# Workshop on Identifying New Interventions To Extend Disability Decline in Elderly Populations<sup>1</sup>

National Institute on Aging Meeting Summary National Academies, National Research Council September 14–15, 2006

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# I. Introduction and Background to the Meeting

The Workshop on Identifying New Interventions To Extend Disability Decline in Elderly Populations was convened September 14–15, 2006, by the Committee on Population at the National Academies and chaired by Robert Wallace (University of Iowa). The goal of the workshop was to consider specific low-cost interventions drawing on the lessons of demography, public health, economics, community medicine, and other fields. The interdisciplinary approach is reflected in the invited presentations. Background readings on causes and consequences of disability among the elderly and interventions to reduce disability and their cost-effectiveness were shared with workshop participants in advance of the meeting. Specific topics included cost-effectiveness analysis to rank interventions, relevant findings from the international Disease Control Priority approach, environmental- and community-based interventions, translating and scaling up interventions, other lessons from clinical and personal interventions to prevent and/or mitigate disability, and prospects for interdisciplinary research.

In his welcome, Michael Feuer, Executive Director of the Division of Behavior of Social Sciences and Education, National Research Council (NRC), explained that the NRC functions as a scientific organization that provides the Federal government with unbiased and unremunerated advice from leading experts on pressing science and public policy issues. As extensive research has focused on extending the disability decline in elderly populations, Feuer reiterated that a primary aim of this meeting was to further focus the research agenda on possible strategies and applications to benefit the aging population.<sup>2</sup>

The following report highlights the main themes from the meeting presentations and discussion. The meeting agenda and roster of participants are included as Appendices A and B.

http://www.nia.nih.gov/ResearchInformation/ExtramuralPrograms/BehavioralAndSocialResearch/ConferencesAndWorkshops.htm

<sup>&</sup>lt;sup>1</sup> The statements, conclusions, and recommendations contained in this document reflect both individual and collective opinions of the workshop participants and are not intended to represent the official position of the U.S. Department of Health and Human Services, the National Institutes of Health, or the National Academies. This document was prepared by Rose Li and Associates, Inc., under contract to the National Institute on Aging (rose@roseliassociates.com).

A brainstorming workshop, "Disability Decline: What We Know; and What We'd Like to Know," was held on November 30, 2001, at the National Institutes of Health. The workshop included discussion of targeted foci for future investigations. A summary of the workshop, which was organized by the National Institute on Aging and the National Bureau of Economic Research is available at

## A. Sponsor Perspective

The study of interventions to improve health comprises many different, isolated communities, and between-discipline interaction among researchers can greatly benefit the research field. Richard Suzman, Director of the Behavioral and Social Research (BSR) Program of the National Institute on Aging (NIA) sought to outline a strategic vision for intervention studies to be conducted over the next 5 to 10 years. Many interventions have been done to improve health and reduce risk factors; for example, (1) the Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE), (2) Resources for Enhancing Alzheimer's Caregiver Health (REACH), (3) the work by James Choi and others focusing on 401(k) retirement savings plans, (4) the work of Linda Fried involving elderly adults in schools to determine if volunteering improves function and cognition,<sup>3</sup> and (5) the Work and Iron Status Evaluation (WISE) involving nutrition supplementation in Indonesia that seeks to determine the causal effect of improvements in health on the economic and social prosperity of individuals and their families. Research also has focused on exercise and lifestyle interventions, changes to healthcare systems, medical care compliance, mental health, health in long-term care units, and environmental factors. In the future, it will be possible to support only a small number of interventions. Deciding the range and size of interventions that are feasible as well as how to incorporate social epidemiological and demographical components from observational studies are main points of emphasis for the BSR Program. This is a difficult task, particularly considering that epidemiological findings often have not stood up to the test of randomized controlled trials. Thus, it is all the more important to subject epidemiological findings to interventions to confirm cause and effect as well as impact.

Other BSR Program foci include (1) the potential of the obesity epidemic negating the decline in disability rates first documented by Kenneth Manton using data from the National Long Term Care Survey (NLTCS) and (2) improving the measurement of disability in elderly populations beyond the traditional survey measures of activities of daily living (ADL) and instrumental activities of daily living (IADL). For example, the possibility of 24-hour participant time-use observation appears promising. Suzman plans to request that the NAS convene a meeting on improving measurement of physical and cognitive functioning outcomes in the near future. In paraphrasing Geoffrey Rose's notion that an intervention that reduces widespread risk factors by a small amount has a greater impact at the population level than an intervention affecting only a few very ill individuals, Suzman emphasized that the BSR Program must consider how to allocate support for interventions thought to be most useful across broader but well-defined populations; e.g., community members, population subgroups, health plan participants, company employees, profession members. Likewise, cost-effectiveness must be considered in order to determine which combinations of interventions would have the most impact for a given dollar amount.

Suzman emphasized that future research is not limited to the United States; countries with high education and low income would be considered, as would a large-scale collaboration focusing on coordinated interventions in population aging. Different interventions should be considered for

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<sup>&</sup>lt;sup>3</sup> Fried LP, Carlson MC, Freedman M, et al. A social model for health promotion for an aging population: initial evidence on the experience corps model. *J Urban Health*. 2004;81:64-78.

<sup>&</sup>lt;sup>4</sup> Rose G. Sick individuals and sick populations. *Int J Epidemiol*. 2001 Jun; 30(3):427-32.

those in a variety of age groups; for example, 55–64, 65–79, and 80 and above. Suzman challenged the group to consider interventions with time horizons from 5 to 10 years (though for some interventions, showing an impact within 12 months would be important) and help the BSR Program develop a framework for determining which health problems require immediate interventions within that timeframe. Finally, Suzman emphasized that collaborating within the National Institutes of Health (NIH) and with agencies such as the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC) could be considered.

## B. Intervening in Disability: An Overview

To reflect the heterogeneous set of processes and conditions in the face of age-related changes, Wallace considered two disabled communities of older adults: (1) Individuals with adult-acquired disability, and (2) mentally retarded and/or developmentally disabled individuals. Gerontology teaches that some disability prevention should occur early in life, but behavior changes are often difficult to implement. Although the role of disease prevention is paramount in preventing disability, a substantial number of disabling conditions (e.g., bunions, psoriasis, bursitis, anemia) that do not receive as much attention as major illnesses collectively contribute substantially to disability in the population.

Wallace presented a conceptual framework for disability that relies on an international classification of impairments, disabilities, and handicaps. In this framework, diseases are pathological processes, impairments are physiological abnormalities, disability is defined as decreased function in a standardized environment (also termed dysfunction), and handicap is consonant with psychosocial disadvantage. Wallace also explained the convention of primary, secondary, and tertiary levels of intervention. Primary refers to before disease onset, secondary to early and asymptomatic detection and intervention, and tertiary to altering the progression of overt disease.

Venues of intervention could include clinical settings and community and healthcare organizations. Methods of intervention could include clinical trials, community trials, participatory research, social engineering, and professional practice programs. Other methods related to the environment, social marketing or media, nutrition, and political change, while all important, were not planned to be discussed at this meeting. Physical measurements; environmental change; improved quality of life; decreased mortality, morbidity, and disease progression; and decreased cost of care, as well as selected social and behavioral dimensions, are examples of approaches to determine when outcomes are reached. Wallace observed that the technical advances that have decreased the amount of physical exertion required by the disabled to complete daily tasks could be have unanticipated negative consequences for nondisabled individuals.

Mental illness contributes significantly to disability, as lifetime prevalence is nearly 45 percent for some types of mental illness.<sup>5</sup> Social situations also are important to understand when

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<sup>&</sup>lt;sup>5</sup> Kessler RC, Berglund P, Demler O, Jin R, Walters EE. Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*. 2005;62(6):593-602.

considering interventions to decrease disability. As an example, an association between reported instances of elder mistreatment and increased mortality rate demonstrates room for improvement in terms of interventions that benefit the frail and vulnerable older population. Wallace also discussed the role of iatrogenesis on health and disability.

Neurophysiologic bases of disability are increasingly being understood, and tools such as functional magnetic resonance imaging (fMRI) have been used to track changes in the brain throughout the progression of the rehabilitative process. Suzman added that research is increasingly focused on understanding where in the brain habits are formed, learned, or unlearned, and greater appreciation of this process will help in determining which interventions are most successful for decreasing disability. Use of fMRIs can show, for example, how the brain changes with therapy, and this will undoubtedly be useful technology as it becomes more refined.

## C. Cost-Effectiveness: The Disease Control Priority (DCP2) Approach

Philip Musgrove (*Health Affairs*) spoke about determining cost-effectiveness of interventions using the Disease Control Priorities in Developing Countries (DCP2) approach. The DCP2 was designed to provide policymakers in low-income countries a framework to choose interventions based on best buys and at the same time discourage adoption of poor buys for interventions with dismal cost-effectiveness ratios. A summary of the main findings of the research (which covers over 300 interventions), organized by purpose of intervention, condition to be changed, target age group, and cost-effectiveness of the intervention, was included among the background readings. For the purpose of this meeting, Musgrove concentrated on cost-effectiveness as the specific measure, relating costs and outcomes of cost-benefit analysis to maximize efficient spending on health.

The DCP2 defines intervention as "actions taken by or for individuals to reduce the risk, duration, or severity of an adverse health condition" and divides interventions into those that are population-based and those that are individual-based or personal. Interventions have a number of objectives, including primary or secondary prevention, cure, acute or chronic care, rehabilitation, and palliation. Any deliberately induced improvement in health status may be examined for cost-effectiveness.

Interventions are always being conducted in low- and middle-income countries, but their costs have been difficult to track. This is in part because many interventions are occurring through private providers that focus on revenue but not on costs. At the same time, available public information does not provide clear cost accounting for interventions; often only budgetary information is available. DCP2 derived cost estimates from two sources: (1) Actual observations

<sup>&</sup>lt;sup>6</sup> Lachs MS, Williams CS, O'Brien S, Pillemer KA, Charlson ME. The Mortality of Elder Mistreatment. *JAMA*. 1998; 280:428-432.

<sup>&</sup>lt;sup>7</sup> Laxminarayan R, Chow J, Shahid-Salles SA. 2006. Intervention Cost-Effectiveness: Overview of Main Messages. In: Jamison DT, Breman JG, Measham AG, et al, eds. *Disease Control Priorities in Developing Countries*. New York: Oxford University Press; 2006: 35-86.

<sup>&</sup>lt;sup>8</sup> Ibid, p.59.

where costs were tracked and (2) regional averages of prices of inputs such as cost of a doctor's time, nurse's time, laboratory tasks, and other variables.

The other part of the ratio, effectiveness, was defined as reduction in disease burden. The World Health Organization (WHO) calculated disease burden from premature mortality by taking the age of death and uniform world age-specific life expectancy (so as not to discriminate against regions where life expectancy is low) and discounted this at 3 percent per year to yield a discounted sum of years of life lost. DCP2 used disability adjusted life years (DALYs) as the outcome measure of interest as it captures effects from the postponement of both disability and mortality. For example, DALYs gained from preventing malaria results overwhelmingly from averted mortality; DALYs gained from treating mental illness results mostly from averted disability.

For disability, specific functional measures were not used; instead, the generally accepted set of WHO disability weights was attached to diseases or conditions. These weights do not connect to the specific kinds of conditions used to define disability but, rather, recognize that a particular condition or health problem results in some loss of health, possibly from several different specific disabilities. To compute the burden of disease associated with a disability, one integrates the disability weight over the duration of the condition or disease, which could be until death or until the natural recovery from disease. DALYs are much like quality adjusted life years (QALYs), except that the former is highly disease specific and the latter has a more functional basis. As such, there is no simple conversion between the two measures where disability is concerned; they coincide for years of life lost to death.

Other than the discount rate and the disability weights, subjective valuations were not included in the DALY measure of burden of disease. DCP2 does not weight a year of childhood differently from a year of adult life. Ratios of cost to effect were expressed as the cost of saving one DALY added up across the population; this is total expenditure on the intervention divided by all the DALYs gained from it. No distinction was made between saving 1 year for 10 people and 10 years for 1 person.

DCP2 grouped some interventions by type of disease or condition (tuberculosis, HIV/AIDS, childhood illnesses and mortality, malaria and other tropical diseases, maternal and neonatal health, nutritional deficiencies, cancer prevention and treatment, mental and neurological disorders, cardiovascular disease, injuries). Others were classified according to their effect on risk factors, such as alcohol and tobacco use, and still others dealt with health services delivery. Cost-effectiveness estimates assessed whether one intervention was better than another intervention within each type and also across types. No comparisons were made between diseases or conditions in terms of how well people can cope with them or become accustomed to them.

DCP2 was an exercise in priority setting, but simply ranking interventions by cost-effectiveness ratio would ignore some ethical considerations. Likewise, the cost-effectiveness ratio helps to determine only if the intervention is worth doing but says nothing about who should pay for it. That value judgments must play a role is illustrated by the need to weigh the benefits from applying \$1 million to a particular intervention as compared to applying the same amount to (1) a

different intervention for the same disease or (2) the same intervention for a different disease. Musgrove observed that there are interventions that are explicitly aimed at medical and health processes and others that use policy or other platforms for change. Certain interventions (such as cigarette taxes) can successfully promote health but do not necessarily generate goodwill among those who must pay the cost.

The DCP2 approach does not address when in the lifespan interventions for disability should occur. Broad age groups are analyzed, with the oldest age group being adults over 40; distinctions, therefore, are not made among elderly age groups. With regard to lead times and expected outcomes, the effect of discounting is severe for long-running projects or interventions with expected outcomes in the distant future. Musgrove acknowledged that all cost-effectiveness determinations are based on the assumption that best practices are being used in a country on a reasonable scale. This means that the cost-effectiveness ratio of dollars per DALY are actually lower bounds when one considers the poor level of healthcare services in many lower to middle-income countries.

A new intervention must be tried out to learn whether it is cost-effective compared to existing interventions. If a trial shows no effect but still has cost, the cost-effectiveness ratio is zero. One question to consider in designing a trial is, When can it be assumed that effects will be observed in an interval reasonable enough to allow the trial to continue? Depending on the interventions, effectiveness can sometimes be estimated over a 10- to 20-year horizon just as well as over a 2-year horizon.

# II. Overview of Community Interventions and Prospects for Interdisciplinary Research

## A. Comparing Population-Level Effects of Disability Interventions

Vicki Freedman (University of Medicine and Dentistry of New Jersey) outlined three goals of her presentation: (1) To suggest information needed to compare the population-level impacts of disability-related interventions, (2) to illustrate how comparisons can be made based on existing literature in both the short and long term, and (3) to highlight several gaps in the literature, particularly those that would allow longer term comparisons.<sup>9</sup>

Freedman defined disability conceptually as dependency; that is, the inability to carry out tasks independently without help from another person. ADL disability, IADL disability, and mobility are included in this definition. Use of this definition means that an environmental modification (e.g., addition of grab bars or ramp) that allows an individual to maintain independence would be considered an intervention that reduces the prevalence of disability, even if it does not change an individual's underlying functional capability. A specific intervention could target singly or in combination many factors that contribute to disability, such as strength or endurance, depressive symptomology, and barriers in the home. Most intervention studies do not include "disability" as

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<sup>&</sup>lt;sup>9</sup> This presentation was based upon findings reported in Freedman VA, Hodgson N, Lynn J, Spillman B, Waidmann T, Wilkinson A, Wolf DA. Promoting late-life disability decline: A comparison of three potentially high-impact interventions. *Milbank Memorial Quarterly*. 2006;84(3):493-520.

an outcome but instead target proximate risk factors. It is, therefore, important to distinguish efficacy in influencing a risk factor from efficacy in reducing disability.

The comparative framework developed by Freedman and colleagues suggests that in the short term, the effect of a widespread intervention on the prevalence of disability in the population depends on (1) the size of the target population with the specific risk factor for disability, (2) the relationship between risk factor and disablement process, and (3) the effectiveness of the intervention in changing the distribution of the risk factor in the population.

Effectiveness of an intervention is a function of the intervention's efficacy, or how much risks are reduced under ideal laboratory conditions. In actual practice, the extent of adherence and any differences between the study population and the true target group are also important contributors to intervention effectiveness. When considering effects of an intervention over a longer period of time, two additional considerations are important: (1) Knowledge of the future composition of the target population, such as if the risk factor will be as prevalent in the future in the absence of any intervention; and (2) any information about the influence of the intervention on length of life and competing risks, in which case the question of compression of morbidity is of paramount importance.

Freedman next illustrated how comparisons can be made based on a systematic literature review of intervention approaches and clinical trials involving the older population. To focus the review, a panel of experts identified existing interventions that seemed likely to have a significant impact on population-level disability prevalence. Consideration was limited to interventions not already widespread that had some published evidence demonstrating efficacy and that, if implemented, could provide benefit within a few years in terms of reducing disability in the older population. Freedman focused on three interventions that were highly ranked: (1) Exercise, including aerobic exercise, strength or endurance training, quadriceps training, and walking; (2) fall prevention including multifactor interventions that most often combined education about risks with exercise, home safety, and health assessments; and (3) depression screening with feedback and referral and treatment using antidepressants and combination therapies.

Short-term comparisons of the targeted risk factors showed that the greatest number of people are at risk of inactivity (19 million or 51 percent), compared to 12 million (33 percent) at risk for falls, and 10 million (30 percent) at risk for unrecognized depression. However, falls had the highest relative risk for disability (2.0–3.0) compared to inactivity (2.0) and unrecognized depression (1.5–2.0). About 20 to 30 percent of those who fall each year—roughly three times the average rate of disability incidence—suffer severe injuries such as hip fracture or head trauma that may lead to death, disability, and/or institutionalization.

Aerobic activity and strength-building exercises showed strong evidence of changing muscle mass and endurance (the risk factor) but had inconsistent effects on disability. A multifactor fall prevention approach showed more moderate efficacy on averting falls and on changing disability, while depression screening and treatment programs to enhance recognition of the problem in the population had small to no efficacy in changing disability outcomes and a small effect on remission. Adherence was either problematic or not addressed. For example, exercise adherence ranged from 60–90 percent for relatively short periods of time, but lower rates were

evident over longer periods of time. The fall prevention trials did not give a good sense of the extent of adherence as samples were often small and not diverse. Adherence rates for depression treatment were in the 60–80-percent range. Generalizability proved to be an issue due to small samples, biased toward healthy subjects for exercise, often not diverse for fall prevention, and too few studies with depression screening in older samples. In general, combining strategies to target multiple risk factors (e.g., manage physical and mental health, avoid injuries, and adapt the home environment) led to more consistent results than single-factor approaches. In the short term, multifactor fall prevention interventions appeared more promising than exercise or depression screening and/or treatment alone.

In reviewing longer term comparisons based on simple simulations, Freedman presented four prototypical trajectories that individuals follow at the end of life based on studies by Joanne Lynn, June Lunney, and others: (1) Cancer, (2) organ failure, (3) sudden death, and (4) dementia/frailty. About 20 percent of the older population eventually dies of cancer, with a short period of decline before death. Another 20 percent die of organ failure (conditions such as congestive heart failure and chronic obstructive pulmonary disease), in which there are about 3 years of flare-ups punctuated by periods of recovery, with death, on average, by age 80. A slow but relentless decline in function is common among those with strokes, dementia, and frailty; the average period of disability before death for this trajectory is about 5 years.

As a thought experiment, Freedman asked how the steady-state prevalence would change if people were moved across trajectories or the length of trajectories were shifted. Compared to the baseline case of 20-percent disability prevalence, Freedman reported that (1) preventing cancer and organ system failures have almost no effect on population disability (even though they do increase life expectancy), (2) delaying disability by 1 year among those in the frailty trajectory can reduce disability to about 17 percent, and (3) smoothing out disability in the organ failure trajectory reduced disability by only 0.6 percentage points. Given that the largest trajectory is frailty/dementia and on average the affected population experiences the longest period of dependence, it seems reasonable to target interventions early in the frailty trajectory.

Finally, Freedman identified a number of gaps in the literature, including (1) no comprehensive study of the causes of disability that include not just chronic disease but also physical, social, and environmental aspects (little is known about how much disability could be resolved solely through environmental changes, how many individuals need multifactor interventions, or what factors are most needed); (2) few studies that evaluate long-term disability and mortality outcomes; (3) lack of understanding of factors that improve adherence to protocols; and (4) the exclusion of frail elderly from clinical trials.

## B. Pathways to Disability

David Cutler (Harvard University) presented two important pathways to disability: (1) An adverse medical event leading to disability, the type usually associated with interventions; or (2) a pathway independent of an event, usually characterized as "old age." To date, most disability reductions in the elderly have been a result of reduced impact of a disease rather than reduced incidence of disease. Frailty is also an important consideration; nearly 15 percent of respondents

in the National Long-Term Care Survey (NLTCS) with no condition are disabled within a 5-year period.

There are many opportunities for intervention. Prevention can occur through behavior change (e.g., smoking, diet, exercise), medical intervention (e.g., medications), and social and physical environmental changes. Cutler emphasized that prevention is haphazard; no more than 50 percent of preventable disease is actually prevented. He also cautioned that focusing only on prevention among the elderly is too narrow: many interventions that have been successful in reducing disability were developed for other reasons. Specifically, convenience products, such as microwaves, cleaning technology, shopping technology, that were developed to make coping easier for the general population have proved useful for the elderly.

Cutler offered some economic considerations for judging interventions:

- Price matters: smoking, drinking, and food consumption are sensitive to price. Taxes can explain some of the decline in smoking over time. Implicit taxes (e.g., drunk driving penalties) explain some of the reduction in alcohol deaths, and the falling price (including preparation time) of food explains a good share of the increasing prevalence of obesity.
- Arguments about long-term benefits generally are not persuasive because long-term considerations are subsumed by immediate needs. Evidence suggests that people know what to do to be better off in the future; they simply do not change their behavior.
- Technology can help people optimize if it is able to simplify decisions. Examples of this type of technology include a "PolyPill" of all necessary medications, pill boxes that remind patients to take medicines, coaches who help patients work through the disease process, and improved assistive devices for home use; e.g., microwaves, lighter cleaning brushes.
- Peer influences are important because people take cues from their environment. Much of the decline in smoking and drunk driving can be attributed to peer influence.

# C. History of Interventions: Lessons from Enhancing Recovery in Coronary Heart Disease (ENRICHD)

Lisa Berkman (Harvard University) discussed lessons from randomized controlled trials (RCT) and observational studies that can help improve health in older populations. The results of psychosocial RCTs have been disappointing, as have recent trials aiming to change diet, obesity, or osteoporosis risk and those involving pharmacologic interventions. Berkman argued that the outcomes of these trials could be improved by (1) adopting a life course approach in which we identify the etiologic period of risk, (2) developing approaches that more fully incorporate a deeper understanding of the role of social context and public policy in creating change, and (3) identifying populations most in need and most likely to benefit from interventions. Experimental methods are important to add to psychosocial intervention approaches because selection and confounding are serious issues in observational studies, and the ultimate intention of interventions is to improve population health.

Berkman presented data from the Enhancing Recovery in Coronary Heart Disease (ENRICHD) trial, which aimed to test the hypothesis that treatment of depression and low social support early after an acute myocardial infarction (MI) will reduce death and nonfatal recurrent infarctions,

compared to usual care.<sup>10</sup> This hypothesis was based on observational data showing (1) low social support associated with an increased risk for mortality and cardiovascular morbidity, (1) depression associated with an increased risk for mortality and cardiovascular morbidity after MI, and (3) inconsistent results from psychosocial interventions in relation to cardiac morbidity and mortality. ENRICHD was a randomized, parallel-group clinical trial of 2,481 post-MI patients with depression or low social support who had an average of 3.4 years of followup. The intervention improved social support and reduced depression 6 months after baseline, but the control group did almost as well and there were no statistically significant differences in the survival curves between the study and control groups.

In assessing why the ENRCHD trial did not show an improvement in medical outcomes, Berkman noted that it was not known at the time (1) the etiologic period (i.e., whether changing social and psychological conditions only *after* an MI would alter risk); (2) the extent to which the assessment of social isolation reflected cumulative risk; or (3) the pathways—how social support and depression might biologically impact post-MI survival.

Similar results were observed from the Families In Recovery from Stroke Trial (FIRST). This randomized clinical trial examined whether a family systems intervention designed to influence social support and self-efficacy affected functional outcome in older stroke patients. The impact of the intervention was measured on secondary outcomes (IADLs, mortality) and, again, the results were non-significant; over time, those receiving interventions versus those in usual care exhibited no significant differences. A subgroup analysis of FIRST showed differential treatment effects. Healthier individuals (those with lower depression, less severe strokes, fewer preexisting conditions) and males had a greater chance of being impacted by the interventions. Individuals who were characterized as less frail improved significantly from the interventions, while individuals who were frailer and/or vulnerable may have been unable to benefit from the intervention. Data from ENRICHD also showed that White men had better survival compared to other individuals; White men were more likely to be married, less likely to live alone, had the fewest comorbidities, were in the most favorable ejection fraction (EF) categories and were least likely to be in Killip class III–IV, 12 were most likely to receive treatment for MI (thrombolytic therapy, cardiac catheterization, coronary revascularization), and were the most educated.

While there are reasonably consistent observational findings with regard to social conditions, the results from controlled trials continue to be disappointing. Possible explanations for this include (1) the exposure is not causally related to the outcome, (2) the intervention failed to change the

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<sup>&</sup>lt;sup>10</sup> Writing Committee for the ENRICHD Investigators. Effects of Treating Depression and Low Perceived Social Support on Clinical Events after Myocardial Infarction: The Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomized Trial. *JAMA*. 2003;289:3106-16.

<sup>&</sup>lt;sup>11</sup> Glass TA, Berkman LF, Hiltunen EF, et al. The Families In Recovery From Stroke Trial (FIRST): Primary Study Results. *Psychosom Med.* 2004;66:889-897.

<sup>&</sup>lt;sup>12</sup> Ejection fraction (EF) is the ratio of stroke volume to end-diastolic volume. EF categories are (1) severe dysfunction, (2) moderate dysfunction, and (3) mild dysfunction or normal. Killip class III is characterized by severe left ventricular failure: pulmonary edema and a hospital mortality rate in the range of 20–30 percent. Killip class IV is characterized by cardiogenic shock: hypotension, tachycardia, mental obtundation, cool extremities, oliguria hypoxia, and a hospital mortality rate greater than 80 percent. Both classes are associated with severely abnormal partial pressure of alveolar O<sub>2</sub>.

exposure or the relevant exposure (i.e., the etiologic period is incorrect), or (3) the exposure is causally linked to the outcome but there are heterogeneous treatment effects.

Life course perspectives on risk interventions can be used to inform future interventions. Latency models suggest that early life social conditions affect adult social and health outcomes; intervening later in life will not result in significant change. The cumulative exposure model suggests that early life exposures become embodied immediately, but adult social conditions also influence adult health; in this case, interventions in adulthood can partially offset harm incurred in childhood. Finally, the social trajectory model (which is the model the discussed research implicitly uses) suggests that early life exposures do not directly affect adult health but influence adult social conditions that affect adult health; in this case, interventions in adulthood can completely offset harm incurred in childhood.

Berkman concluded that life course issues are central to understanding risk modifications. She called for increased attention to the etiologic period in which risk occurs and observed that cumulative exposure models are typically used in current intervention research. She reiterated that interventions in some frail populations might not be helpful and could, in fact, be harmful, although limited research supports this observation. Finally, Berkman suggested that interventions can be improved with increased understanding of biological pathways resulting from the identification of conditions with acute versus chronic biological effects.

## D. Modeling the Potential for Disability Interventions

Baoping Shang (RAND Corporation) presented the RAND Future Elderly Model (FEM), a demographic and economic microsimulation model. <sup>13</sup> The model tracks individuals through time to project their health conditions, functional status, and ultimately their healthcare spending. The model can be used as an evaluation tool for disability-related interventions to project their long-term health benefits and costs and to produce cost-effectiveness measures such as dollars per DALY gain.

The FEM begins with a representative sample of individuals age 51+ in 2004 from the Health and Retirement Study (HRS). It predicts healthcare spending and other economic outcomes for each individual in 2004. Some individuals died in 2004 and would be dropped from the sample. For survivors, the model ages them by simulating their health conditions and functional status in the subsequent year using the estimated health transition models. As the initial sample ages, it becomes representative of the 52+ population in 2005. A new cohort of 51-year-olds is then added to the initial sample so that it is still representative of the 51+ population. This process is repeated until 2050.

Elements of the model included health-related outcomes, economic outcomes, and other demographic factors. Health-related outcomes included disease conditions (heart disease, diabetes, lung diseases, cancer, hypertension, stroke), functional status (ADLs and IADLs, nursing home, death), and risk factors (body mass index [BMI], smoking). Economic outcomes included labor market variables (employment, earnings), Social Security—related variables

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<sup>&</sup>lt;sup>13</sup> Goldman DP, Shang B, Bhattacharya J, Garber AM, et al. Consequences of Health Trends and Medical Innovation for the Future Elderly. *Health Affairs*. 2005;24 (Suppl 2):W5R5-R29.

(benefit receipt and amount, Social Security tax revenues, widowhood), and spending variables (total medical spending, out-of-pocket spending). Other demographic variables included age, gender, race, education, and marital status.

Baseline projections for disability from 2006 to 2050 resulted in an increase in prevalence of one or more ADLs of about 3 percentage points (not age adjusted). In 2006, the population will consist of 86 million individuals age 51 and older; in 2050 there will be an estimated 143 million individuals in the same category. During the same period, total spending is expected to double from \$767 billion to \$1,573 billion, and (age adjusted) per capita spending is expected to increase from \$8,944 to \$9,862. Likewise, all the age-adjusted prevalence is expected to increase, while age-adjusted prevalence for one or more ADLs is expected to decrease. In this presentation, the FEM was used to examine several prevention scenarios by assuming that no one in the 51 and older population has diabetes, heart disease, or hypertension. The obesity scenario assumes that there is some type of intervention that shifts all individuals in obesity status to overweight status.

Shang demonstrated that for the scenario in which heart disease is eliminated, the population age 51 and above in 2050 would reach 153 million. Total expenditures in 2050 would decrease from \$1,573 billion in the baseline to \$1,455 billion in the prevention scenario. Note that the treatment cost associated with curing heart disease is not included in this calculation but it is expected to be substantial. If heart disease were to be cured in 2050, there likely would be an increase in cancer prevalence from 14.4 percent to 15.1 percent, while the prevalence of one or more ADLs likely would decrease from 15.3 percent to 14.0 percent. The change in the population composition in 2050 versus the baseline shows the highest percent change in the 85 and older population. The disability prevalence in the prevention scenario is 1.3 percentage points lower than the disability prevalence in the baseline in 2050, and this change in disability prevalence is greatest in the 80–84 age group where there is a near 14-percent decrease. Likewise, there is a savings in total healthcare spending for the heart disease scenario for all age groups (51–64, 65–69, 70–74, 75–79, 80–84) except for ages 85 and older, where the percent change increases by more than 10 percent due to the fact that many more people will be in that group.

# E. Economic/Social Welfare Interventions That May Prevent Disability Among Older Persons

Robert Schoeni (University of Michigan) contended that the most significant way public policy has influenced the economic and social welfare of individuals has been through income transfers. The focus of his presentation was on the ways in which income transfer policies affect disability among the elderly.

Data from the National Health Interview Survey (NHIS) and the HRS confirm that income and disability are highly correlated; therefore, income is a good marker for determining who is disabled. Furthermore, this relationship is strongest at the bottom of the distribution. For example, in 2005, 10.1 percent of the 65 and older population were living in poverty. Another approach for examining the relationship between disability and poverty is to observe trends in disability and trends in old-age poverty. While aggregate trends cannot demonstrate causality,

the correspondence in trends is quite striking: the simple correlation between the disability rate and the poverty rate is 0.93.

The two most important income transfer programs for the elderly are Social Security and the Supplemental Security Income (SSI). Social Security provides nearly universal coverage for the elderly and is the primary source of income for the poor. Among the poorest 20 percent of elderly, Social Security accounts for 80 percent of total income. SSI was created in 1972 to guarantee a minimum income. SSI eligibility is based on income; 55–60 percent of eligible elderly participate. SSI covers 2 million elderly participants (December 2004), all near or below poverty, which is 6 percent of all elderly. In 2000, the Federal maximum SSI benefit per month was \$512 for singles and \$769 for couples; 26 States supplement Federal benefits. Monthly State supplements for singles range from over \$850 in Arkansas to slightly over \$500 in Oregon.

Two studies have examined the effects of SSI on health and disability, concluding that receipt of SSI improved health<sup>14</sup> and that more generous State SSI benefits lead to a reduction in old-age disability among single persons age 65 and over in the 1990 and 2000 censuses.<sup>15</sup> The latter study contributed several important insights, including the following:

- A 20-percent increase (\$100) in SSI maximum monthly benefits reduced disability among all single persons age 65 and over by 0.46 percentage points, a roughly 10-percent decline in disability.
- There was no effect on people in the top income quartile.
- The effect was three times larger on people in the bottom income quartile.

The number of studies that have examined the effects of income transfer policies on either disability or, more broadly, health has been surprisingly few. <sup>16</sup> Alternatively, there are many more studies relating income itself to health. The social epidemiological literature is extensive, and various populations and measures of health or disability virtually all show a strong association between income and health, including limited evidence related to disability. Income can influence disability through accommodations and/or personal care. The key question surrounding these associations is whether the relationship between income and health is causal.

It can be argued that the ideal time to have an intervention and associated experimental evaluation. There are strong arguments both for and against undertaking an income intervention and evaluation. Arguments favoring an intervention cite strong disagreement about estimated effects, the need for some type of test to address existing study design limitations, and the high

<sup>&</sup>lt;sup>14</sup> Taubman PJ, Sickles RC. Supplemental Social Insurance and the Health of the Poor. NBER Working Paper No. 1062. January 1983. Cambridge, MA: National Bureau of Economic Research.

<sup>&</sup>lt;sup>15</sup> Herd P, House J, Schoeni R. Does Supplemental Security Income (SSI) Affect Health? National Poverty Center Working Paper Series. October 2005; #05-21.

<sup>&</sup>lt;sup>16</sup> Case A, Hosegood V, Lund F. The Reach and Impact of Child Support Grants: Evidence from KwaZulu-Natal. *Development Southern Africa*. 2005;22(4):467-82.

Currie J, Cole N. Welfare and child health: The link between AFDC participation and birth weight. *American Economic Review*. 1993;83:971-985.

Gertler P. Final Report: The Impact of PROGRESA on Health. Washington, DC: International Food Policy Research Institute; 2000.

Taubman PJ, Sickles RC. Supplemental Social Insurance and the Health of the Poor. NBER Working Paper No. 1062. January 1983. Cambridge, MA: National Bureau of Economic Research.

stakes—billions are spent on income transfers each year. Opponents counter that (1) use of existing policy mechanisms, like State SSI payments, means that the intervention will not be well targeted because most people with disabilities are not poor and will not benefit from the intervention and because the majority of people with low income are not disabled; (2) the intervention will likely require great resources; and (3) the engagement and sponsorship of social and economic policymakers is required to implement such an intervention.

If the goal is to maximize reduction in disability, then any intervention should be expected to have a large marginal impact on disability and/or benefit a large share of people. Data from the 2005 NHIS show that among disabled individuals age 70 years and older, the reported causes of disability were mainly heart/circulatory and musculoskeletal conditions. Reviewing the trends in reported causal conditions among all elderly since 1982, Schoeni found that the total population of noninstitutionalized individuals 70 and older had experienced a decline in disability that can be attributed to declines in both heart/circulatory and musculoskeletal conditions over this time period. Potential mechanisms to explore include basic needs (good nutrition, safe and healthy environment), psychosocial and behavioral risk factors (stress, social support, control, smoking, exercise), and ability to purchase technology or personal care.

Suzman commented that the labor economics field has experimented with interventions to reduce poverty; this field, whose work has been completely separated or isolated from many public health and health interventions, offers significant expertise to evaluate research designs and impacts. This is an area in which the BSR Program would like to build collaboration, especially in light of the notion that the extent to which health and functioning are improving can also improve income. Schoeni agreed and revisited his earlier comment that an interest in studying disability only will lead to different interventions than if the interest encompasses not only mortality and health but also nonhealth outcomes.

## F. Cost-effectiveness of Potential Interventions To Reduce Disability: A Review

Kenneth Manton (Duke University) discussed cost-effectiveness of potential interventions to reduce disability. He reviewed a number of major policy changes that have affected declines in disability. The 1997 Balanced Budget Act sought to curb the rapid growth in home health expenditures by capping payments per beneficiary to home health agencies. These restrictions were refined in 1999. In 2003 the Medicare Modernization Act instituted additional changes in policy including the introduction of Part D (the Prescription Drug Benefit). The decline in disability rate among the older population, first observed beginning in the 1980s, continued to be detected with the 2004 round of the NLTCS. The 2004 round also documented a surprisingly large drop in institutionalization rate—a continuation of the decline initiated 1994 to 1999.

The results from 2004 solidified the notion that the combined number of noninstitutionalized and institutionalized elderly with severe disability is declining. Prospective payment system restrictions on Medicare using the Resource Utilization Groups as a method of reimbursement for rehabilitation services in nursing homes have helped to reduce significantly the size of the institutionalized population. Despite the number of people who dropped out of institutionalized care, the number of severely disabled in the community did not increase. The total population of

severely disabled is decreasing over time and is actually decreasing faster than the milder disabled group who benefit from special equipment and assisted living.<sup>17</sup>

Individual-level data from linked Medicare expenditure files point to another interesting trend: a continued drop in per capita Medicare Part A services, which includes hospital and acute care among nondisabled persons. The per capita reimbursement for major acute medical services after adjustment for the medical care consumer price index continues to decline among the nondisabled. It was initially thought that efforts focused on reducing disability would result in more medical care use in the nondisabled population, but this has not been observed. It appears instead that the policy changes in 1997, 1999, and, perhaps, 2003 have led to more tailored services better targeted to individuals. People with higher levels of disability have more total Medicare expenditures and more Part A expenditures than people with fewer ADL limitations. These data are still preliminary, but they suggest that Medicare has been having a significant impact on disability in the population over the past 8 years (since 1997) through its policy of reimbursing nursing homes to provide systematic rehabilitation services. This is not an analysis of which rehabilitative services are impacting which groups. It is unknown whether the impact of Medicare policies on health feeds back into forecasts of Medicare expenditures. Human capital models suggest that if expenditures in Medicare and Medicaid are increased, their effects could feed back to the future health status of the population. For developed economies experiencing population aging, the effect on human capital becomes very important. Better nourishment, education, and investments in health can have an impact on worker productivity.

To extend the declines in disability prevalence out to 2050, Manton asserted that investing in interventions for the oldest old must be a focus. There are a number of surveys that have looked at the rate of expenditures by age in the last several years of life, which is where much of health expenditures are concentrated. At age 90, there is a crossover of acute care expenditures and long-term care (LTC) services. If LTC is more labor intensive and less biotechnology sensitive, then this is where the action has to be taken in terms of future changes in disability if there is to be a continuing impact on total U.S. healthcare expenditures to 2050.

Manton also commented on the discussions about clinical trials and the many methodological issues that have been raised including questions of randomization, population heterogeneity, and the chosen algorithm for the intervention. He cautioned against concluding that a particular intervention failed based on a single clinical trial; such conclusions must consider the context and conditions under which the clinical trial took place.

Suzman emphasized that when thinking of potential interventions it is essential to keep in mind what type of trials the BSR Program is able to support. NIA can approach Social Security and Medicare about waivers and demonstration projects if these would be effective for small areas, but they would need to be very specific. Behavioral, social, and economic interventions could be combined with medical interventions. Manton concluded that regardless of the type of trial, any long-range intervention will be affected by the policy context; i.e., changes in the combination of Medicare and Medicaid services.

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<sup>&</sup>lt;sup>17</sup> Manton KG, Gu X, Lamb VL. Long-Term Trends in Life Expectancy and Active Life Expectancy in the United States. *Population and Development Review*. 2006;32(1):81-105.

## G. Principles and Direction of Disability Interventions: Behavioral Science Prospective

Lynda Powell (Rush University Medical Center) reflected on interventions from epidemiology and behavioral sciences with the main emphasis on cognitive aspects of successful interventions targeting prevention. As the decline in disability rates is not affecting all ethnic and economic categories equally, Powell highlighted the importance of targeting specific interventions to special populations. To more effectively target these populations, Powell called for three changes in practice: (1) Addressing problems related to trust between researchers and minority populations in an effort to build stronger relationships, (2) refocusing the goal of shifting from short-term behavioral changes to long-term sustainable practices (e.g., affordable medicines), and (3) refocusing the emphasis from promoting change in those at high risk (e.g., losing weight in the obese) to preventing high-risk status by maintaining positive health behavior throughout the life course.

Part of the problem with healthcare messages is that they are always presented with distal (i.e., long-term) reinforcement using phrases such as "lose weight," "glucose control," "lower blood pressure," and "live longer." However, proximal (i.e., immediate) reinforcement such as "no disturbances," "breathe fresh air," and "reduce stress" are actually more powerful for reinforcing behavior such as walking. People are focused on maximizing their utility; a change is more likely to be made if they enjoy immediate benefits.

Changing a behavior is a function of time and effort. Initiating behavior change requires little effort; but soon after, the effort required increases rapidly and self-control is needed to maintain the activity. If self-control can be used to maintain the behavior for a long enough period, self-regulation eventually takes over and the amount of effort needed to maintain the activity decreases. Thus, interventions should continue for a longer time and should include ongoing maintenance programs.

Comparing interventions that have succeeded in the past (such as the Diabetes Prevention Program and the Recurrent Coronary Prevention Project) with interventions that have failed (such as ENRICHD), Powell claimed that the intensive interventions followed by intensive maintenance programs greatly affected the success of the interventions. While some arguments against intensive intervention and maintenance periods cite the high costs of such practices, Powell pointed out that no more than monthly contacts are sufficient to maintain weight loss, and such contacts are not very costly. Moreover, thinking about maintenance programs that continue for one's lifetime is similar to current thinking about drugs, which, to be effective, must also continue for a lifetime. Cost-effectiveness of interventions must take into account the cost of intensive interventions with ongoing maintenance programs to promote sustained change relative to the cost of having an acute event and resultant disability.

Sustained change requires patient discovery. Health education delivered by a professional is necessary but not sufficient. A major problem with the community intervention studies of the 1980s was the belief that education alone was sufficient to make sustained behavior changes. The power of patients discovering for themselves the positive effects of engaging in lifestyle changes cannot be overlooked. Negative emotions often subvert motivation to change behavior, a

problem that differentially affects underserved minorities. Recognition and treatment of depression is essential to the promotion of sustained change.

The psychological theory of reciprocal determinism suggests that the initiation of behavioral change can occur at any one of several points of entry (cognitions, behaviors, emotions, physiology, environment). The theory suggests that if a change is made in one of these domains, it will affect the other domains because they are all interrelated. Multilevel interventions suggest that sustained change results from the occurrence of the "tipping point," achieved by targeting several of these domains at the same time.

Public health experts focus less on the individual and more on aspects of the social, physical, and political environment. The integration of the behavioral science and the public health perspectives forms the basis of multilevel interventions. Powell suggested that these interventions represent the future for producing sustained change. Wisdom for guiding successful interventions can be gleaned from nonacademic areas such as advertising (focus relentlessly), politics (stay on message), and the military (appeal to the strongest emotions).

An intervention must take place at the right time in order to be effective. Rather than beginning interventions haphazardly, sensing and waiting for the right time to intervene might be the best way to get the most out of interventions. In the 1970s, researchers focused on efficacy trials in high-risk males, such as the Multiple Risk Factor Intervention Trial (MRFIT). In this trial, the risk factors on which the study attempted to intervene were the same risk factors that were already changing in the wider culture. As such, the control group made significant changes and the trial was a failure. In other trials such as ENRICHD and the Women's Health Initiative, statistically significant changes in target behaviors were evident, but clinically significant changes, *a priori* aspirations of the trial design, were not attained, arguably due to an inadequate dose of intervention. In the 1980s, large-scale educational community trials largely failed. The 1990s saw the advent of less ambitious component-based interventions focusing on the agent, setting, environment, and policy, while in the 2000s, self-management, community-based participatory research, and public health—dominated intervention studies placed the focus on patient discovery. For the future, application of multilevel interventions and technology-assisted interventions will be of paramount importance.

## H. Group Discussion on Principles and Direction of Disability Interventions

There is a practical question about knowing which way trends are already going. Evan Hadley (NIA) illustrated this point by referring to the MRFIT trials in which the control group discovered and adopted healthy practices on their own. Powell commented that community-based research is currently struggling with this issue of whether a control group is needed at all. The alternative is to test the efficacy of interventions on a larger scale, although large-scale, multilevel interventions are probably not understood well enough to be undertaken in the immediate future. A multilevel intervention trial, such as in a hospital where employee health is promoted and where leaders can make policy changes, may be a reasonable place to start.

It is important to consider heterogeneity within populations. With respect to community interventions, much can be learned from marketing firms in terms of optimal timing of an

intervention and segments of the population to target initially as opposed to a blanket approach. Risk factors for one group may not apply to another, such as in the case where the risk factor is by nature biochemical versus cases where behavioral interventions could be effective. It may be useful to focus on the growing subpopulation of the long-term disabled because they are very skilled in disability management and in interventions. In the entire population (all ages), midlife shows the greatest diversity in disability duration from time of first onset. Members of this group can provide insights from their individual experiences that are much different than those obtained from the public health cost-effectiveness perspective and provide clues about directions to pursue based on their sense of satisfaction and efficacy.

Compelling data from Miller showing that African-American older adults in the inner city are heavily disabled after age 65<sup>18</sup> points to the importance of disaggregating by age of onset and development of disability. These individuals, who are generally of lower socioeconomic status, are compensating for declines, and by the time they reach age 65, they are heavily disabled. Different groups may require targeting with different agents. Subgrouping is especially important in studies of musculoskeletal disability decline. In selecting an appropriate intervention, one needs to consider whether (1) the intervention is addressing the issue of learning to cope with disability so that IADL limitations are not reported on surveys, or (2) interventions are aiming to prevent onset of limitations with IADLs, which age and socioeconomic status groups will express differently. These considerations need to be resolved before one can determine the appropriate type of intervention.

The health promotion literature suggests a practical approach that has been largely unexplored. According to James Fries, research focused on senior risk reduction programs (see Section III.C.) involves surveys based on health risk assessments, which are used to triage people to particular intervention arms. Powell questioned whether the uniquely tailored interventions discussed by Fries could be disadvantageous due to the number of different interventions, especially given the profound influence of peers. It may be of interest to explore the social science theory of collective behavior by which the behavior of a few individuals (i.e., early adopters) coalesces into the behavior of the community and how to effect this diffusion. A certain level of saturation can have effects throughout the entire community.

There is a very large body of research on social network analysis of the applications of innovations in public health for behavior change. This research does not just study the proportion of people needed to model a set of behaviors in order for others to adopt the practices, but also investigates the structures in social networks, like opinion leaders in communities and conversation networks that facilitate diffusion and the shape of social network that most rapidly transfers information and new technologies within a community. This research literature has not been referenced in discussions about interventions for disability among the elderly, but it is a possible source of inspiration. The strategy in social marketing relies on a mass media campaign and saturation, followed by interventions on another level that reinforce the behavior. Simply telling individuals that something is bad may not work, but the message itself can justify other actions or incentives to effect behavior change.

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<sup>&</sup>lt;sup>18</sup> Miller DK, Carter ME, Miller JP, et al. Inner-city older blacks have high levels of functional disability. *J Am Geriatr Soc.* 1996;44:1166–1173.

From a clinician's perspective, the disease conditions that have most contributed to disability decline (cardiovascular and musculoskeletal conditions) are very different. Declines in cardiovascular disability can be attributed to both advances in medical technology and behavioral changes with respect to diet, exercise, and smoking cessation, but musculoskeletal disability changes have been mainly affected by medical technology. Is this a useful way to think about disability decline and ways to target interventions under discussion? The components at work in the conditions need to be disaggregated in order to fully understand which interventions have led to decreased disability.

Despite the challenges, Wallace expressed optimism about clinical and community trials, given so many stunning successes outside of the social sciences. It is hard to think of a large hypertension, lipid management trial, diabetes glucose control trial, or fracture prevention trial that has not demonstrated efficacy. There is a long record of successful clinical interventions, and a similar trajectory may be the new frontier for interventions in the behavioral and social sciences. Suzman clarified that the NIA/BSR Program will consider interventions aimed toward age groups other than the elderly (such as 50–64), perhaps sampled through companies or health plans. The NIA/BSR Program also is open to collaborations involving interventions to increase productivity of older workers both inside and outside the United States.

#### III. **Lessons From Environmental and Community-Based interventions**

#### **Interventions in the Home Environment** Α.

The challenges for intervening in the home environment include (1) relatively few standardized assessments of the home environment other than for falls, (2) daily changes in the home environment, and (3) that fact that older people are often reluctant to make changes to their homes. Thomas Gill (Yale University School of Medicine) highlighted several successful homebased interventions targeting relevant disability-related outcomes in older persons. Successful RCTs include (1) comprehensive geriatric assessments that delayed development of disability and reduced permanent nursing home stays among persons age 75 years and older; <sup>19</sup> (2) a resistance exercise program that reduced disability by 15 to 18 percent among persons age 60 years and older; <sup>20</sup> (3) a multifactorial intervention that reduced risk of falling by 31 percent among persons age 70 years and older;<sup>21</sup> and (4) a prehabilitation program that slowed the rate of functional decline among frail persons age 75 years and older. 22 A recent home-based intervention that included a prominent environmental component resulted in improved function and self-efficacy, but the effect sizes were small (ranging from 0.12 to 0.33), and the reduction in

<sup>&</sup>lt;sup>19</sup> Stuck AE, Aronow HU, Steiner A, et al. A trial of annual in-home comprehensive geriatric assessments for elderly people living in the community. N Engl J Med. 1995;333:1184-1189.

<sup>&</sup>lt;sup>20</sup> Jette AM, Lachman M, Giorgetti MM, et al. Exercise - it's never too late: the strong-for-life program. Am J Public Health. 1999;89:66-72.

<sup>&</sup>lt;sup>21</sup> Tinetti ME, Baker DI, McAvay G, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med*. 1994;331:821-827. <sup>22</sup> Gill TM, Baker DI, Gottschalk M, et al. A program to prevent functional decline in physically frail, elderly

persons who live at home. N Engl J Med. 2003;347:1068–1074.

the number of home hazards was modest.<sup>23</sup> Two successful interventions have focused solely on the home environment <sup>24</sup>

Several clinical trials have evaluated home modification to reduce falls, which have been linked to functional decline and disability. Gill's longitudinal study found that fall-related injuries (hip fracture, head injury, etc.) conferred the highest risk of disability, with 79.4 percent of hospital admissions for a fall-related injury leading to any disability and 58.8 percent to disability with nursing home admission. Unfortunately, the results of the home modification interventions have been rather disappointing. One intervention included a single, 1-hour visit by an occupational therapist who assessed the home for environmental hazards and subsequently facilitated necessary home modifications; there was a nonsignificant 23 percent reduction in time to the first fall, but a significant 44 percent reduction among the subgroup with a fall in the past year. This suggests that high-risk groups should be targeted.<sup>25</sup> A second study of a larger sample intervened with a single visit by a registered nurse in which home hazards were assessed, educational strategies on general fall hazard reductions were provided, ways to reduce identified home hazards were discussed, and free installation of safety devices took place. Despite a reduction in most hazards, there was no reduction in the occurrence of falls over 12 months.<sup>26</sup>

Though the conceptual framework is generally strong and epidemiological studies have documented high rates of environmental hazards and impediments to independent function, the evidence linking the home environment to adverse functional outcomes is weak. The framework proposed by Lois Verbrugge and Alan Jette contends that disability occurs when there is a gap or mismatch between personal capabilities and environmental demands. The capacity-demand hypothesis of disability, which was derived from the original competence-environmental press theory proposed by Powell Lawton, suggests that the everyday function of frail, older persons can be improved by either enhancing physical capabilities or by reducing environment demands.

There are several potential targets for assessing and subsequently intervening in the home environment. One can consider the housing type (house, apartment, condominium, assisted living, board and care; age-restricted versus non-age-restricted), potential hazards for falls, placement of stairs (inside, outside), adaptive equipment (bathing, toileting), safety features (smoke alarms, locks, security system), samples (water, radon), life space, and neighborhood characteristics (safety, sidewalks, public transportation). Universal design also has been the focus of much interest due to its ability to accommodate people with changing abilities over time. For example, such accommodations could allow someone using a walker or wheelchair more space

<sup>&</sup>lt;sup>23</sup> Gitlin LN, Winter L, Dennis, MP, Corcoran M, Schinfeld S, Hauck WW. A Randomized Trial of a Multicomponent Home Intervention to Reduce Functional Difficulties in Older Adults. *Journal of the American Geriatrics Society*. 2006;54(5):809-816.

<sup>&</sup>lt;sup>24</sup> Hart D, Bowling A., Ellis M, Silman A. Locomotor disability in very elderly people: value of a programme for screening and provision of aids for daily living. *BMJ*. 1990;301(6745):216-220.

Mann WC, Ottenbacher KJ, Fraas L, Tomita M, Granger CV. Effectiveness of Assistive Technology and Environmental Interventions in Maintaining Independence and Reducing Home Care Costs for the Frail Elderly: A Randomized Controlled Trial. *Arch Fam Med.* 1999;8:210-217.

<sup>&</sup>lt;sup>25</sup> Cumming RG, Thomas M, Szonyi G, et al. Home visits by an occupational therapist for assessment and modification of environmental hazards: a randomized trial of falls prevention. *J Am Geriatr Soc.* 1999;47:1397-402. <sup>26</sup> Stevens M, D'Arcy J, Holman C, Bennett N. Preventing falls in older people: impact of an intervention to reduce environmental hazards in the home. *J Am Geriatr Soc.* 2001;49:1442-7.

to travel between rooms, ease strain caused by bending to plug in an appliance, and make light switches more accessible

One activity that warrants further investigation in terms of the home environment is bathing. Disability in bathing is common, involves multiple subtasks, and is attributable to an array of physical and psychological problems and environmental deficits. The burden of bathing disability is quite large. Disability in bathing develops commonly in the absence of disability in other essential activities of daily living and often serves as a gateway to subsequent disability. In a prospective cohort study of community-living older persons, Gill found that the occurrence of persistent bathing disability was strongly associated with the risk of a long-term nursing home admission.<sup>27</sup> This relationship persisted despite adjustment for several potential confounders, including the occurrence of persistent disability in other essential activities of daily living, and was not observed for short-term nursing home admissions. An earlier study demonstrated that potentially valuable environmental adaptations, such as grab bars, bathtub bench, and handheld shower spray, are absent from the homes of many older persons with bathing disability and that these adaptations may be especially underutilized by older persons reporting difficulty with bathing.<sup>28</sup>

A major dilemma is that researchers have been unable to demonstrate any association between the absence of an assistive device and subsequent bathing disability; this suggests inherent limitations to epidemiologic studies since it is difficult to adequately account for selection effects. Furthermore, assessments of the bathing environment are generally static while the phenomenon is likely dynamic. An RCT evaluating an intervention directed at deficiencies in the bathing environment may be the only way to address this dilemma.

## B. Interventions To Improve Social Engagements and Functions

In an aging society, one-third of an individual's life will be lived after retirement. Linda Fried (Johns Hopkins University) hypothesized that one key to successful psychological aging is "generativity," or the opportunity to leave the world better for future generations. Generative roles not only give meaning and purpose but also provide social engagement, which has been shown to maintain cognition, decrease disability, and delay mortality. Aligned with this notion are findings from John Cacioppo indicating that loneliness has implications for health. The challenge is to provide opportunities for the elderly to engage in productive, meaningful roles after retirement.

Individual actions related to physical activity, cognitive activity, and social engagement can attenuate risk factors for disability. Regular exercise has been found to be associated with 50 percent lower rates of disability and a 10-year delay in the onset of disability, as well as reducing falls by 12 percent. The challenge has been that 22 to 76 percent of those who start exercise programs drop out within 6 months, and those subsets at the greatest risk for health disparities are also the least likely to start and maintain an exercise program.

<sup>&</sup>lt;sup>27</sup> Gill TM, Guo Z, Allore HG. The Epidemiology of Bathing Disability in Older Persons. *J Am Geriatr Soc.* 2006;54(10):1524-1530.

<sup>&</sup>lt;sup>28</sup> Niak A, Gill TM. Underutilization of Environmental Adaptations for Bathing in Community-Living Older Persons. *J Am Geriatr Soc.* 2005;53(9):1497-1503.

Generative roles might be a vehicle to attract and retain more—and more diverse—older adults than standard exercise programs; increase usual physical activity, particularly if done multiple days per week; and be intentionally designed to enhance cognitive and social activity and provide stimulating environments. If successful, society benefits through the harnessing of the social capital of these individuals and their desire to "give back." Older adults can contribute wisdom, complex problem-solving skills, creativity, and their time. In addition to being grandparents, role models, and mentors, they are increasingly volunteering, working part time, and binding communities together.

Experience Corps is designed to be a high-intensity senior volunteer program with a health program embedded in the design.<sup>29</sup> Volunteers age 60 years and older serve in public elementary schools (kindergarten through third grade) to address important unmet academic needs of children. Volunteers form a critical mass of older adults in each school, must commit to 15 hours per week for a full school year, and are paid a monthly stipend to reimburse for expenses. In this program, older adults seek to make a difference in the lives of children, and it is theorized that their physical activity increases by having to report to the school three to four times a week. The program also is designed to enhance cognitive activity and social engagement and supports through team development and the critical mass per school. The program is now in 19 cities, and adults are involved in many different roles including academic support (literacy, math, and computer support; opening and maintaining school libraries), behavioral support (conflict resolution, positive attention), school attendance, parental outreach, and public health (asthma club). In the Baltimore Experience Corps program, the oldest volunteer is 91 years old, and 80– 90 percent of volunteers are African American. Health status of the volunteers ranges from excellent or very good (47 percent), good (38 percent), to fair (15 percent). On average volunteers have two to three chronic diseases, while 62 percent report disability in climbing stairs and 37 percent report disability in walking 3-4 blocks.

A pilot RCT examining short-term (4- to 8-month) change in risk factors for disability concluded that (1) high intensity volunteerism can lead, in the short-term, to improvements in the level of physical, cognitive, and social activity of previously inactive volunteers; (2) there is potential for addressing disparities as Experience Corps was able to demonstrate participation by African-American older adults who are generally not reached by exercise programs; and (3) high retention rates suggest the potential for sustaining increased activity. The intervention group increased number of blocks walked per week by 31 percent, and the group initially in fair health improved the most. A comparison of change in executive function among Experience Corps volunteers and controls with low normal function at baseline showed improvements among the volunteers across the board for word list, delayed memory, and trail making tasks, while controls performed worse in some areas. The measured outcomes for children included meaningful improvements in reading scores and changes in behavioral problems by grade.

The Baltimore Experience Corps has enjoyed high volunteer retention (97 percent during the first year and 80 percent the following year). Fried attributed the high retention rate to a sense of collective efficacy, as well as design elements constructed to support retention. A pilot RCT of 1,000 Experience Corps volunteers and controls from 48 public elementary schools in Baltimore, sponsored by the NIA BSR Program, will measure primary outcomes of disability (mobility and

<sup>&</sup>lt;sup>29</sup> Fried. et al., 2004.

IADLs) and secondary outcomes of memory, frailty, and falls. This program will be done in collaboration with the city and various community organizations to evaluate the feasibility of scaling up the program over time. It is hoped that the intervention might contribute to a compression of morbidity, act as a delivery vehicle to decrease health disparities, and serve as a social model for health promotion with benefits for, and from, an aging society. A strong evaluation component is important for informing policymakers and communities about what interventions are worth doing.

In response to several questions and comments, Fried clarified that (1) there was intentionally no alteration or modification in the way that health services were delivered to the volunteers; (2) psychological testing of volunteers was added this year; (3) re-entry assistance was built into the program as it was anticipated that people would drop out (e.g., due to illness) and want to return; and (4) the pilot RCT controls were older adults who had applied and were eligible and randomized to wait-list control status. Only 38 percent of the people who initially contacted the program eventually became volunteers. It was acknowledged that other activities might be more attractive to some older adults, such as working with high school students, involvement in social action programs, and working with police departments. It would be worth investigating characteristics of the volunteers and if brain plasticity and cognition could be improved in high-risk individuals.

The NIA/BSR Program continue to be intrigued about the role of social engagement and cognition. Suzman welcomed similar large projects, but also would like to see new approaches that can be incorporated into other trials that integrate the information and insights gained from efforts such as the Experience Corps as well as work on social engagement as related to overall wellbeing. Offering incentives, perhaps through Medicare, could be one way to broaden the attractiveness of programs like Experience Corps.

## C. The Medicare Senior Risk Reduction Demonstration

The Medicare Senior Risk Reduction Demonstration (SRRD) was initiated in response to Medicare's interest in seeking ways to reduce healthcare costs and increase the compression of morbidity in the last years of life. The SRRD was designed by The MEDSTAT Group and the Cornell University Institute for Policy Research, under a contract to CMS, and CMS is planning to implement the Demonstration in the coming year. David Stapleton (Cornell University) focused his presentation on design aspects rather than the evaluation aspects of the demonstration. He explained that the project began with a literature review by RAND on workplace interventions by major corporations and health plans aimed at reducing health problems and increasing productivity among workers. The objectives of the SRRD are to (1) estimate the impact of a risk reduction intervention on Medicare beneficiary risk, health, healthcare utilization, and health care expenditures; (2) identify and test tailored intervention materials; (3) test the program's ability to make referrals to community/volunteer programs; (4) determine whether program features are acceptable to beneficiaries, and (5) obtain other information that would help CMS design and launch a national program. The operating

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<sup>&</sup>lt;sup>30</sup> Centers for Medicare and Medicaid Services. Senior Risk Reduction Demonstration Design Presentation. Available at: <a href="http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Senior\_Risk\_Reduction\_Design.pdf">http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Senior\_Risk\_Reduction\_Design.pdf</a> Accessed November 17, 2006.

assumptions included a voluntary program that offers beneficiaries advice on how to maintain their health, reduce their risk of illness and disability, and take advantage of community resources that are available to support their efforts.

The program was designed to offer a random sample of eligible beneficiaries an opportunity to complete a health risk assessment (HRA) and return it to a vendor. Those who choose to return the HRA will be randomly assigned to one of three arms: (1) Standard intervention, (2) enhanced intervention, or (3) untailored information ("placebo"). All beneficiaries offered the opportunity to complete an HRA will also be compared to another randomly selected group of beneficiaries using administrative data.

Participants assigned to treatment arms will receive a centrally administered initial HRA assessment followed by a tailored feedback report; prioritization of risk factors; computerized triage of participants into various risk reduction modules; provision of tailored risk reduction materials delivered via mail, Internet, or telephone (health coaching); and linking to national community resources, social support networks, and volunteer opportunities. Arm 1 will offer a lower cost, "standard" intervention, and Arm 2 will offer a higher cost, "enhanced" intervention expected to achieve improved risk reduction results. In the placebo arm, the participant receives only a generic letter with tips on staying healthy.

One incentive for vendors to perform well is that they can demonstrate to Medicare that they offer better health outcomes for beneficiaries. The HRA is designed by the vendor with the specifications that it must be tailored to seniors, administered to all target beneficiaries at least once a year over 3 years, offer a \$10 incentive to return the annual HRA, and include an informed consent form that must be returned with the first HRA. Vendors are free to administer the HRA more frequently, especially as part of the enhanced intervention. The behavior change modules designed by the vendors will be algorithm driven and will triage individuals into risk-specific interventions. Individualized counseling will be offered in the standard intervention, with more extensive counseling in the enhanced intervention.

There are two different pieces of the demonstration: (1) The national demonstration (SRRD-N), in which vendors are not directly in touch with local service providers and only make referrals to generic providers, and (2) the local component in 10 communities where a substantial informational and referral/assistance (I&R/A) system is already in place. Vendors will work with those systems to see whether existence and use of such systems lead to greater success.

The researchers expect to achieve (1) high participation (40–50 percent) driven by beneficiary acceptance of and satisfaction with the program; (2) health improvement, risk reduction, behavior change, improved functioning, and reduced disability (on the order of a 5-percent improvement); and (3) at a minimum, cost neutrality and potentially a positive return on investment over 3 years for Medicare reimbursements to healthcare providers. Administrative data will be used to follow up on the individuals who choose not to participate to support analysis of the differences in people who do and do not participate.

Senior Risk Reduction Demonstration: Final Project Report. MEDSTAT/Cornell report to CMS, March 8, 2004.

The targeted beneficiaries are Medicare fee-for-service enrollees with the following exclusion criteria: (1) Under 65 years of age, (2) Medicare HMO members, (3) Part A only, and (3) institutionalized. The national component (SSRD-N) involves a nationally representative sample of target beneficiaries who are referred to national resources and organizations. Assignment of ZIP code areas to vendors was done to preclude multiple vendors contacting beneficiaries in the same household and to avoid conflicts with other demonstrations and the SRRD-I&R/A component. Relevant new enrollees or ZIP code areas were excluded from the SRRD-N sampling frame. The I&R/A component tested the incremental effects of using the SRRD along with best practice I&R/A systems and was designed to be conducted in communities with best practice systems as identified by the National Council on Aging (NCOA). The national component contacted over 69,500 beneficiaries in order to enroll about 4,000 in each study arm.

Examples of topical areas to be included in the HRA and clinical prevention services are physical activities, falls prevention, depression, and smoking. In addition to ascertaining outcome data (e.g., particular medical conditions, number of outpatient visits) from Medicare claims data, analysts can review data from a survey administered to beneficiaries independently by the evaluator. This survey contains questions about ADLs and IADLs. Fries, who has served as a consultant to the SRRD project, shared that a 6-month pilot is scheduled, followed by a 3-year trial.

Suzman expressed interest in the possibility of the NIA playing a role in refining future versions of the demonstration, including application to well-defined population-based groups such as those approaching retirement years (e.g., 50–64-year-olds) by working with health plans or allying with employer worksite health promotion activities to fine-tune cost-effectiveness of the demonstration. Stapleton endorsed this idea, as he believes that the demonstration design actually might work better for those nearing retirement. He observed that individuals under 65 with disability are at high risk for health problems and often need to invest heavily in self-care to prevent negative outcomes; this might be a high-risk group that should be further addressed.

### D. General Discussion on Environmental and Community-Based Interventions

Participants offered a number of comments and questions about the presented programs and new types of interventions that might be considered. Five general observations were made about the design of social interventions such as the Experience Corps:

- There are selection effects.
- There could be a placebo or Hawthorne effect that only can be addressed by comparing the intervention with another intervention in a third arm.
- Measurement of certain confounders could be missed; e.g., volunteers might have higher adherence to medical or treatment regimens that results in a biomedical influence on behavior.
- Unless the underlying mechanisms can be established, there is always skepticism about how the intervention works.
- Randomizing groups creates a clustering effect that decreases power.

From the perspective of the NCOA, Whitelaw stated that Experience Corps is exactly the kind of program that can make a difference in ordinary lives and that also is intuitively attractive for volunteers. The Experience Corps was not meant to be exhaustive for all types of personalities,

but merely a starting point for these types of interventions. There have been concerns that Experience Corps competes with other volunteer programs. In the first national demonstration, there was a backlash due to the small stipend (\$100-150 per month) volunteers received. This issue has been addressed, and results showed that over half of the volunteers had not volunteered before, while many of the Experience Corps volunteers continued their other volunteer duties.

Musgrove commented that as long as people are volunteering, self-selection is taking place. In Brazil, older adults go to health centers as gathering places; this is a fairly common practice in Latin America, and there is the possibility that spending a little money to emphasize the positive effects of social engagement could go a long way to improving health. If it turns out that the person providing the volunteer services is having a health benefit, this is the effectiveness, while the costs of the program include the administrative and stipend amounts.

It was noted that the focus on social engagement activities in the presented interventions could reflect an American bias. For example, solitary activities have been found to be strongly related to wellbeing in China. Verbrugge stressed that it is essential to recognize methods of helping individuals in ways that are satisfactory to them but that may not be strikingly innovative; e.g., taking care of plants, quilting for community centers.

The issue of incentives paid to volunteers is a complicated one. Fried mentioned that during the national demonstration, volunteers for an experimental group in Portland, Oregon, were recruited only after a stipend to cover gas and other expenses was offered. The goal should be to use financial or symbolic incentives to encourage participation in such volunteer programs. Sowers raised the importance of studying nonvolunteers and minority volunteers to understand differences in incentives and behavior. Indeed, there are meaningful differences in volunteerism by gender, age group, and economic status. Suzman remarked that the Federal Office of Management and Budget does not permit use of incentives for people to do things that are good for them. He imagined that additional Medicare benefits for volunteerism might be possible if cost-savings could be demonstrated, although others worried that involvement by CMS would further the "medicalization" of aging.

Suzman commented that CMS has been proactive in setting up risk-reduction activities and other types of health promotions, despite their lack of success in obtaining new preventive services authority, which would require legislative action. Although collaborations with the Administration on Aging (AOA), the CDC, or other organizations are possible, Suzman emphasized that the NIA is a research organization, not a service provider. The NIA/BSR Program is interested in funding the research, but eventually their applications will have to be implemented by another organization, private company, or individuals. Countries other than the United States also can be considered potential venues for interventions.

The possible shifts in the milieu in which people live have been absent from the meeting discourse. While home modifications were discussed, much of what happens to older people outside of the home is missed. A number of IADLs are of activities outside of the home. The professionals involved with this outside environment, such as urban planners, architects, and design engineers, have much insight on how to aid the elderly in these arenas. It might be helpful to review interventions supported by other NIH Institutes that involve both younger and older

participants and interactions with the neighborhood physical environment. Interesting interventions could be done to look at neighborhood effects through the Department of Housing and Urban Development (HUD) using randomized housing vouchers or other methods. While it is believed that the new urbanist movement is producing designs for neighborhoods that promote healthy behavior and social interaction, this notion is not backed by any data from interventions.

Suzman underscored the NIA/BSR Program's interest in supporting a series of smaller interventions with sufficient power with the following considerations:

- What are the prospects for choosing interventions to reduce disability or the risk factors for disability as defined by population-level ADL and IADL based on some measure of cost-effectiveness?
- What is the measure of cost-effectiveness?
- Can preclinical measures of disability be used to obtain greater sensitivity?
- What combination or portfolios of interventions have potential?
- What are the targeted time horizons and age groups that should be targeted for interventions?
- What is the possibility of using planning grants or small business innovation research (SBIR) projects to develop interventions?

Interventions under consideration must be cost-effective and easily delivered.

# IV. Lessons From Clinical and Personal Interventions To Prevent/Mitigate Disability

## A. Pharmaceutical Interventions: The Various Dimensions of the "PolyPill"

In most developed countries, and increasingly in less developed countries, the major cause of disability is noncommunicable diseases (NCDs) such as cancers, diabetes mellitus, cardiovascular disease (CVD), kidney disease, and dementia. The idea of the PolyPill was articulated in three papers published in the *British Journal of Medicine* based on a meta-analysis of clinical trials and observational studies of low-density lipoprotein (LDL) cholesterol, blood pressure, and platelet aggregation interventions.<sup>31</sup> They determined that a combination pill using (1) a statin to reduce LDL cholesterol could reduce the risk of ischemic heart disease and stroke; (2) half of a standard dose of any two antihypertensive drugs (e.g., thiazide, beta blocker, or ACE-inhibitor) could control blood pressure; and (3) aspirin to control platelet aggregation could reduce coronary heart disease and stroke incidence by about 80 percent. The side effect profile of the combinations was estimated as quite small; thus, the prevention strategy proposed was to use a single PolyPill per day composed of active ingredients to be taken without medical exam by all people age 55 and older without screening, or by anyone with diabetes or CVD regardless of age. The Steno Diabetes Center in Denmark conducted a trial that was roughly similar to the concept of the PolyPill. The trial followed a group of people with diabetes with microalbuminuria for 8 years, and there was a 50- to 60-percent reduction in CVD, kidney, and eye disease for patients

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<sup>&</sup>lt;sup>31</sup> Wald NJ, Law MR. A strategy to reduce cardiovascular disease by more than 80%. *BMJ*. 2003;326:1419. Law MR, Wald NJ, Rudnicka AR. Quantifying effect of statins on low density lipoprotein cholesterol, ischaemic heart disease, and stroke: systematic review and meta-analysis. BMJ. 2003;326:1423.

Law MR, Wald NJ, Morris JK, Jordan RE. Value of low dose combination treatment with blood pressure lowering drugs: analysis of 354 randomised trials. *BMJ*. 2003;326:1427.

with diabetes mellitus and microalbuminuria who were given therapy to control blood pressure, lipids, and platelet aggregation than for the controls who were given only standard care.

K. M. Venkat Narayan (Emory University) reviewed several advantages and disadvantages of the PolyPill concept and its implications for public health. Although use of the PolyPill in the general population could complement ongoing efforts, it also could theoretically lead to decreased efforts by individuals, policymakers, and society as a whole to improve key lifestyle factors for prevention of CVD (e.g., physical activity, healthy diet, not smoking). Another concern is that the PolyPill may increase health disparities within disadvantaged communities that currently are at the highest risk for CVD. One encouraging prospect is that the use of PolyPill by all persons age 55 and above may cause a reduction in the risk of serious cognitive decline experienced by older adults as they age, though substantial evidence is lacking for this point. In any case, the concept of the PolyPill deserves formal evaluation through a well-designed RCT.

The key design features of a public health trial of the PolyPill should include an emphasis on effectiveness instead of efficacy because many of these single interventions have been addressed in efficacy trials. As the PolyPill represents a novel concept of delivery, a generalizable effectiveness trial might be desirable. The cost-effectiveness of the PolyPill was assessed for people with diabetes by a model for two scenarios: The control scenario relied on the recommendations of standard care for tight glycemic control and intensive blood pressure control and cholesterol control as needed, while the PolyPill intervention involved glycemic control and only the PolyPill intervention. Based on the model used, the results showed that (1) the PolyPill is cost-effective for newly diagnosed type 2 diabetes and more cost-effective for older patients; (2) the application of the PolyPill may increase life years compared to current treatment; (3) the break-even point for the PolyPill using coronary heart disease (CHD) and stroke risk reductions is \$1.28—at this price, the cost of interventions could be met by the savings from prevented complications;<sup>32</sup> and (4) the benefits of the PolyPill depend on the risk reductions for CHD and stroke—these should be formally determined by clinical trials. Other considerations for the PolyPill include the possibility of developing a version of the pill without aspirin or versions for people with diabetes; what the impact will be on disability, cognitive decline, quality of life, and cost; the politics and practicalities involved with pharmaceutical issues; and the implications of the PolyPill in low- to middle-income countries (which thus far have expressed great enthusiasm).

Majid Ezzati reasoned that a trial of effectiveness would have to include an arm focused on lifestyle and perhaps another arm with a combination of lifestyle and the PolyPill. There have been lengthy discussions on the range of risk factors that exist just below the level of clinical diagnosis; workshop participants did not appear to favor delivering the PolyPill to everyone but thought that there should be some measure of blood pressure, lipid tests, and a consideration of titrations due to the ethical issues that arise from giving the pills to individuals without risk factors. Narayan agreed, but noted that data from the National Health and Nutrition Examination

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<sup>&</sup>lt;sup>32</sup> Green L, Weintraub W, Narayan KM, et al. Combination Pharmacotherapy and Cardiovascular Disease Prevention. *Ann Int Med.* 2005;143:593-599.

Narayan KM, Mensah GA, Sorensen S, et al. Combination Pharmacotherapy for Cardiovascular Disease Prevention: Threat or Opportunity for Public Health? *Am J Prev Med*. 2005;29(Suppl 1):134-138.

Survey (NHANES) has show that 99 percent of the U.S. population over the age of 55 have at least one risk factor (depending on how risk factor is defined), and it is possible that the major risk factor is simply age.

People not receiving care are usually those who cannot afford treatment. An affordable PolyPill, therefore, is not expected to increase disparities. Fries added that because there are individuals who should not be given the PolyPill due to other health problems, it would be helpful to provide a checklist of considerations before taking the medication. Suzman observed that because the PolyPill could be given to a large population over a long period of time and cognitive effects could result, it could be very interesting for studying dementia. Marcelle Morrison-Bogorad agreed but noted that there has been no clinical trial data to support this idea.

### B. Exercise and Fall Prevention

Jack Guralnik (NIA) presented lessons from interventions to prevent falls and disability. There have been many observational studies in which low physical activity and sedentary lifestyles have been identified as risk factors for disability. For example, in the late 1980s and early 1990s, exercise interventions were shown to have positive effects on physiologic impairments such as poor strength and balance. In recent years a better understanding of the framework of disability has formed. There are intrinsic factors (disease, impairment, functional limitations) along the pathway to disability, and it is now understood that several factors (e.g., exercise) overlie this pathway. While it is known that impairments such as weakness and poor balance can be improved, and observational studies have concluded that these impairments predict disability, a number of experts have pointed out that exercise has not been shown clearly to prevent or minimize physical disability. There have pointed must move toward randomized controlled clinical trials for more definitive conclusions about whether treating impairments will prevent disability and if, for example, an underlying condition that caused muscle weakness will still lead to disability even if muscle strength is improved with exercise or other intervention.

As an example, Guralnik noted a *post hoc* analysis of the Fitness, Arthritis and Seniors Trial (FAST) involving comparisons of three groups—aerobic exercise, resistance exercise, and control, which showed significant improvement among treatment groups compared to the control group in the probability of survival without ADL difficulty.<sup>34</sup> The Lifestyle Interventions and Independence For Elders (LIFE) study is a multicenter pilot RCT of exercise to prevent mobility disability in nondisabled older persons with functional limitations. The sample includes 424 nondisabled, community-dwelling sedentary persons age 70–89 years with a followup of 1–1.5 years. The outcome of interest is the loss of ability to walk 400 meters. The Short Physical Performance Battery (SPPB), developed by NIA in the early 1990s, was used to screen for individuals with functional limitations and who were at risk of becoming disabled (summary

<sup>&</sup>lt;sup>33</sup> Keysor JJ. Does Late-Life Physical Activity or Exercise Prevent or Minimize Disablement: A Critical Review of the Literature. *Am J Prev Med*. 2003;3 (Suppl 2):129-136.

Singh MA. Exercise to Prevent and Treat Functional Disability. *Clin Geriatr Med*. 2002;18(3):431-62, vi-vii. Latham N, Anderson C, Bennett D, Stretton C. Progressive resistance strength training for physical disability in older people (Cochrane Review). *The Cochrane Database of Systematic Reviews*. 2003, Issue 2. Art No.: CD002759. DOI:10.1002/14651858.CD002759.

<sup>&</sup>lt;sup>34</sup> Penninx BWJH, Messier SP, Rejeski WJ, et al. Physical Exercise and the Prevention of Disability in Activities of Daily Living in Older Persons With Osteoarthritis. *Arch Intern Med.* 2001;161:2309-2316.

score  $\leq$  9 on a scale of 0 to 12 on the SPPB) but who could complete a 400-meter walk. Sedentary lifestyle was defined as less than 20 minutes per week in the past month in regular physical activity. Based on data from the Iowa Established Populations for Epidemiologic Studies of the Elderly (EPESE), 40–50 percent of the population was expected to have the characteristics that meet inclusion criteria for the trial. The exercise arm includes aerobic and strength training as well as balance and range of motion exercises while the control group receives successful aging health information.

The LIFE clinical trial is an opportunity to maximize public health impact to push exercise as an intervention for which there is a discrete, easily understood outcome that can be achieved with a practical and potentially cost-effective intervention. The study began as an intramural project that became a cooperative agreement with outside researchers. Guralnik advised that when considering trials for disability prevention, pilot studies should be considered because much can be learned about the primary outcome definitions, sample size calculations, and best practices. The successful pilot study was characterized by (1) recruitment of 424 participants in 9 months, (2) sufficient outcome rates in the control group, (3) implementation of the intervention, (4) adherence to intervention in excess of 70 percent after 1 year, (5) no safety concerns from the Data Safety Monitoring Board, (6) favorable trends in multiple outcomes, and (7) less than 5-percent loss to followup. Factors that helped achieve such high adherence rates in the LIFE trial included a 10-session intervention in a group setting to address barriers to exercise and the development of social cohesiveness in the intervention group

Turning next to fall-prevention interventions, Guralnik presented research by Mary Tinetti, which began as an observational study that evolved into a multifactorial intervention. Tinetti identified six risk factors for falls among elderly persons living in the community: Environmental hazards, sedative use, cognitive impairment, lower extremity disability, impairments of balance and gait, and foot problems. An intervention was subsequently fielded to counter these risk factors with four general domains: (1) Medication adjustment, (2) behavioral training, (3) exercise program, and (4) environmental change. Compared to the control group, the treatment group experienced a 25-percent reduction in falls within the first year. This intervention cost about \$1,000 per person with an average cost savings of \$2,000 per person.

Despite the cost savings, the intervention was not widely adopted. As a result, the Connecticut Collaboration for Fall Prevention was created to incorporate fall risk factor assessment and management evidence from RCTs into clinical care of older, community-dwelling ambulatory persons and to create multicomponent strategies to inform professional practice changes. Since then, physical therapists and healthcare providers have reported significant increases in referrals for fall interventions.

<sup>&</sup>lt;sup>35</sup> Tinetti ME, Speechly M, Ginter SF. Risk factors for falls among elderly persons living in the community. *N Engl J Med.* 1988;319: 1701-1707.

<sup>&</sup>lt;sup>36</sup> Tinetti ME, Baker DI, McAvay G, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med*. 1994;331:821-827.

Guralnik identified a number of lessons from trials to prevent falls and disability including (1) using a theoretical framework that can guide the work; (2) applying observational findings to identify target populations; (3) testing practical, feasible interventions; (4) identifying a primary outcome and carefully choosing a short list of secondary outcomes; (5) considering multifactorial interventions, if appropriate; (6) delivering an adequate dose of intervention; and (7) assuming that a successful trial will not lead to immediate utilization of the intervention.

## C. Interventions To Mitigate Degenerative Arthritis

MaryFran Sowers (University of Michigan) discussed impact and trends related to degenerative arthritis and disability. Osteoarthritis (OA) is the most common form of arthritis in the United States. The hallmark of OA is progressive degeneration of the articular cartilage and compromise of adjacent bone and soft tissue structures. It is characterized by joint pain, tenderness, limitations in movement, crepitus (cracking sound from bone rubbing against bone), effusion (fluid into the joint space), and localized inflammation. Prevalence estimates of OA are highly dependent on the reporting method (i.e., self report, self-report of physician diagnosis, X-ray). The estimated prevalence is 25–30 percent in adult populations over the age of 55. There are few studies that look at the prevalence of X-ray-defined OA over the lifespan. Data from one such study suggest that a substantial number of individuals for whom productivity is a major issue have prevalent OA before the age of 55. Data from the Study of Women's Health Across the Nation (SWAN) showed that after 40 years of age, the prevalence of OA greatly increases; this is an important consideration for prevention. Current OA prevalence estimates are likely to underestimate true prevalence, and OA prevalence is likely to be increasing.

There currently is no cure for OA. The primary goals for OA therapy are to reduce pain and edema, maintain or improve functional status, and minimize deformity. Other than symptomatic management, there is no uniformly accepted treatment for OA, in part because a number of key clinical questions remain unanswered. The European League Against Rheumatism (EULAR) Standing Committee for International Clinical Studies Including Therapeutic Trials has issued guidelines for several types of OA treatments.<sup>37</sup> Sowers summarized the clinical trials for OA knee treatments that have had more than five trials and demonstrated some efficacy for functioning and disability. Sowers described three major interventions for which there are consistent demonstrations of efficacy in at least five clinical trials. These included the use of hyaluronic acid, NSAIDS (nonsteroidal inflammatory therapeutics), and land-based exercise programs (as opposed to water-based programs).

Land-based (in contrast to water-based) exercise has been examined frequently and found to be associated with less pain and more functioning. Participation seems to matter more than intensity or duration, which suggests that social management could play an important role. Prevention activities for OA include the curtailment of increasing weight where the key is decreasing fat mass without losing muscle mass, joint protection programs, physical activity programs, and differentiating other pain syndromes that have different etiologies. There is limited evidence that current treatment for OA actually impacts disabilities estimated by ADL or IADL limitations.

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<sup>&</sup>lt;sup>37</sup> Jordan KM, Arden NK, Doherty M, et al. EULAR recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force for the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis.* 2003;62:1145-1155.

Many treatments in use may actually increase morbidities associated with OA. Surgery is the only treatment that can be considered to have a curative effect (though this is questionable). Finally, early-stage prevention in ages 35–55 may be effective but has not yet been tested.

Fries noted that the definition of OA is further complicated because some cases of OA do not show any marked changes in X-rays. In fact, OA is several diseases; while there is an association between OA of the fingers, knees, spine, and neck, these operate independently with different syndromes and different risk factors.

Sowers emphasized that there are very few studies that have actually looked at performance-based functioning measures and OA. Suzman observed that studies of OA are an interesting issue for countries where physical labor is more common. Although there are studies of OA in other countries, little has been done in terms of prevention trials that the BSR Program could consider. Workshop participants suggested further consideration of a number of treatments, including estrogen therapy, <sup>38</sup> glucose, and lifelong exercise programs.

## D. Interventions To Deliver Assistive Technology for Long-term Care

Emily Agree (Johns Hopkins University) addressed assistive technology (AT) interventions and how they can reduce disability. Unlike other interventions that are aimed at the prevention of underlying disability, the use of AT is a means of accommodating disability and thus offers the greatest potential impact by enhancing the capacity for independent activity. While prevention is an important goal in the long term, for many chronic disabling conditions the emphasis must be on strategies that ameliorate disability and reduce dependency. AT can be used as a strategy for coping with disability, to prevent additional injuries such as falls, as part of a rehabilitation program, and for monitoring.

Most of what is known about AT comes from observational studies, which suggest that it can reduce difficulty with daily activities and reduce dependence on personal care. AT also has the potential to increase physical activity, promote participation in valued activities, improve psychosocial well-being, improve safety, decrease risks of secondary disability, and protect the health of caregivers.<sup>39</sup>

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<sup>&</sup>lt;sup>38</sup> Cirillo DJ, Wallace RB, Wu L, Yood RA.. Effect of hormone therapy on risk of hip and knee joint replacement in the women's health initiative. *Arthritis & Rheumatism*. 2006;54(1):3194-3204.

<sup>&</sup>lt;sup>39</sup> Agree, EM. The influence of personal care and assistive devices on the measurement of disability. *Soc Sci Med.* 1999:48(4):427-443.

Agree EM, Freedman VA. Incorporating assistive devices into community-based long-term care: an analysis of the potential for substitution and supplementation. *J Aging Health*. 2000;12(3):426-450.

Agree EM, Freedman VA, Cornman JC, Wolf DA, Marcotte JE. Reconsidering Substitution: Can Assistive Technology Substitute For Personal Care? *J Gerontol B Psychol Sci Soc Sci.* 2005;60B(5):S272–S280.

Allen S, Foster A., Berg K. Receiving help at home: the interplay of human and technological assistance. *J Gerontol B Psychol Sci Soc Sci.* 2001;56B(6):S374-382.

Allen S, Resnik L, Roy J. Promoting independence for wheelchair users: the role of home accommodations. *Gerontologist*. 2006;46(1):115-23.

de Klerk M, Huijsman R. [Effects of technical aids on the utilization of professional care. A study among single 75-year olds]. *Tijdschr Gerontol Geriatr*. 1996;27(3):105-114.

Hoenig H, Taylor D, Sloan F. Does assistive technology substitute for personal assistance among the disabled elderly? *Am J Public Health*. 2003;93(2):330-337.

Few interventions are focused on delivery of assistive devices as the primary goal. Exceptions are where the efficacy of specific devices are being studied; e.g., after hip replacement<sup>40</sup> or for stroke rehabilitation<sup>41</sup>. Reports on experimental or quasi-experimental designs for interventions involving provision of AT are generally embedded in occupational therapy (OT)— and physical therapy (PT)—based interventions. OT interventions include functional assessments of person and home, recommendations and prescriptions for AT and home modifications, provision and installation of devices, training in use of devices (both new and already in home), and followup assessment and reassessment as needs change. The latter is critical because events can change needs for AT and devices require maintenance and repair.

The outcomes of these intervention studies generally do not include disability or functioning per se, presumably because they assume that AT will be effective if properly used. Some studies have found increased participation in valued activities and home-leaving with the use of a package that includes AT. <sup>42</sup> Analyses tend to focus instead on intermediary outcomes such as the uptake of devices (number, use, abandonment), user satisfaction, home healthcare hours or cost, fall prevention, and/or participation in valued and social activities. The impact of AT on disability has been examined only in a small number of studies, but the nature of these interventions is highly variable. <sup>43</sup> Some allow individual therapists complete autonomy to design services for clients; others more closely document provision and use of AT and other services. These studies are limited because the samples are usually small and purposive, often composed of existing clients. Attempts to deliver OT to community samples (e.g., at-risk populations) show high refusal rates. Additionally, the standard care received by the control groups was hard to classify from publications and also appears to be tailored rather than standardized

Two high-quality randomized trials have reported effects on disability that are attributable to AT or home modifications: Mann and colleagues, in a study that remains the most oft-cited in this area, conducted an RCT that involved the provision of AT to older persons in Buffalo, New York. They found that the use of AT led to improvements in functioning over 18 months. Gitlin and colleagues conducted a large prospective RCT that included both occupational and

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Taylor D, Hoenig H. The effect of equipment usage and residual task difficulty on use of personal assistance, days in bed, and nursing home placement. *J Am Geriatr Soc.* 2004;52(1):72-79.

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Verbrugge LM, Juarez L. Profile of Arthritis Disability: II. Arthritis & Rheumatism. 2006;55(1): 02-113.

<sup>&</sup>lt;sup>40</sup> Haworth RJ. Use of aids during the first three months after total hip replacement. *British Journal of Rheumatology*. 1999;22(1):29-35.

<sup>&</sup>lt;sup>41</sup> Sackley C, Wade DT, Mant D, et al. Cluster randomized pilot controlled trial of an occupational therapy intervention for residents with stroke in UK care homes. *Stroke*, 2006;37(9):2336-41.

<sup>&</sup>lt;sup>42</sup> Steultjens EMJ, Dekker J, Bouter LM, Jellema S, Bakker EB, van den Ende CHM. Occupational therapy for community dwelling elderly people: a systematic review. *Age and Ageing*. 2004;33:453–460

<sup>&</sup>lt;sup>43</sup> van den Ende CHM, Steultjens EMJ, Bouter LM, Dekker J. Clinical heterogeneity was a common problem in Cochrane reviews of physiotherapy and occupational therapy. *J Clin Epi*. 2006;59:914–919.

<sup>&</sup>lt;sup>44</sup> Mann W, Ottenbacher K, Fraas L, Tomita M, Granger C. Effectiveness of assistive technology and environmental interventions in maintaining independence and reducing home care costs for the frail elderly: A randomized controlled trial. *Arch Fam Med.* 1999;8(3):210-217.

physical therapy, as well as home modifications.<sup>45</sup> They attributed a small to moderate effect on functional limitations to environmental modifications. While the cost-effectiveness of AT was not estimated in these studies, Gitlin indicated that the cost to provide AT devices (including the price of the device, delivery, and installation) was on average \$439 out of a total cost of \$1,222 (including OT visits and followup). AT is considered a relatively low-cost means of addressing disabling conditions.<sup>46</sup>

Agree offered the following suggestions to improve the beneficial impact of AT interventions on disability: (1) Better identify the at-risk population by indicating discrepancies between environmental features and individual capabilities; (2) target the domains of disability most relevant for AT interventions (mobility impairment, sensory impairment, bathing); (3) tailor interventions for groups with conditions (e.g., impaired cognitive functioning, depression, pain) that impede use of AT-based solutions; and (4) include the individual in the decisionmaking process and in priority setting.

Findings from the 2005 Pilot Study of Aging and Technology illustrate how survey data can help estimate the number of persons with potential needs for AT interventions, such as those with lower body limitations and unmodified environmental barriers. Among individuals with any lower body limitation, 28 percent had unmodified barriers at the entry, inside, or in the bathing area of the home, while 15 percent of the individuals with severe lower body limitations had such barriers.<sup>47</sup>

Innovative AT delivery intervention programs also need to be developed and tested. For example, a national AT service delivery system in Ireland involves people with disabilities as Technology Liaison Officers (TLOs) to other people with disabilities in their area. Another novel intervention is an inhome tele-rehabilitation program using videoconferencing equipment to allow trained OT/PT to provide a "home visit" from a central location.<sup>48</sup>

### E. General Discussion: Clinical and Personal Interventions

Lois Verbrugge (University of Michigan) distinguished between two types of interventions: Those targeted at the person and those targeted at the environment. Changing the environment is essentially changing the nature of the task at hand, which often can be more easily accomplished than altering individual behavior. There are many ways to modify the environment so that people can maintain their ability to complete tasks. Due to the nature of data collection surveys where individuals are interviewed, interventions tend to focus on ways to change the individual. In contrast, task modification has been studied little at the population level in terms of medical and

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<sup>&</sup>lt;sup>45</sup> Gitlin LN, Hauck WW, Winter L, Dennis MP, Schulz R. Effect of an in-home occupational and physical therapy intervention on reducing mortality in functionally vulnerable older people: preliminary findings. *J Am Geriatr Soc.* 2006;54(6):950-955.

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<sup>&</sup>lt;sup>46</sup> Wolff DA, et al. Perspectives on the Recent Decline in Disability at Older Ages. *Milbank Quarterly*. 2005;83(8):365-95.

<sup>&</sup>lt;sup>47</sup> Freedman, et al., 2006

<sup>&</sup>lt;sup>48</sup> Hoenig H, Sanford JA, Butterfield T, Griffiths PC, Richardson P, Hargraves K. Development of a teletechnology protocol for in-home rehabilitation. *J Rehabil Res Dev.* 2006;43(2):287-98.

functional problems. Use of AT is actually a task-modification approach. Diminishing the difficulty of the task in turn diminishes disabilities.

Interventions differ according to who chooses them. Medical professionals and physical and speech therapists tend to take a person-oriented approach for an intervention, while potential collaborators such as OTs, architects, and rural and urban planners are often keenly interested in disability with respect to the environment. Verbrugge hypothesized that environmental interventions for disability are longer lasting, more efficacious, more satisfying, and ultimately less expensive than person-based interventions, which often have a large upfront cost. One prospect for a low-cost, cost-effective intervention with population benefits for disability is to design inexpensive devices that are low-maintenance, safe, attractive, and culturally acceptable. For example, in Singapore, because medical devices (e.g., canes and walkers) are culturally unacceptable, designing an assistive device to look like an umbrella or shopping cart might be more suitable. A second idea is to have OTs help individuals with task modifications to speed and enhance personal adaptation. A third idea is to frame a message according to cultures in different countries to get people out and moving; for the United States and other postindustrialized countries, the message could be one to start exercising, while in other countries where people are less sedentary, the message could be to get out and about. A final idea is to make user-friendly cell phones for older persons that can be used to monitor disability and reduce injuries.

In countries where the population is aging quickly, lessons learned from interventions must be durable and applicable in the long term. The framing of the research question must consider the cultural context. Verbrugge noted that in Asian societies, older people are routinely assisted in daily tasks; elderly Asians do not necessarily recognize the boundary between daily assistance that is the norm and assistance necessitated by disability. She acknowledged that there are a variety of types of observational data that give clues about the types of activities that older individuals want to do but do rarely or not at all because of barriers; this knowledge can provide a basis for choosing interventions with results that are satisfying to older individuals.

Suzman noted that the global burden of disease and the DCP2 list of interventions ranked speed bumps near the top with respect to cost-effectiveness in terms of reducing disability life years. He also presented the option of substitution, where someone else is paid to handle tasks one can no longer do easily, which can be considered a type of task modification.

## F. Group Discussion: Clinical and Personal Interventions

Returning to the discussion of cost-effectiveness, Musgrove emphasized that cost-effectiveness is the relationship between the cost of doing something and some defined outcome (e.g., falls prevented, years of life gained) that is not a monetary amount. Two different interventions must be compared by the same type of measure of effectiveness; for example, one QALY and one prevented fall cannot be compared other than on a subjective basis. In order to compare interventions, there must be comparable measures of cost-effectiveness; the DCP2 uses the synthetic notion of DALYs. Various studies discussed at the meeting examine different outcomes. Without a standard scale of effectiveness, these outcomes cannot be compared. Deaths

and years of life are natural units and easy to compare; problems arise when analyzing nonfatal outcomes and when connecting specific events such as a fall to fatal or nonfatal results.

There is no absolute standard that dictates when an intervention becomes cost-effective. The total cost of an intervention depends on how many times it must be repeated in the population. For example, an intervention that costs \$1,000 per life year may be affordable if it is only offered for one person in a million, while an intervention that costs \$100 per life year may not be affordable if it is something the entire population must receive.

If an intervention is truly cost saving, then cost-effectiveness need not be considered. Only when there is a net positive cost is a cost-effectiveness analysis needed. Cost saving is only meaningful when a more expensive approach would be applied; if the more expensive alternative is not in use, there is no cost saving. This is important with respect to poor countries where coverage of more expensive interventions is lacking. Sometimes results of an intervention are valued economically. For example, when water is brought to a village and people save 2 hours a day previously spent fetching water (and time is worth the wage in the village), it can be said that people are in effect earning more even if there is no extra money involved. Money-to-money comparisons go beyond health effects, and this is important when there are multiple outcomes such as time saved or more income as well as better health.

A difficult problem with money-to-money comparisons arises when comparing individuals with very different incomes. An intervention might appear justified in a rich country and not a poor country because although the intervention costs the same, the payoff is very small for individuals who make \$2 per day versus \$200 per day. Even when costs go down in the same proportion as the outcome, differences in income are likely to be greater than differences in cost of the intervention. This is a reason for comparing only via cost-effectiveness and not via cost-benefit analysis, where income differences may matter greatly. Some interventions (water, sanitation) have nonhealth effects that are probably more highly valued by individuals than the health effects. Taking into account how people value the interventions means that one intervention cannot be compared necessarily to another intervention based only on health outcome. There does not seem to be a way to avoid this discrepancy. Musgrove stressed that it must be clear whether one is referring to economic or health outcomes, whether they are measured in the same way, whether the time in which they occur is taken into account, and if the ultimate impact of the intervention compared to another can be anticipated.

Interventions have been analyzed for controlling only some of the many risk factors for ill health. A survey that includes all of the relevant risk factors together is conceivable but difficult; one single source of information would need to include measures of physical environment, AT, various behaviors that would affect health, and what medicines people were already using. There is some skepticism about epidemiological correlations. Unless there is an RCT, it is unclear for some interventions that the risk factors from survey data are causal. Many risk factors for disability are known, but it cannot be known if they are reversible unless RCTs are conducted. Combining information from observational data with clinical information can help with estimating risk factors' effects.

Musgrove agreed that aiming interventions at risk factors rather than diseases is often correct, in part because a single risk factor may be affecting many different sources of disability. This does not negate the problem of measuring the end results—in lives or DALYs—in a comparable way.

Cost-effectiveness numbers have been established for many interventions; how well these interventions do under real circumstances must be considered. Unless there are abundant data to suggest otherwise, Richard Besdine believes that making the argument for cost savings to CMS is futile; there is a fixed belief that there has never been a preventive intervention that has documented cost savings. Rather, individuals who understand clinical utility, as well as the epidemiology and cost-benefit analyses, should together prioritize interventions. Avoiding cynicism is important; approaching CMS with a plan that assists the beneficiaries by prolonging independence might be the best way to engage their interest. Suzman added that the NIH is not mandated to save money. Its mandate is to promote health, well-being, and functioning, and it is believed that these are worthwhile goals that will come at some cost. Cost-effectiveness analyses are intended only to help inform decisions, but the perspective (whether it is the CMS budget or the national health) must thoroughly be considered. Suzman explained that the reason to push cost measurement is not necessarily to reduce costs but to have a metric to help determine the best way to prioritize activities to reduce population disability within the constraints of a limited budget and specific time horizons and for specific groups.

While the need for common metrics is accepted, not everyone was convinced that DALYs are the correct measure because they seem to be linked to single conditions as opposed to multiple conditions and do not address disability directly. NIA seeks to develop different metrics for addressing disability. Suzman outlined two different metrics that currently are under development: (1) Cutler is developing a set of national health accounts similar to the notion of the GNP, and (2) Daniel Kahneman and others are focused on measuring improved well-being. Kahneman is trying to combine both the evaluative (e.g., "how are you?") and experiential (e.g., how individuals actually function over a week) parts of well-being. Suzman also called for improved third generation approaches that measure functioning beyond ADL/IADL limitations to get at performance or measures targeting preclinical signs of ADL/IADL limitations that are more sensitive to interventions and require smaller sample sizes.

Manton raised three important methodological points: (1) The effect of a risk factor should be integrated over time (e.g., a single instance of elevated blood pressure is very different from having a long history of elevated blood pressure and cumulative damage); (2) genetics and the importance of heterogeneity of the population, some of which can be controlled; and (3) models other than for economics that can be used to model changes in variability and means of underlying phenomena, whether it be risk factors, interventions, or disease outcomes. Major improvements are needed with regard to outcomes. The Patient-Reported Outcomes Measurement Information System (PROMIS) network is a trans-NIH initiative devoted to determining better self-reported endpoints for clinical trials. Possibilities include item banking models, computer adaptive testing in real-time application to decrease questionnaire burden, and other refined processes to yield continuous variables with high precision and allow for better before-and-after comparisons for study and control groups.

According to Narayan, few interventions are truly cost saving in a lifetime. Likewise, in clinical trials the control group does not reflect what is really happening in the community. This leads to underestimates of the marginal cost of the intervention and overestimates of the marginal benefit. Another problem is that marginal cost and benefits are presumed to be linear functions according to scale, though they may not be. For example, shifting from 10 percent of the population to 50 percent of the population receiving an intervention could be a lot cheaper at the margin than shifting from 80-percent to 90-percent coverage; the average cost-effectiveness ratio ignores the scale at which the interventions are being applied. David Evans noted that, apart from multifactorial interventions, cost-effectiveness is measured one intervention at a time and does not take into account different interventions done at the same time. Musgrove acknowledged that the impact of a second intervention is different if a first intervention already has been delivered. In the ideal scenario, the impact of the package as a whole would be considered, but this is not feasible if the interventions are done irregularly.

Discussion turned next to differences between multifactorial and tailored interventions. There are no data that describe the cost-effectiveness of tailored packages. Tailoring an unlimited number of different interventions to specific people could be much more expensive than having a limited set of standardized interventions from which to select a package for each individual. Behaviors are multiply determined and very resistant to change. For this reason, it is essential to have interventions that operate at different levels (e.g., individual and community based) and that are multifactorial. Suzman noted that this is conceptually a good idea but it lacks evidence. Other than for the North Karelia Project, Suzman has not seen documentation of impact from a truly integrated, multilevel intervention. Freedman reported that in Europe, interventions at the community level have educated doctors about the risk of falls, leading to a reduction in emergency room entries due to falls.

Fries observed that the approaches discussed have not been based on reductionism but have focused on combining different interventions for different people. For these types of interventions, decomposition and subgroup analyses are necessary to find where the biggest benefit is gained. RCTs may not be the most cost-effective interventions, especially in light of the new budget constraints. Observational studies are still needed in order to see differences in magnitude and better assess before-and-after measures; they should not necessarily be forsaken for RCTs.

#### How To Spend \$5 Million/Year

Suzman posed a thought experiment: Suppose we could identify the 100 U.S. counties (100,000 people per county) with the highest levels of disability for the 50–75 age group and could sample five of the counties as controls and five as interventions. For \$5 million a year, how would one decide how to change that population over a period of 2 years?

Having multiple outcomes and improving quality of life are sensible. Narayan would like a set of guidelines to direct multilevel interventions with at least two components: (1) Some evidence that each level has some benefit and (2) positive interaction between the two levels. Maybe one approach is to use rich geocode resources to tease out the risk factors that are strongly associated with disease.

Nancy Whitelaw asserted that in the multilevel set of interventions aimed at policy, community, organization, and individual levels in five counties across the country, population changes in functioning or disability could be observed. Whitelaw does not believe that there has been a group of people who understand both the science as well as what is going on in communities; as such, there have not been conversations with possible intervention areas. Manton added that some programs give money to individuals who then make the decision on how to use it; this has been observed to work well financially and in terms of outcomes. Suzman agreed that this approach should be considered, although it is difficult to do within the context of NIH studies.

Fries added that randomizing on different counties would be inadvisable due to the great disparities between counties. Census tracts would be a better basis for randomization, but even then, delivering multilevel interventions to many different sites would greatly increase the cost of the intervention. Suzman agreed that census tracts could work and underscored that the essential part is to have one intervention in some sites, multiple interventions in others sites, multiply integrated interventions in other sites, and system-level interventions in others. Census tracts also can be useful for understanding environments. However, census tracts have limited analytical usefulness because they do not necessarily hold geographic meaning for individuals, nor are they political units with governing authority.

Powell suggested focusing on simple walking. Walking is a function of a series of choices made on a moment-by-moment basis and is related to CVD, musculoskeletal disease, and diabetes—three major causes of disability. Partnering with other organizations (funding agencies and community organizations) could ease the financial strain on the NIA; the conversation should not be derailed by cost. Perhaps it is premature to propose an entire intervention plan; the first wave of studies could target developing the pieces that would go into the larger multilevel intervention study. If an intervention is undercut at the outset due to worry about cost, an ineffective intervention may result. Powell suggested that the multidisciplinary group gathered should focus on targeting a simple message (e.g., walking) at the policy, environmental, and individual levels. Verbrugge suggested that the walking intervention could offer the opportunity to learn about people who cannot or will not walk; it is an opportunity to learn about the milieu. The United States is not designed for walking; it is designed for cars. A program aimed at walking also can send the message of getting out and about.

It is helpful to consider effectiveness and cost separately. Trials should focus on developing gold standard interventions. Subsequently, figuring out how to deliver the intervention to the population in a broader and cost-effective way should be the focus. Soliciting solutions from individual communities might stimulate innovation. While there is not direct evidence of effectiveness from multilevel interventions, some factors would seem to be intuitive (e.g., prescribing walking to individuals without a place to exercise will not be effective). Implicitly, the outcome should be observed in the field in a reasonable amount of time and, at best, should be operational within 4 or 5 years.

Many of the interventions presented target specific conditions and/or domains (e.g., mobility, vision). Some sought a large aggregate improvement while others sought to benefit the specific subgroups of the population. Suzman clarified that the goal for the NIA/BSR Program is to have defined communities or populations for which one can show aggregated impact from a specific

array of interventions. Listing four or five examples could provide the political basis for scaling up an intervention. For this purpose, it might be helpful to rank the disabilities that are most prevalent and the risk factors that are most prevalent, most reduce functioning, and are most susceptible to change. Ezzati suggested that the NIA/BSR Program should have three concerns that trump cost-effectiveness: (1) The baseline prevalence, (2) the community effectiveness of the interventions, and (3) distribution of the intervention. The intervention must be reasonably simple so that it can be transferred with some fidelity and tailored to be applicable to the wider community. Suzman welcomed suggestions for coordinated approaches, including small-scale projects in the pipeline that could be developed into or embedded in larger studies.

Marcelle Morrison-Bogorad (NIA) cautioned that before deciding on a community intervention, one needs to identify the intervention that has the best chance of working. A trial on some intervention related to diabetes might be most appropriate for this purpose, while an intervention in walking is most interesting with respect to social results.

Manton acknowledged that the one goal of researching the disability decline is to help the United States deal with the aging population in a way that is supportive of economic productivity. At the macro level, Congress is interested in increasing human capital in order to sustain economic growth. In light of this, the fact that the United States is an information society must be considered; cognitive interventions should not be neglected. Acknowledging the goal of keeping the United States competitive with other aging societies does not establish which intervention is best, but it can illuminate the outcomes toward which interventions should be directed. Suzman concurred and reported that the BSR Program has considered starting interventions with an older working population. Interventions to improve and maintain cognition have had a checkered past: The ACTIVE preliminary results suggest that the relatively short period of intervention (about 10 hours) had a very narrow and specific effect but did not generalize to other domains.

### V. Converging on Candidate Interventions To Decrease Elderly Disability

#### A. Low-Cost Effective Interventions

James Fries (Stanford University) described the health of seniors as a major national health and economic concern. We do know how to postpone ill health and infirmity by 10 or more years, how to moderate medical costs by reducing the illness burden, and which interventions work. Healthy people need less medical care but cost more by living longer. The period of adult vigor may be extended by health enhancement programs. An important issue is the lag between health risk reduction and positive health and cost benefits.

The central thesis of the compression of morbidity states that the age at first appearance of aging and chronic disease symptoms can increase more rapidly than life expectancy. This thesis is supported by evidence from multiple longitudinal studies documenting morbidity compression by social class, exercise level, education level, risk factors, multiple national surveys of disability since 1982, and by multiple randomized trials showing disability and cost reductions with risk factor reductions.

Health risk data on students at the University of Pennsylvania in 1939 originally placed individuals in high risk, low risk, and moderate risk of disability based on body weight, exercise, and smoking. After 20 years of data collection, the original high-risk group experienced the highest mean disability, while the original medium- and low-risk groups experienced medium and low disability, respectively. A second study of exercise over a 20-year period showed that the exercise group and control group continue to diverge in their mean disability levels, where the exercise group has much lower mean disability. It is hard to imagine that anything is not causal in this relationship given all of the confounders that could affect it. This observational study is a good example of what cannot be assessed by RCTs. Compression of mortality cannot be determined by these studies because not enough deaths have occurred, but delays such as the 10-year span between controls reaching 0.1 mean disability and exercisers reaching that level can be observed.

There are many candidate causes for the decline in disability, which must satisfy the following criteria: (1) Have to have increased in use since 1982, (2) must apply to a lot of people, (3) must have a major effect on disability in those people, and (4) preferably, do not have a large effect on increasing life expectancy. With the exception of smoking, lifestyle changes including obesity (which has increased) and exercise (which has remained constant) are not attractive candidates. Medical interventions (e.g., antihypertensives, statins, low-dose aspirin, diabetes control, cholesterol control, total joint replacement) and social interventions (e.g., reducing secondhand smoke, highway redesigns, use of air bags) are possible candidates. Workshop participants also mentioned the following as possible contributors to the disability decline: Fewer cataracts, lower consumption of dairy and red meat, and interventions that have improved in quality but not in use.

Fries next discussed the characteristics of programs that can improve health and save money:

- Program cost of \$100/year or less (medical costs per senior per year = \$6,000)
- Multiple interventions in one
- Multiple, serial contacts through the year
- Tailored interventions
- No doctor, hospital, or one-on-one interaction necessary (too expensive)
- Computer-driven, mail, and increasingly Internet-delivered
- Focused on big, modifiable health and cost issues.

The key targets for the first year of a program to effect first-year health improvements and cost reduction in senior populations include (1) perceived self-efficacy, (2) health risk reduction, (3) self-management skills, (4) high-risk persons, (5) chronic disease patients, and (6) last year of life. Interventions should be designed to encompass all of these key targets, which will sum up to a substantial change at the end of the first year.

Fries also briefly discussed the Senior Risk Reduction program, a CMS demonstration project (2007–2009) involving tailored health enhancement and cost reduction. Fries was encouraged by the fact that CMS proceeded in an evidence-based way, which involved reviewing the literature, deciding on the demonstration, designing the demonstration in a rigorous way, and funding it.

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<sup>&</sup>lt;sup>49</sup> Vita AJ, Terry RB, Hubert HB, et al. Aging, health risks, and cumulative disability. *N Engl J Med*. 1998;338:1035±41.

While disability is decreasing, health enhancement programs can continue to improve health and reduce cost. This is essential because although the compression of morbidity is feasible, it is not inevitable.

Suzman encouraged a demonstration with older workers through coordination with CMS. He suspected that some methodologies from neuroeconomics and behavioral economics aimed at helping people make better decisions and actually doing what they want to do (carrying out good intentions) could be useful in fine-tuning the demonstrations. In the Diabetes Control Project the education gap was obliterated for the group that received more intensive reminders; <sup>50</sup> this is also a promising piece of evidence that could be incorporated into the demonstration. Fries added that there are many content issues that need to be resolved and there has been an inadequate review of all the materials, so there is definitely room for improvement.

#### **B.** Scaling Up Interventions

David B. Evans (WHO) opened by stating that scaling up requires selection of the appropriate interventions as well as cost considerations. Since 1998, WHO-CHOICE (Choosing Interventions That Are Cost-Effective) has analyzed the population effectiveness and costs of more than 700 interventions in 14 epidemiological subregions of the world and has developed country contextualization tools. It also collaborated with DCP2 on the most recent edition of Disease Control Priorities in Developing Countries. In general, cost-effectiveness analysis should evaluate the appropriateness of current interventions as well as new interventions, should funding become available. The CHOICE analysis does this and deliberately considers interactions among interventions undertaken at the same time to determine the population health impact from all different combinations (personal, nonpersonal, and combined interventions). Also built into the analysis is the fact that unit costs and effects change with increasing coverage.

To illustrate the CHOICE process, Dr. Evans presented data from analyses of multiple interventions, conducted in different regions of the world, focused on primary and secondary prevention for cardiovascular disease. Secondary prevention included the traditional approaches to treating individual risk factors (e.g., hypertension) as well as an absolute risk approach, similar to that of the PolyPill. This approach involves assessing and treating people whose 10-year risk of a cardiovascular event is greater than some cutpoint (for the analysis, 5-, 15-, 25-, or 30-percent cutpoints were analysed). The analyses showed the most appropriate combination of preventive activities at increasing levels of resource availability. WHO-CHOICE found that primary prevention is more cost-effective than secondary prevention in all regions, although the type of primary prevention that is the most cost-effective differs. Secondary prevention, although it costs more, yields much higher population health benefits. Moreover, the absolute risk approach is always more cost-effective than screening for individual risk factors.

Evans raised a number of issues for consideration:

• The appropriate package depends on the risk factors and cost structures in the population concerned; there may not be one intervention that is worth scaling up across all segments

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<sup>&</sup>lt;sup>50</sup> Goldman DP, Smith JP. Can Patient Self-Management Help Explain the SES Health Gradient? *PNAS*. 2002;(99)16:10929-10934.

- or across different countries. Interventions tailored to individual countries are an option, but in most cases the cost would then increase.
- Interventions are rarely done by themselves, and costs and population effects differ according to other interventions being done as well as other programs intending to scale up.
- Cost-effectiveness analyses almost always identify cost-effectiveness of interventions in
  isolation; if two interventions are shown to be cost-effective by themselves, it cannot be
  assumed that they will be cost-effective when scaled up together. Likewise, there is a lack
  of data on cost effectiveness of multiple interventions; therefore, including combination
  arms in trials should be considered.
- A very cost-effective intervention might prevent only a small proportion of the remaining disability in a population.
- Costs (and perhaps effectiveness) are nonlinear—when assessing how far to scale up an intervention, nonlinearities in costs (and effects) should be built into the analyses.
- Interventions that do more than improve health have benefits that are not easy to quantify.
- It has become popular in international health practice to talk about conditional cash transfers wherein households receive cash for immunizing their children and this has impacted both the health and the education of the children. Financial incentives for behavior changes, such as quitting smoking, should be considered.

Evans remarked that in some ways it is easier to tailor interventions to a country than to an individual because the individual requires much more specific information. Suzman suggested that categories of countries by education and income could be established where one country might be more transferable to other countries in the same cross set. Suzman noted that the BSR Program is in the process of developing comparable surveys that can be administered in different countries.

Musgrove acknowledged that while culture cannot be overlooked, it is easy to overstate its importance. Often the detail that matters is a specific piece of misinformation (e.g., people think that diabetes will be cured by limiting sugar intake); sometimes, overcoming ignorance can lessen cultural differences. Musgrove also emphasized that cost-effectiveness might not be the most important basis for an intervention, especially for infrastructures that are not well equipped for a large number of interventions; in this case, focusing on a small number of simple interventions might be the best approach.

# C. Research Needs for Chronic Disease Interventions: Lessons From the Comparative Risk Assessment (CRA) Project

Majid Ezzati (Harvard University) presented summary results from the Comparative Risk Assessment (CRA) project, described an ongoing application to "Eight Americas," and shared lessons for interventions and data gaps.

The global age distribution of disease burden attributable to major risk factors demonstrates the important role for chronic disease risk factors in developed and lower mortality developing countries. A substantial part of this burden occurs before 60 years of age and at even younger

ages in developing countries. Removal of the twenty 20 global risk factors in 14 epidemiological subregions of the world would have increased global healthy life expectancy (HALE) by 9.3 years (17 percent), ranging from 4.4 years (6 percent) in populations with the best health to 16.1 years (43 percent) in the populations with the worst health. <sup>51</sup> Globally, an estimated 39 percent of total disease burden and 47 percent of mortality in 2000 resulted from the joint effects of the leading risk factors that Ezzati and his colleagues identified.

These analyses were based on assumptions that need to be more empirically based. Better data are needed on hazardous effects for fatal and nonfatal events in epidemiological studies for various risk factors. More information also is needed on how risk factors affect mortality and disability separately as well as better correlation of exposures to multiple risks. One interesting correlation between nutritional risks and income across countries shows that mean BMI and cholesterol are somewhat correlated with income, while there is very little correlation at the population level for blood pressure and income. This demonstrates that risk factor correlation at the population or individual level is not necessarily obvious. Likewise, better data on time patterns are essential due to the fact that exposures and hazardous effects are time dependent; in order to model interventions, the patterns and quantifications of these exposures and risks must be known.

Empirical data over the past decade or so have improved greatly. There are now longer and larger epidemiological studies. Large epidemiological studies in nonwestern populations now allow examination of hazards in other populations; questions such as whether smoking is differentially harmful in some populations have been able to be answered. Ezzati asserted that it is timely to go back and revisit the questions for morbidity and mortality.

With respect to U.S. applications, Ezzati and colleagues are investigating the extent to which selected major risk factors contribute to subnational differentials in mortality and disease burden. In focusing on this question, much emphasis is being placed on the validity and subnational comparability of data. The population of the United States was divided into eight distinct groups ("Eight Americas") with different epidemiologic patterns and mortality experience and sufficiently large population size to permit detailed analyses of causes of death, risk factors, and other factors over time. Life expectancy at birth for 2001 in the eight Americas ranged from 66.7 years among the Black high-risk urban male population (America 8) to 87.7 years among Asian females (America 1). Cause of death for the eight groups demonstrates that there is a strong gradient in young and middle ages. Cause of death for the 15–44 age group of Native Americans and urban African-Americans demonstrates that subgroups of the populations continue to have large differentials in young adult mortality rates; the difference is not as great for females but still persists.

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<sup>&</sup>lt;sup>51</sup> Ezzati M, Hoorn SV, Rodgers A, Lopez AD, Mathers CD, Murray CJL; Comparative Risk Assessment Collaborating Group. Estimates of global and regional potential health gains from reducing multiple major risk factors. *The Lancet*. 2003;362:271-280.

<sup>&</sup>lt;sup>52</sup> The eight Americas are defined as follows –America 1: Asians living in counties where Pacific Islanders < 40% of population; America 2: White low-income rural northland; America 3: Middle America; America 4: White poor Appalachia and Mississippi Valley; America 5: Western Native Americans; America 6: Black middle America; America 7: Black poor rural south; America 8: Black high-risk urban. See Murray CJL, Kulkarni S, Michaud C, et al. Eight Americas: investigating causes of mortality disparities across races, counties and race-counties. *PLoS Medicine*. 2006; 3(9):e260.

Some issues to consider in applying interventions for data gaps are as follows:

- A few risks (e.g., smoking, alcohol, obesity, high blood pressure, elevated cholesterol, glucose) may well explain large parts of mortality (and morbidity) differentials.
- Smoking and harmful alcohol consumption are relatively accessible risk factors to target, although there needs to be better separation of epidemiological evidence on nonfatal
- There is a possibility of some geographical clustering of risks (part of correlation is population level)
- Current data sources make it hard to make assessments at levels below State or large clusters of counties; the Behavioral Risk Factor Surveillance System (BRFSS) contains fewer questions than ideal on risk profiles, and data on disability and disabling diseases face similar issues of resolution and validity or comparability. The BRFSS is considering a validation subsample, which may provide a window of opportunity for much better descriptive epidemiology.

#### D. Converging on a Candidate Intervention To Decrease Elder Disability

Nancy Whitelaw spoke in her capacity as the Director of the Center for Healthy Aging at the NCOA about bridging the gap between research and impact. The NCOA is a nonprofit organization that is mission driven and focused on helping older adults manage chronic conditions. It works from the social ecological model<sup>53</sup> with a particular interest in changing the capacity of organizations to deliver efficacious interventions to older adults; typically, the interventions are at the individual level. The NCOA applies the expanded chronic care model<sup>54</sup> to integrate population health promotion by bringing into context two organizational systems that are equally important: The healthcare system and community organizations. Whitelaw suggested that the community context must be better understood in order to decrease disability.

The NCOA's work on building the capacity of organizations to deliver efficacious interventions addresses five problems currently contributing to elder disability:

- The ageism in health promotion and disease prevention apparent through the documentation of systematic exclusion of older adults from health promotion intervention studies (including studies by NIH).
- Science is not shared—while there is a growing body of evidence of interventions that can positively impact health, disability, and quality of life, little of this is shared with the wider health community.
- There is an untapped opportunity to draw upon 29,000 community-based aging service providers (such as social service agencies, senior centers, area agencies on aging, meal programs) to reach of millions of older adults with efficacious interventions.
- Great disparities based on race, ethnicity, location, and income still exist.

<sup>&</sup>lt;sup>53</sup> McLeroy KR, Bibeau D, Steckler A., Glanz K. An ecologic perspective on health promotion programs. *Health* Educ O. 1988;15(4):351-77.

Sallis JF, Bauman A, Pratt M. Environmental and policy interventions to promote physical activity. Am J Prev Med. 1998:15:379-397.

<sup>&</sup>lt;sup>54</sup> Barr VJ, Robinson S, Marin-Link B, et al. The expanded Chronic Care Model: an integration of concepts and strategies from population health promotion and the Chronic Care Model. Hosp Q. 2003;7:73-82.

 Highly fragmented services expose gaps across aging services, healthcare, and public health.

In addition to working closely with many academic and research partners, demonstration sites, and local organizations, the NCOA collaborates with several Federal partners, including the Administration on Aging (AOA), the CDC, the Agency for Healthcare Research and Quality, and the CMS. Whitelaw focused on the AOA, which 3 or 4 years ago developed an interest in evidence-based prevention and the capacity of providers to deliver efficacious interventions around chronic conditions. In July 2006, the Department of Health and Human Services announced the next round of grants for collaboration on prevention for older Americans. All sources of funding (a State match, philanthropies, the AOA, and the NCOA) have combined to make this a \$20–25 million investment.

Whitelaw showed the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework, a standard framework for public health intervention planning and evaluation. <sup>55</sup> This framework for community interventions focuses on (1) reaching the target population (2) replicating the original efficacy trial, (3) successfully adopting the intervention in a variety of settings, (4) targeting implementation to deliver the essential mechanisms of the intervention, and (5) maintaining the intervention over the long term.

The NCOA works with different communities and takes them through the translation process of developing their program, with attention to maintaining fidelity to the core components from the original intervention studies as well as fidelity to the developed program. There has been one round of demonstration projects funded late in 2003. The projects reached out to minority populations with a variety of interventions in over 100 settings at 14 sites; the implementation of the programs, which began in 2004, was successful but the long-term effectiveness is not yet known

Whitelaw considered the term interdisciplinary to be too narrow in the sense that the NCOA focuses more broadly on the context of intersectorial (health are, aging network public health), interorganizational (hospital, doctors' offices, senior centers), and interpersonal relationships (among people in communities and participants of programs). The NCOA is also a policy organization that lobbies to change Federal policy, programs of practice, and the field of research. Whitelaw stressed that there are many people who work with older adults who still lack the skills to provide effective interventions; focusing on this population of workers can be an effective way to improve the programs that are already in place. In addition to work on evidence-based prevention, the NCOA seeks to increase the quality and accessibility of health programming for older adults, advocating for greater support of strong and effective community programs.

#### E. Prioritizing Modifiable Risk Factors for Reducing Disability Among Older Adults

Opening group discussion, Richard Besdine (Brown University) addressed ways to prioritize modifiable risk factors for interventions that will reduce disability among older adults. Besdine discussed several modifiable risk factors for disability that were driven by a sense of urgency to

<sup>55</sup> http://www.re-aim.org

demonstrate outcomes in a reasonable timeframe and that have had abundant interventions in past years.

- In the 1950s it was found that controlling <u>blood pressure</u> was useful in preventing stroke and heart attacks, but it was not until 1991 that the Systolic Hypertension in the Elderly Program (SHEP) applied this wisdom to older adults in the United States. It has been known for 15 years that lowering high blood pressure helps prevent strokes and heart disease and that many more strokes are prevented for every millimeter of mercury blood pressure lowered in octogenarians than in 50-year-olds. It also is known that 80 percent of strokes occur in seniors, yet the majority of U.S. citizens with high blood pressure are not treated, and only a subset of those who are treated have an effective reduction.
- Over the past 30 years countless interventions have addressed <u>exercise</u>, yet only about 10 percent of older Americans engage in meaningful exercise.
- <u>Smoking</u> cessation interventions have been very successful: only about 20 percent of Americans smoke, but this group still accounts for over half of the related cardiovascular mortality in the country.
- <u>Auto crash</u> risk has decreased with the use of seatbelts and airbags, but older drivers have the highest rate of fatal crashes per miles driven even though there are many potential interventions for dealing with this hazard.
- Despite great progress in <u>immunization coverage</u> in the past 20 years, there is only about a 50-percent penetration of immunizations for pneumococcal and influenza vaccines among minority populations.
- <u>Undernutrition</u> explains an enormous amount of morbidity among frail elderly.
- Great progress has been made in <u>cancer</u> prevention among the White male population and in breast cancer for White females, but large disparities in prevention persist.
- Alcohol excess has had little organized attention.
- Oral health care is also a problem when considering undernutrition and social function, yet Medicare does not cover preventative or restorative dental care.
- Osteoporosis has garnered much attention, yet there are >300,000 hip fractures every year.
- <u>Depression</u> is not more likely to occur in older individuals, but when it does occur the consequences tend to be more severe in older adults; depression is also less frequently diagnosed and adequately treated.
- From a risk-reduction perspective, little has been done to deal with the issue of <u>multiple</u> <u>medications</u> and their effect on elder health.
- Sparse <u>social networks</u> have been addressed mainly through funding of senior centers, but there is not a systematic way to reach isolated elders.
- Finally, <u>obesity and metabolic syndrome</u> have had little attention until recently. In western Europe, it is estimated that more than one-third of adults will have metabolic syndrome in the near future, while this is expected to be near 50 percent for the U.S. population.

Besdine offered several criteria for prioritizing interventions, in no particular order:

- Established evidence base for intervention (efficacy)
- Feasibility and sustainability
- Health consequences of the condition targeted

- Number of persons to benefit
- Health status of targeted population at baseline
- Time for effect to occur and the age of intervention
- Fairness
- Opportunity for system change (e.g., including it in the discharge process or process for hospitalization)
- Cost-effectiveness

Participants offered other criteria for prioritizing interventions, including (1) restricting yearly cost per person, (2) requiring delivery by nondoctors, (3) requiring a minimum time for increasing the scale of the intervention if it is successful, (4) packaging the intervention so that it is palatable and sustainable, and (5) simplicity of the trial, which increases the chance of success. Including more people could shorten the length of the trial.

Medicare coverage of several preventative services was enacted only recently in legislation as part of the Balanced Budget Act of 1997 and the Medicare Modernization Act of 2003. One result is that during the "Welcome to Medicare" history and physical, there is a review of risk factors and functional status, counseling on interventions, and certain screenings. Besdine suggested that the first year of Medicare could be used as a delivery arm for any new projects due to the leverage that CMS has in determining what providers do as part of the Medicare visits.

Musgrove noted that many of the criteria for prioritizing interventions addressed by Besdine are not independent. For example, cost-effectiveness analysis depends on having a measure of efficacy. The health consequences of the conditions targeted are relevant, but another question is how much the targeted condition can be improved. The cost-effectiveness could vary depending on how many people benefit. The health status of the population is complicated and related to fairness; should more be done for people who are in better health to start with? Likewise, the amount of time it takes to observe an effect in the population is included in a proper cost-effectiveness analysis, while age matters because it affects the duration of the benefits. Besdine agreed but remarked that the age of intervention is complicated because even a very old individual with a short life expectancy can consume a huge amount of healthcare costs.

Suzman noted impressive multiplier effects from diabetes on the cost of treating other diseases that increase with age: At age 85, costs of hypertension, MI, and stroke were multiplied 7 to 14 times. Diabetes is perhaps one disease that should be targeted. Activities that the BSR Program could consider include treating obese people with a type of PolyPill or interventions that address declines in social networks. Focusing only on the provision of medical healthcare is not within the scope of the BSR Program. Besdine added that CMS could be enticed to mandate which medical provisions could be provided. Suzman welcomed such collaborations and also expressed interest in introducing financial incentives or penalties through contractual agreements to change health behaviors.

Workshop participants suggested a number of other approaches for study consideration:

• Interventions that target metabolic syndrome, inflammatory processes, oxidative processes, and other physiological mechanisms that impact a number of disease

outcomes, although trials for such interventions likely would require longer than a 2- to 3-year period;

- A nutritional drink for frail elderly, noting that undernutrition primarily affects individuals in nursing homes;
- Better drugs for diabetes prevention; and
- Introduction of financial incentives (e.g., good driver discounts).

Haaga added that three Institutes within the NIH have issued a joint program announcement soliciting research on natural and manmade disasters, including heat deaths. The BSR Program would consider an intervention that focuses on this problem in the United States or abroad. French research indicates that the excess mortality caused by unusual heat and social isolation in the month of August is equivalent to pneumonia deaths over the course of an entire winter.

It makes sense to work with already established organizations to uniformly target certain issues in a coordinated way; for example, taking advantage of the 29,000 senior service workers throughout the country as discussed by Whitelaw, or targeting diabetes in Brazil by working through 5,000 municipalities and developing a diabetes register similar to the register that the Brazilian government has established for HIV-positive individuals to provide them with free medication.

One methodological concern about community interventions is that they sometimes do not detect adverse effects as well as do clinical studies. For example, when tobacco education was first introduced into elementary schools, children of smoking parents exhibited mental distress over the fact that their parents smoked.

Suzman would like to involve older workers using a small business incentive model because it is a natural adjunct to the CMS project. Another area to be considered is the mixed generation of outcome measures related to functioning; this is not to condemn ADLs and IADLs to obsolescence but highlights the need for more sensitive measures. Another component is the notion of getting communities to "buy in" on a health promotion, prevention, or disease control program as a demonstration. Suzman contended that the emphasis on cost-effectiveness analysis should be on effectiveness, but the cost issue is important when two interventions are equally effective. The ability to rank interventions according to comparable outcome measure is essential. Multiple-level models have been useful in decomposing variance, but interventions that augment each other at different levels (e.g., at a system level, at a psyche and cognitive level) and would reveal true interactions remain to be developed.

#### Appendix A

#### **FINAL AGENDA**

# Workshop on Identifying New Interventions To Extend Disability Decline in Elderly Populations

National Academies National Research Council Washington, DC 20001

September 14-15, 2006

#### Thursday, September 14, 2006

- 8:30 **Breakfast** (available in meeting room)
- 9:00 Session I: Introduction and Background to the Meeting

#### **Welcome and Introduction**

Michael Feuer, Division of Behavior of Social Sciences and Education, National Research Council

Robert Wallace, University of Iowa (Workshop Chair)

## Sponsor Perspective: The Need for a Rank Ordering of Interventions

Richard Suzman, National Institute on Aging

#### **Setting the Stage for the Meeting**

Robert Wallace, University of Iowa

- Where in the lifespan should preventive interventions for disability begin?
- Primary versus secondary prevention of disability
- Varying definitions and measures of disability
- A draft menu of physical, social, mental, and cognitive interventions
- Targeted populations versus interventions aimed at all elders
- Lead time and expected outcomes of community interventions

#### Cost-Effectiveness: The Disease Control Priority (DCP2) Approach

Philip Musgrove, Health Affairs

# 10:00 Session II: Overview of Community Interventions and Prospects for Interdisciplinary Research

Comparing Population-Level Effects of Disability Interventions Vicki Freedman, University of Medicine and Dentistry of New Jersey

Pathways to Disability

David Cutler, Harvard University

History of Interventions: Lessons From ENRICHD *Lisa Berkman, Harvard University* 

Modeling the Potential for Disability Interventions *Baoping Shang, RAND Corporation* 

Economic Approaches/Social Welfare Interventions That May Prevent Disability Among Older Persons

Robert Schoeni, University of Michigan

Cost-Effectiveness of Potential Interventions To Reduce Disability: A Review *Kenneth Manton, Duke University* 

#### 11:30 **Break**

- 11:45 Group Discussion on the Principles and Direction of Disability Interventions: Perspectives From Various Disciplines (*Discussant: Lynda Powell, Rush University*)
- 12:45 **Lunch**

# 1:45 Session III: Lessons From Environmental and Community-Based Interventions

Interventions in the Home Environment *Thomas Gill, Yale University* 

Interventions To Improve Social Engagement and Function Linda Fried, Johns Hopkins University

The Medicare Senior Risk Reduction Demonstration David Stapleton, Cornell University

- 2:45 Group Discussion of the Top Environmental and Community-Based Interventions *Robert Wallace, University of Iowa*
- 3:30 **Break**
- 4:45 Wrap-Up Comments
- 5:00 Adjourn
- 6:00 Working Dinner

#### Friday, September 15, 2006

- 8:00 **Breakfast** (available in meeting room)
- 8:30 Session IV: Lessons From Clinical and Personal Interventions To Prevent/Mitigate Disability

Pharmaceutical Interventions: The Various Dimensions of the "PolyPill" *K.M. Venkat Narayan, Emory University* 

Exercise and Falls Prevention

Jack Guralnik, National Institute on Aging, National Institutes of Health

Interventions To Mitigate Degenerative Arthritis MaryFran Sowers, University of Michigan

Interventions To Deliver Assistive Technology for Long-Term Care *Emily Agree, Johns Hopkins University* 

- 9:45 General Discussion of Clinical and Personal Interventions (*Discussant: Lois Verbrugge, University of Michigan*)
- 11:00 **Break**
- 11:30 Group Discussion of the Top Clinical and Personal Interventions (*Discussant: Robert Wallace, University of Iowa*)
- 12:30 **Lunch**

# 12:45 Session V: Roundtable on Converging on Candidate Interventions To Decrease Elderly Disability: Bridging the Gap on Interdisciplinary Approaches to Disability Prevention

Low-Cost Effective Interventions James Fries, Stanford University

Scaling Up Interventions

David B. Evans, World Health Organization

Data Needs for Chronic Disease Interventions: Lessons From the Comparative Risk Assessment (CRA) Project and Its U.S. Applications *Majid Ezzati, Harvard University* 

Converging on a Candidate Intervention To Decrease Elder Disability Nancy Whitelaw, National Council on Aging

- How to allocate \$1 million to learn something that will accelerate declining disability on a wide-scale?
- Can we come up with a rank ordering of interventions? Failing that, what would it take to come up with such a ranking?
- 2:00 Guided Discussion (Discussant: Richard Besdine, Brown University)
- 3:00 **Wrap-Up Comments** *Robert Wallace, University of Iowa*
- 4:30 Adjourn

#### Appendix B

# **Participant Roster**

Workshop on Identifying New Interventions To Extend Disability

Decline in Elderly Populations

September 14–15, 2006

## **Presenters and Discussants**

#### **Robert B. Wallace (Chair)**

Professor of Epidemiology and Internal Medicine Department of Epidemiology University of Iowa

#### **Emily Agree**

Director, Hopkins Population Center Associate Professor, Population and Family Heath Sciences Johns Hopkins Bloomberg School of Public Health

#### Susan M. Allen

Associate Professor of Community Health and Sociology Deputy Director, Center for Gerontology and Health Care Research Brown University

#### Lisa Berkman

Thomas D. Cabot Professor of Public Policy Departments of Society, Human Development, and Health and Epidemiology Harvard School of Public Health

#### Richard W. Besdine

Professor of Medicine Director, Center for Gerontology and Healthcare Research Brown Medical School

#### **David Cutler**

Otto Eckstein Professor of Applied Economics and Dean for the Social Sciences Kennedy School of Government Harvard University

#### David B. Evans

Director, Department of Health Systems Financing World Health Organization

#### Majid Ezzati

Associate Professor of International Health Department of Population and International Health Harvard School of Public Health

#### Vicki A. Freedman

Professor, Department of Health Systems and Policy University of Medicine and Dentistry of New Jersey

#### Linda P. Fried

Professor and Director, Center on Aging and Health Johns Hopkins Medical Institute

#### James F. Fries

Professor of Medicine Stanford University

#### Thomas M. Gill

Professor of Medicine, Epidemiology & Public Health Yale University School of Medicine

#### Jack M. Guralnik

Acting Chief Epidemiology, Demography, and Biometry Program National Institute on Aging

#### Kenneth G. Manton

Center for Demographic Studies Duke University

#### **Philip Musgrove**

Deputy Editor, Health Affairs

#### Lynda H. Powell

Professor and Acting Chair Department of Preventative Medicine Rush University Medical Center

#### Robert F. Schoeni

Associate Professor Institute for Social Research University of Michigan

#### **Baoping Shang**

Fellow RAND Corporation

#### **MaryFran Sowers**

Professor of Epidemiology University of Michigan

#### **David Stapleton**

Director, Cornell Center for Policy Research Cornell University Institute for Policy Research

#### Kabayam M. Venkat Narayan

Hubert Professor of Global Health and Epidemiology The Rollins School of Public Health Emory University

#### Lois M. Verbrugge

Research Professor Emerita University of Michigan

#### **Nancy Whitelaw**

Director, Center for Healthy Aging National Council on Aging

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