down the stairs, and then walking after the bag.

It was a successful intervention for the moderately frail group. Seven months and one year after the program started they were a little less disabled, while the control group, who received an educational “successful aging” intervention, got worse. At the end of 12 months, there was about a 40 percent protective effect for the prehab intervention. Individuals who had problems in both rapid gait and standing from a chair, and who were therefore considered severely frail, received much smaller benefits that were not statistically significant.

The LIFE Study: Lifestyle Interventions & Independence for Elders

In relatively small studies, physical activity (PA) and exercise have been shown to preserve and gain back muscle, preserve and gain back bone, improve strength and balance—and subsequently reduce injuries; reduce arthritis symptoms; improve mood, self-esteem, self-confidence; decrease depression; improve sleep; and yes, reduce disability and maintain independence. We’re hoping to confirm these benefits with an elderly, sedentary population in the LIFE trial.

This is designed as a secondary prevention trial and will be the largest and longest PA trial to date, involving 1,600 individuals in 8 sites followed for an average of 3 years. We are going to compare two different lifestyle interventions in preventing major mobility disability in a group that is 70 to 89 years old with SPPB scores equal or less than 9 (out of 12), but who can walk 400 meters on a standard walking course in less than 15 minutes. Participants in the PA group will receive a structured physical activity program consisting primarily of walking at a moderate intensity for at least 150 minutes a week, coupled with leg stretches, balance exercises and leg-strengthening exercises. Participants in the other group will be given “successful aging” instruction on good living practices, including information on nutrition, medications, foot care and preventive services.

We have already completed a pilot study of 424 older persons in four sites across the country, in which the primary outcome was the SPPB. We found that SPPB scores improved between zero and 6 months, and those improvements were largely maintained over the subsequent 6 months, compared to the Successful Aging (SA) educational intervention (Espeland et al. 2007).

The primary outcome for the full scale trial that we are about to launch is major mobility disability, defined as the inability to walk a quarter mile or 400 meters. Data collected in the pilot, which was not powered to evaluate this definitively, suggests that the intervention is likely to be successful in preserving the ability to walk around in the community.

We also found that increasing exercise and physical activity leads to more falls, but fewer fall-related injuries. Although the pilot project was not powered to evaluate this either, the SA group had a rate of serious fall injuries of 3.3 percent relative to 1.4 percent in the PA group, which represents a 60 percent reduction. More people in the PA group fell, but they were less likely to be injured. That's been suggested by other studies as well. It probably reflects the opportunity time; the more active persons are, the more opportunity they have to fall. But as they become more robust they're able to protect themselves and are less likely to become injured.

Fall Prevention

In 1994, Mary Tinetti, the world's expert in falls, and her colleagues completed the Yale FICSIT Trial (Frailty and Injuries Cooperative Studies of Intervention Techniques), a clinical trial of community-living older people who could walk unassisted, did not exercise regularly, and possessed at least one of several risk factors previously associated with falling (Tinetti et al. 1994). These factors include:

- postural hypotension, i.e., drop in blood pressure when moving from lying down to standing up;
- use of prescription or nonprescription sleeping medications;
- use of 4 or more medications;
- unsafe tub or toilet transfer observed during assessment;
- gait or balance impairment observed during assessment;
- strength or range-of-motion impairment in arm and/or leg.

Participants in the intervention received an assessment of their medications by a physician, behavioral adjustments, and exercise programs aimed at modifying their risk factors. Tinetti and her colleagues showed a one-third reduction in the incidence of falls. But nothing changed, and practice continued as before, until 1998. That year a report was issued saying that falls were the major unintentional injury for which people went to the ER or were hospitalized in Connecticut. In response, the Connecticut Collaboration for Fall Prevention (CCFP) was formed to disseminate fall assessment and fall management strategies derived from the FICSIT Trial to clinicians in a designated geographic area of the state, including Hartford (Baker et al. 2005).

Subsequently, Tinetti and her colleagues compared the rate of injuries from falls in the region where information dissemination had taken place to another region where clinicians were still practicing in the usual way (Tinetti et al. 2008). Prior to the intervention, the rates of fall injuries in the two regions were comparable. During the intervention phase (October 2001 - September 2004), the adjusted rate of serious fall-related injuries—hip and other fractures, head injuries, and joint dislocations—was 9 percent lower in the intervention region, and this change persisted into the evaluation phase (October 2004 - September 2006). Currently, there is no fall benefit in Medicare, and doctors are not compensated for doing a fall risk assessment. Perhaps with

health care reform, these types of practices will be supported and reimbursed.

Pharmaceutical Prevention of Disability

If only there were a pill to prevent all this! Pharmaceutical companies are very interested in the possibility. They've discovered sarcopenia, functional decline, and disability. They can't develop any more cholesterol drugs, they already have everything we need for hypertension, they've already addressed osteoporosis, and they are now ready to focus on muscle and functional outcomes.

We are participating in an NIA-funded trial, the largest testosterone trial to date, with a sample of about 800 men over 12 sites. These are men who are clearly hypogonadal, with low testosterone levels documented on two occasions. They're symptomatic and they have objective evidence of specific deficits. There are five trials within the larger clinical trial, focusing on physical function, sexual function, vitality or well-being, cognitive function, and anemia. We are also assessing the benefits in cardiovascular health, and, if an ancillary study is funded, bone health.

Conclusion

Frail older persons at high risk for disability can be easily identified with simple tests of physical performance, the so-called "geriatric vital signs." Disability often results when a precipitating event is superimposed upon a vulnerable host. Functional decline and disability are dynamic processes with high rates of recovery. And, finally, disability is clearly preventable through exercise and physical activity, through fall prevention, and perhaps in the future through pharmacologic treatment.

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