### PREVENTION RESEARCH: THE CENTER FOR HEALTHY AGING DEMONSTRATION PROJECT

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University of Pittsburgh, 2008

The number of Americans over 65 years of age has increased rapidly in recent years. This population of older Americans will increase even more as the Baby Boomers begin reaching 65 in the year 2010. One of the greatest challenges in public health today is the increasing number of older adults who suffer disproportionately from chronic diseases and disability. Chronic diseases can be addressed by modifying risk factors and are not an inevitable consequence of aging. There is a great need to design community based multiple risk factor interventions that emphasize disease prevention.

The Center for Healthy Aging recruited a population of healthy, at risk, older adults in southwestern Pennsylvania for a randomized community based intervention program. The program targeted adults aged ≥65, based upon "10 Keys"<sup>TM</sup> to Healthy Aging. The intervention evaluated (1) Brief Education and Counseling Intervention or (2) Brief Education and Counseling Intervention plus a Physical Activity and Dietary intervention for individuals with hypertension. Recruitment strategies included a direct mail campaign using voter registration lists and telephone follow-up. Health assessment data was collected at six month intervals through 24 month follow-up. Health behavior counseling and the Prevention in Practice Report were provided to participants in both programs as tools to advocate behavior change.

A total of 951 households responded (8.2% response rate) and 541 participants from 444 households were randomized. After 24 months adherence to the "10 Keys" improved

significantly in a number of areas. There was, however, no difference between the two groups in physical activity or changes in performance based measures related to physical activity.

This prevention program resulted in significant reduction in key risk factors, immunization and screening over 2 years to established prevention guidelines for older adults. Further public health research is needed on the use of health advisors/health counselors to maximize public health prevention in individuals over 65. Empowering individuals regarding their own risk factor status for screenings, immunizations, and lifestyle changes could successfully impact the quality of health in community settings.

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#### 1.0 INTRODUCTION

#### 1.1 OLDER ADULT PREVENTION RESEARCH

At the turn of the twentieth century 40% of the United States population was under the age of eighteen, with only 4% of the population aged 65 or older. This was a time when public health focused mostly on sanitation conditions and control of infectious diseases. Since then the field of public health has experienced changes that impact the health and well-being of society.

We have seen an epidemiologic transition from infectious diseases like pneumonia, influenza and tuberculosis to chronic diseases such as heart disease, cancer and stroke [1-3]. With this shift there has been a steady older adult population growth. Currently the 65 and older population comprise 12% of the U.S. population, with over 80% of them having one or more chronic conditions or diseases [2, 3].

As modern medicine becomes more expensive and continues to exacerbate health care resources, the public health field is transitioning to the need to prevent disease. The number of older adults continues to rise rapidly and statistics show that this trend will continue. This population is expected to double to approximately 72 million by 2030, making older adults nearly 20% of the entire United States population [2, 3]. There is an increased emphasis on decreasing the risk for chronic diseases and maintaining a higher quality of life with functional independence.

Given these trends this paper will review the history of "prevention" and the shift towards preventive research initiatives. Also, this paper will describe selective prevention research efforts that focus on the older adult. The future of prevention research will be addressed at the end.

#### 1.2 HISTORY OF PREVENTION

The meaning of "Prevention" is not a new theory and can be traced back to ancient times. When you examine customs, culture and religions from the past, prevention was recorded in most societies. Health and illness have played an integral role throughout history to mold behavior(s) to prevent harm and protect the health of people. The use of amulets, dietary restrictions and rituals surrounded health maintenance and protected against "evil spirits". These practices and behaviors range from adding salt to water after working in the fields to isolating the sick [4].

As early as 1850, Lemuel Shattuck discussed the importance of prevention to the Massachusetts legislature and advocated a "comprehensive plan of sanitary reform by which the greatest possible amount of physical suffering may be prevented, and the greatest possible amount of physical, social and moral enjoyment may be attained". Subsequently this legislature created boards of health with the responsibility for prevention and quarantine [5, 6].

During the late 19<sup>th</sup> century, various health movements spread across the United States and organizations such as the American Public Health Association (1872), the American Red Cross (1882) and the American Tuberculosis Association (1904) were established. In 1920, William Welch of Johns Hopkins proclaimed to a group of philanthropists that "merely from a

mercenary and commercial point of view it is for the interest of the community to take care of the health of the poor. Philanthropy assumes a totally different aspect in the eyes of the world when it is able to demonstrate that it pays to keep people healthy" [5, 7]. It has been said that this speech mobilized efforts for disease prevention and health promotion; fundraising for academic health centers, and research studying the cost-effectiveness of public health campaigns.

The development of academic centers that trained practitioners to develop a scientific base for public health practice also contributed to the recognition of prevention as a health priority [5]. In the early 1940's the American Medical Association and the American Public Health Association were initiated. Several years later the Centers for Disease Control and Prevention was established [8]. The next few decades were consumed by disturbing trends in chronic diseases. Subsequently efforts shifted once again toward the need for prevention.

In the 1980's the United States Congress passed legislation that created a national network of Health Promotion and Disease Prevention Research Centers (PRC) Programs at various institutions. This network has grown to 33 centers throughout the country. Each center collaborates with their local communities to develop, implement, and evaluate research activities. In 1997 an independent assessment completed by the Institute of Medicine (IOM), concluded that over the 10 year period, substantial progress in disease prevention and health promotion policy, programs, and practices was evident [9].

I like this elegant quote by Charles C. Colton regarding perception of health.

"There is a difference between the two temporal blessings—health and money; money is the most envied, but the least enjoyed; health is the most enjoyed,

but the least envied; and this superiority of the latter is still more obvious when we reflect that the poorest man would not part with health for money, but that the riches would gladly part will all his money for health" [10].

#### 1.3 PREVENTION RESEARCH

Traditional medical care that once focused on disease treatment has recognized the need to include prevention. This expansion prompted the need to broaden the delivery of service, the mechanism for payment, and revisions in the education of health prevention. At the close of the 20<sup>th</sup> Century, public health services began to deviate from traditional clinical medical practice, and private health insurance evolved [5, 11]. Unfortunately some often did not include preventive services. In the last few decades, governmental health agencies intervened and accepted some responsibility for preventive services [5]. Many medical schools now include prevention in their curriculums. The gap between public health practice and clinical medicine has been narrowing. This trend is largely due to increases in the older adult population, especially 75+; increases in preventable diseases; and recent success in converting public health research into practice [5].

Considering this tremendous improvement in technology and disease treatment, it is humbling to remind our self that over one million preventable deaths occur each year in the United States. Analysis completed by the Centers for Disease Control and Prevention showed that 50% of these deaths are related to behavioral functions, 20% environmental causes, 20% primarily biological and genetic factors, and 10% inadequate health care [4].

Disturbing trends in chronic disease rates are affecting virtually every age group and prevention is heralded as a reversible antidote. Numerous studies have been undertaken to demonstrate the positive impact of prevention. The Chronic Disease Self Management Program (CDSMP) is one such program. After only two years, conservative estimate reported cost savings of \$590 per participant due to reduced utilization costs. The total cost of sustaining the program was estimated at \$70-\$200 per participant depending on the demographics of the community [12].

Researchers must ask tough questions to determine whether interventions are cost effective and significant to justify continuation of the program. There is a wide range of perceptions/concepts that encompass numerous definitions of prevention research depending on discipline and/or field. According to the National Institutes of Health (NIH) the general concept is the "prevention of disease and disability and preservation of health that are endorsed by the public, health care providers, and researchers" [13].

The NIH's relevant research definition states "prevention research includes research with a high probability of yielding results that will likely be applicable to disease prevention or health promotion, including studies aimed at elucidating the chain of causation, the etiology and mechanisms of acute and chronic diseases. Such basic research efforts generate the fundamental knowledge that contributes to the development of future preventive interventions" [13].

The main components of prevention research according to the NIH are;

- 1. Investigation of the factors that place individuals and groups at risk of disease and disability.
- 2. Trials of the interventions that can modify this risk.
- 3. Testing the approaches that can effectively implement beneficial changes [13].

Whatever definition is accepted most agree that prevention research is multidimensional and should include both applied and community based research. While most health related research can be included in "prevention research" there are drastic differences in how each program targets the prevention method, objectives for each program and the level of prevention vary widely [14].

The three main levels of prevention are;

- 1. Primary prevention—measures taken to prevent the onset of a specific disease or condition in individuals. Primary prevention examples includes passive and active immunization, health education and counseling for the use of bicycle helmets and seatbelts in automobiles [15].
- 2. Secondary prevention—identifies at risk populations who are asymptomatic of disease but have developed risk factors for the disease. Secondary prevention examples include screening tests for cancer, high blood pressure and high cholesterol [15].
- 3. Tertiary Prevention—focuses on high risk populations that have established disease or condition and attempt to prevent complications and restore complete function. Tertiary prevention examples include surgery after a heart attack or rehabilitation after a stroke [15].

According to Scrimshaw [4] there are four key characteristics that are used to describe public health prevention research.

- 1. Preventing disease and promoting health
- 2. Solution-oriented research
- 3. Multi-disciplinary
- 4. Population based.

Projects and programs following these characteristics can now be classified under the public health prevention research umbrella. This will ensure increased funding opportunities for prevention research. It will allow researchers to identify gaps in the translation from research and practice and increase the rate at which information is disseminated to the public.

In 1988 the United States spent over 30 billion dollars towards prevention of disease, sounds like a lot, but when compared to the entire gross national product it only accounted for 0.7%. It is generally accepted that 95% of health care costs in the United States go to direct medical services. From 2002-2004, over 86% of our nations health care dollar approximately \$1.66-1.80 trillion dollars was consumed by the costs of the personal health system, designed for alleviating pain and suffering, curing disease after it has become manifest. Chronic diseases, the most common and costly of preventable health problems, account for ~75% of these health care costs each year. Although preventable the national expenditure for prevention research and prevention activities is insignificantly low [5, 16-18].

According to Dr. Lewis Kuller, a professor at the University Of Pittsburgh Graduate School Of Public Health, "prevention of disease is the only method to substantially reduce morbidity and mortality in a population".

To effectively reduce the soaring increases in national health care costs, prevention programs that combine community-based services, clinical services, and social policies must become more widely supported [19].

The cost effectiveness of prevention varies tremendously. Prevention research explores how effective prevention can be, how prevalent is the condition or disease to be prevented, what the prevention programs cost in dollars per life saved, years of life or quality-adjusted life added, and to what extent disability is averted. An example of one of the most cost effective public health campaigns is smoking cessation/prevention. Anti-smoking initiatives over the past several years have dramatically reduced the prevalence of smoking in the United States. The decline is due to health education and health promotion activities conducted by public health agencies, private organizations, schools, hospitals, work sites, and private medical practitioners, as well as tax increases on cigarettes and restrictions on smoking [5].

#### 1.3.1 Role of Public Health Professionals:

Public health professionals possess knowledge and skills needed to address complex needs of specific groups, communities, and/or the entire population [20]. This knowledge and specific skills allows the use of a transdiciplinary approach to better develop, implement, sustain, and evaluate preventative health initiatives.

This section will explore the knowledge and skills health professionals employ to promote and disseminate health behavior changes at the community level.

Public health professionals are at the forefront for disease prevention and health promotion in older adult populations. These professionals have educational training in

epidemiologic trends, evidence based research findings, research methodologies, and valid data collection techniques [21]. This knowledge enhances trust, community collaboration, ability to assess and identify health needs, design (develop), implement, and evaluate effectiveness to increase sustainability and advocacy for health initiatives. This prior knowledge requires the following skills that have been developed through training and education, to increase the health and well being of the community.

- 1. Ability to affectively communicate; using different communication techniques such as informing, influencing, and motivating, professionals are able to illicit positive behavioral change over time.
- 2. Ability to engage diverse populations in disease prevention and health promotion initiatives. With increased communication and collaboration with community partners, this allows efforts to target specific populations and also reduce duplication of health services.
- 3. Ability for ethical decision making with the focus on the health of the public. According to Rogers there are eight values of importance when making decisions regarding community based participatory research. These eight values listed below can increase the success and longevity of the program because community members will see it as benefiting relationship over time as opposed to the sense of urgency for program transition [22].
  - 1. Open, honest, transparent
  - 2. Democratic, consensual
  - 3. Inclusive, consultative
  - 4. Rational, deliberative, systematic
  - 5. Evidence based
  - 6. Weighing costs and benefits, affordable
  - 7. Respectful
  - 8. Mindful of equality

4. Ability to evaluate outcomes data for purposes of sustaining and/or redesigning health initiatives. One fundamental way public health professionals are able to benefit the community at large is by having a well thought out framework which allows increased collaboration among partners and helps accelerate research to practice [23-29]. Also health professionals have the know how to campaign for policy change even when faced with resistance by special interests i.e. insurance companies, privately funded organizations.

#### 1.3.2 Prevention Research Strategies:

Presently there is not a "gold standard" for examining evidence based quality for prevention research programs. The type of research, the proposed hypothesis, the population of interest, the type of strategy used, and the phase of prevention targeted, all play a key role in how prevention research programs are evaluated.

To fully understand prevention research strategies we must first realize that it is multidimensional and multidisciplinary [14, 30] (Figure 1.1). The following will discuss 5 themes to ensure the proper research strategy is being used [30]. The themes are as follows:

#### 1. Three major prevention research strategies

- i. Directed at strengthening individuals
- ii. Directed at strengthening smaller social groups
  - 1. Family
  - 2. Class-rooms
  - 3. Peer groups
- iii. Directed at strengthening the larger social environment
  - 1. Cities
  - 2. States
  - 3. National policies

#### 2. Prevention research must be evidence based.

i. Each phase of prevention research examines "evidence" differently

- 3. Prevention research must have economic analysis as a central part.
- 4. Collaboration is a must.
- 5. Multidimensional acceptance based on "evidence" is a must [30].

#### 1. Three major prevention research strategies:

- 1.1 Directed at strengthening individuals
- 1.2 Directed at strengthening smaller social groups
- 1.3 Directed at strengthening the large social environment.

The previous prevention research strategies focus on directing efforts into different segments of the population based on level of risk for the disease. Some research examines the individual, entire population, and then smaller subpopulations at higher risk are evaluated. Then even smaller subpopulations at the highest risk are extracted. Understanding the contributions of these three strategies allows researchers to advance prevention science by building the evidence based strategies to decrease targeted risk factors [30, 31].

#### 2. Prevention research must be evidence based:

The reasoning is our present meaning of "evidence", researchers have to look at efficacy, effectiveness, and sustainability of programs, this causes a focus on a specific population do to monies allocated in that area [30, 31]. With the many different types and phases of prevention research, the word "evidence" has its own set of rules depending on the phase and rigorous prevention research. The following examples clarify the different phases of evidence based trials.

- 2.1 Efficacy trials (phase 1) test whether the proposed program works under optimal community conditions. This phase uses highly trained professionals and regulates conditions so the cleanest data are collected. By allowing minimal variation during data collection the possibility of happening by chance decreases.
- 2.2 Effectiveness trials (phase 2) take the program one step further and test whether the intervention will produce the same results when applied to real world conditions, this trial examines the cost effectiveness of the trial. Interventionists are trained to implement the program, and the quality of the implementation affects the analysis and the impact the intervention has in the real world. Variation is expected during this phase. But can be utilized to make inferences to how much variation may occur and still result in statistically significant results. This phase is also done for longer periods of time, which allows researchers to test long term impact.
- 2.3. Sustainability trials (phase 3) are implemented to examine what type of support the program will need from a social standpoint. This phase also utilizes the support for training and mentoring to maintain the highest quality during implementation across cohorts. Researchers during this phase are tracking the interventionists from different cohorts rather than tracking participants over time like the effectiveness trial. The researchers are able to draw more accurate conclusions of how to maintain the highest quality practice by testing different models with different social and political structure. Researchers are then able to see which model is most effective for sustaining high quality implementation.
- 2.4 Going to scale trials (phase 4) test the program using a broader scale to evaluate how the cost of the program changes depending on operations to become

community based or institution based. The intervention is taken system wide and the methods and support are designed and once again tested. This phase allows researchers to focus on the operations of the model to answer specific questions.

2.5 Sustainability system wide trials (phase 5) examine the program models, once it is considered good enough, and how well the program is able to maintain "good practice" standards over time. Specific questions pertaining to evaluation of the program are answered during this phase.

What kind of monitoring is most useful?

What kind of continued mentoring is necessary?

Who should conduct this mentoring? Etc. [14, 30].

Currently the progress of prevention research has greatly improved in the first two phases; efficacy and effectiveness, but still lacks the next three phases (Figure 1.2). With politics playing a crucial role in the refunding process, leading to sustainability of a program, collaboration is ever more important to maintain monies. In the past few years there have been some improvement in federal funding so programs don't have to stop short and can complete all phases. Using the phases as a cyclical process allows for future programs to learn from past problems and redesign for future endeavors [14, 30].

#### 3. Prevention research must have economic analysis as a central part:

If prevention research is going to work as a whole, economic analysis must be used to ensure that policy and the decision making process is focusing on the long term benefits of the program rather than immediate outcomes.

Cost effective studies can be used to help develop strategies for decision making when implementing various phases of the program. They are also used to assess the impact the program is having, by evaluating projected long term benefits compared to the absence of the program.

Specific questions need to be addressed before program effectiveness should be judged.

What are the costs of the prevention program in dollars? How does the cost of the new program compare to the cost of the current program?

What are the long term benefits of conducting the program compared to not conducting? [30].

Economic analysis for prevention research is in dire need of developing scientific methods. This would allow calculating costs fairly and straightforward, allowing the differentiation between cost benefit. Funding agencies now have a broader illustration and help utilize and allocate the small amounts of federal prevention grants more strategically and fairly [18, 30, 32-36]. This paper respects the importance of this ever growing topic, but due to the extreme complexity there will be no further discussion.

#### 4. Collaboration is a must:

Collaboration is the strength and backbone of any public health program. Collaboration consists of other researchers, government leaders (local, state and federal), community leaders and institutional leaders. This enables the program to become broader with respect to ownership and helps with easing the research process as well as sustaining the future of the program. Collaborations also help to ensure the necessary cultural adaptations are taking place to help the decision making process and implementation by respecting the actual needs and realities of the community and political environment [14, 30, 31]. Multidisciplinary collaborations allow for a more holistic view of prevention research and the available expertise allows for multiple

outcomes to be measured across studies [37]. This increases the turnaround time for evaluating strategies for interventions. Dissemination of these findings can then be introduced to communities more efficiently and effectively to improve health on a larger scale as opposed to single disease interventions which target specific populations and limit the dissemination possibilities.

#### 5. Multidimensional acceptance based on "evidence" is a must:

Diverse participant engagement in the program allows the framework of the program to grow and advances the process of debate, correction, and implementation to further advance the program. All disciplines are needed in this process to ensure the efficacy and sustainability. Prevention researchers, administrators, practitioners, community leaders and the participants themselves ensure the experience necessary to guide the research [14, 30, 31]. The formation of boards is useful in this situation. Boards allow a multitude of disciplines to come together and discuss the future direction of the program in an organized fashion. By utilizing the knowledge gained from these collaborations the better the quality of prevention research is conducted and disseminated to communities.

Dr. Blumenthal from the Morehouse School of Medicine Prevention Research Center emphasizes the importance of community collaborations to drive the research to reflect and address community concerns and needs. Blumenthal stresses the importance of the board as governance rather than an advisory capacity so the partnership can design and agree on a set of research priorities. The board was given the governance as opposed to advisory power, because the term advisory implies powerlessness, and an equal partnership is needed to improve the publics' welfare [38].

By focusing on the following 10 values, researchers will be able to apply and conduct community based participatory research more efficiently and effectively and increase the likelihood for reproducible results in diverse communities [38].

1. Policies and programs should be based on mutual respect and justice for all people, free from any form of discrimination or bias [38].

Designing programs that are based upon mutual respect is the fundamental ground rule that all prevention research centers address. This diminishes the exploitative and discriminatory experiences that minority populations have experienced in the past.

2. All people have a right to political, economic, cultural, and environmental self-determination [38].

This value is specifically related to utilizing the community to decide where the research office(s) should be located. By doing so this increases self determination by the community members.

3. The community has the right to participate as an equal partner at every level of decision making, including needs assessment, planning, implementation, enforcement, and evaluation [38].

By allowing the community members to serve as equal members and protect their own interests. There are limitations to how this value will function such as resource limitations will restrict certain decisions by the community members.

4. Principles of individual and community informed consent should be strictly enforced [38, 39].

Ensuring the community members along with the assistance of a trusted professional time to review all research protocols and recommend changes to better

address community concerns will help decrease issues when obtaining individual and community consent. Community consent is the community board collectively acting on behalf of the community to provide consent to serve collectively as the participant of the large prevention program.

5. The community repudiates the targeting of people of color and lower socioeconomic status for the purpose of testing reproductive and medical procedures and vaccinations [38].

By collaborating with the community the perception of "dangerous procedures" will be decreased. Historically, dangerous procedures, vaccines, and contraceptives have been tested on minority populations without adequate informed consent [40-42]. To date none of the prevention research projects has proposed to test reproductive, medical procedures, or vaccines.

- 6. Present and future generations should be provided an education that emphasizes social and environmental issues, based on our experience and an appreciation of our diverse cultural perspectives [38]. The emphasis on education is relevant for all health promotion research. The intervention project should be designed to be culturally sensitive.
- 7. Research processes and outcomes should benefit the community.

Community members should be hired and trained whenever possible and appropriate and the research should help build and enhance community assets [38].

Researchers need to remember that the community's most immediate needs are for services and jobs, not research. Focusing on the latter will increase the potential for the project to benefit the community by hiring staff members from within the community.

8. Community members should be part of the analysis and interpretation of data and should have input into how the results are distributed [38].
This does not imply censorship of data or of publication, but rather the opportunity to make clear the community's views about the interpretation prior to final publication. The tendency is for researchers to describe low-income communities with negative terms. Utilizing community member input will help to

decrease the use of these negative terms. In time this will help to decrease the

existing community perception of negativity by researchers.

- 9. Productive partnerships between researchers and community members should be encouraged to last beyond the life of the project [38].
  - This will make it more likely that research findings will be incorporated into ongoing community programs and therefore provide the greatest possible benefit to the community from research.
- 10. Community members should be empowered to initiate their own research projects that address needs they identify themselves [38].

Researchers should empower and encourage community members to apply for grants that focus on community needs. Project ideas do not have to be researched based, but rather service based which will immediately benefit the community. Researchers can help by providing their expertise in areas such as grant writing workshops.

#### 1.3.3 Prevention Research Programs and Initiatives for Older Adults:

Health promotion and disease prevention programs are becoming more and more prevalent in communities because of the growth and projected growth of the older adult

population. Poor health was previously thought of as the normal aging process, but years of credible research has showed health does not have to diminish and be an inevitable consequence of growing older. The Centers for Disease Control and Prevention Research Centers Healthy Aging Research Network (CDC-PRC-HAN) forms the backbone for developing and conducting prevention research to meet the needs of the older adult population. The CDC-PRC-HAN network comprises of 9 universities under the umbrella of the 33 prevention research centers. This network of researchers focuses on increasing the health of older adults in the community (Figure 1.3) [43].

Externally the CDC collaborates with other agencies such as the U.S. Administration on Aging (AoA), American Association of Retired Persons (AARP), the National Institute on Aging (NIA), the American Society on Aging (ASA), the National Council on the Aging (NCOA), the National Association of State Units on Aging (NASUA), and the National Association of Area Agencies on Aging (NAoAAA). All of these agencies work to promote health and well being among older adults through community based programs across the United States [44]. Presently the NCOA in partnership with the CDC has designed the National Program to Promote Healthy Aging through Community Programs. This program has established a National Advisory Committee which will examine and evaluate 630 community based programs around the United States focusing on older adult health and supportive programs. The committee will identify examples of promising programs to allow the development of guidelines for the purposes of replication and implementation of these programs in different communities through out the United States [45, 46]. The majority of the 630 community based programs are funded through the State-Based Examples of Network Innovation, Opportunity, and Replication (SENIOR) Grants. These projects will be funded for one year as demonstration projects [46]. The

supporting partnerships aim is to implement disease prevention and health promotion programs in the areas of physical activity, preventive services, disease self management, and oral health assessment and promotion.

The following (table 1.1) describes programs that represent the latest best practice prevention programs funded by the CDC through their vast collaboration network.

#### Table 1.1

Program Name Racial and Ethnic Approaches to Community Health (REACH) Program Description
Racial and Ethnic Approaches to Community
Health (REACH) programs were established
in 1999. To date REACH has forty programs
around the United States focusing on
eliminating health disparities in racial and
ethnic communities. REACH programs are
composed of a central community based
organization which collaborates with at least
three other organizations. REACH has
focused on the following objectives.

- ✓ Empowering community members to seek better health.
- ✓ Bridging gaps between the health care system and the community by encouraging residents to seek appropriate care and by changing local health care practices.
- Changing local social and physical environments to overcome barriers to good health.
- Mobilizing to implement evidencebased public health programs that fit their unique social, political, economic, and cultural circumstances.
- Moving beyond interventions that address individual behavior to the systematic study of community and systems change.

Figures 1.4 and 1.5 focus on REACH funded sites across the country and data showing the effectiveness for the program through the REACH Risk Factor Survey

Program Funding Centers for Disease Control and Prevention [46-48]

#### Table 1.1 continued

Racial and Ethnic Adult Disparities Multi-centered demonstration project Centers for Disease Control and Immunization Initiative (READII) focusing on understanding and increasing Prevention [44, 46] vaccination rates in older adult African American and Hispanic communities. Presently this program is offered in Chicago IL, Rochester NY, San Antonio TX, Milwaukee WS, and 19 counties in the Mississippi Delta region. READII sites have multiple collaborations with public health practitioners, medical providers, and community organizations. The goal of the program is to develop scientifically based creative interventions to increase immunization levels. Interventions focus on non-traditional and traditional approaches. Sickness Prevention Achieved through Regional SPARC was established in 1994 and is Centers for Disease Control and Collaboration (SPARC) designed as a service program to effectively Prevention [44-46, 49] organize and enhance communication bridges between healthcare, public health, and aging and social services networks. SPARC has four well established sites strategically placed throughout the New England states. Over the years SPARC, has established local accountability and successful coordination strategies for implementing prevention services. SPARC's success has been documented using evaluation methods designed and implemented by the CDC. Flying Sparks—University of Alabama at Flying Sparks is an intervention focusing on Centers for Disease Control and Birmingham: Center for Health Promotion African American residents in 20 Alabama Prevention 2004-2009 [50] communities in the "Black Belt". Goals are to reduce diabetes, cancer, and CHD with the help from community health advisors (CHAs) and community tool boxes (health promotion instructions and materials). Internet-Based Smoking Cessation Intervention This intervention uses the internet to recruit Centers for Disease Control and for Korean-American Men- University of and randomly assign to one of two self-help Prevention 2004-2009 [50] California at Berkeley: Center for Family and quit smoking internet programs. Primary goals are to explore the process used to quit Community Health smoking and which program is most effective. Korean-American Community Health in Using surveys to identify health issues in the Centers for Disease Control and California- University of California at Berkeley: Korean-American population focusing on Prevention 2004-2009 [50] Center for Family and Community Health eating patterns, physical activity, tobacco use, medical conditions, medical insurance, use of health care services and participation in cancer prevention screenings. The centers advisory board has established health priorities the Korean American community will focus on. Preventing Cancer through Environmental Conducting cancer prevention research in Centers for Disease Control and southwest Georgia. Researchers and Prevention 2004-2009 [50] Changes-Emory University: Prevention Research Center community collaborators are trying to identify key environmental changes to reduce cancer risk and improve health of all residents.

Making the Connection: Healthy Living Program- University of Illinois at Chicago: Illinois Prevention Research Center

Training Community-Based Organizations to Promote Physical Activity and Nutrition-University of Iowa: Prevention Research Center

Prevention and Early Detection of colorectal Cancer in Appalachian Kentucky- University of Kentucky: Prevention Research Center

Increasing Physical Activity in Rural Communities- State University of New York at Albany: Prevention Research Center

Community Ambassador Program- University of Pittsburgh: Center for Healthy Aging

Coalition Efforts to Prevent Chronic Diseases-Saint Louis University: Prevention Research Center Based in Chicago's Greater Lawn community and focuses on increasing physical activity, overweight/obesity, and diabetes. This program is using the evidence based Diabetes Prevention Program (DPP) intervention by training lay health advisors (LHAs). The program is offered in English and Spanish in various community settings. This training program focuses on decreasing obesity and overweight rates by implementing a community based intervention utilizing local organizations. The Intervention encompasses residents, restaurant and grocery store owners, local leaders and government officials to help decrease barriers for physical activity and healthy eating.

This program is divided into two trials. Trial one will try to increase community awareness for colorectal cancer screenings through the local media. Trial two will educate primary care providers about colorectal screening through counseling and referrals for patients.

Researchers have designed the program to decrease barriers for physical activity. This program encourages walking for physical activity throughout the year by utilizing local organizations and facilities.

The training program is a certificate course for individuals who want to help promote and support healthy aging in their communities. Volunteers promote disease prevention through early screening and detection, control of risk factors, and the promotion of safety and independence based on the "10 Keys to Healthy Aging". Ambassadors assist in the dissemination process by educating their community as part of the continuum of care management for seniors, supplementing but not replacing the current medical care system in the community.

Program is designed to decrease risk for chronic diseases for all residents in underserved rural areas in Missouri. The center collaborates with the Department of Health and local advisory committees in 12 established communities.

Centers for Disease Control and Prevention 2004-2009 [50]

Changing Policies and Environmental Conditions to Promote Physical Activity-University of South Carolina: Prevention Research Center

Increasing Physical Activity Through Environmental changes- Tulane University: Prevention Research Center

Physical Activity for Lifetime Success (PALS)-University of Washington: Health Promotion Research Center

Collaboration and Teamwork to Reduce the Effects of Diabetes- Yale University: Yale University-Griffin Hospital Prevention Research Center

Tribal Vision Impairment Prevention Project-Oregon Health and Science University: Center for Healthy Native Communities

Using Clinical and Community Guidelines to Improve the Health of Rural and Underserved Populations- Texas A&M University System Health Science Center: Center for Community Health Development

Fit and Strong! University of Chicago University of North Carolina West Virginia University

Matter of Balance (MOB)- Roybal Center for Late-Life Function, Boston University

EnhanceFitness (EF)- University of Washington Health Promotion Research Center

Researchers are collaboratively working to design strategies to promote physical activity. The coalition focuses on community education, policy and media advocacy, community improvement projects, and partnership development. The coalition is helping the community to obtain grants to improve physical activity programs.

The center is training lay health ambassadors (LHAs) to lead health education programs, recreational activities, and conduct assessments of low income neighborhoods. Researchers are interested in physical activity levels, environmental factors, and social factors that promote increased physical activity.

PALS focuses on increasing physical activity in ethnically diverse older adults in King County Seattle. Health education counseling is provided and tailored for each patient. Objectives are to decrease diabetes, CHD, and minor depression.

The program is developing strategies to reduce the risk of diabetes and prevent complications in low income African American residents. Using community health advisors (CHAs) to disseminate health education materials in faith based organizations is a primary goal.

The center works in collaboration with the Tribal Community Advisory Council, the Northwest Portland Area Indian Health Board, and the Devers Eye Institute to increase residents access to eye care and decrease visual eye impairments do to complications from diabetes.

The program utilizes published guidelines for diabetes. Goals are to prevent, screen for, diagnose and treat diabetes to prevent future complications for underserved minority residents in rural communities.

The program is designed to increase physical activity/behavior change in older adults with osteoarthritis of the lower extremities.

The program focuses on reducing the fear of falling and increasing activity level in older adults. Program classes are taught by volunteer lay leaders "coaches".

The program offers classes taught by certified fitness instructors. The classes focus on stretching, flexibility, balance, low-impact aerobics, and strength training to help decrease functional disability and increase independence in older adults

Centers for Disease Control and Prevention 2004-2009 [50]

Centers for Disease Control and Prevention [51]

National Institute on Aging, Centers for Disease Control and Prevention [51]

Centers for Disease Control and Prevention [51]

Active for Life- Texas A&M University Health Science Center School of Rural Public Health

Healthy Moves for Aging Well- National Counsel on Aging

Healthy IDEAS for a Better Life- National Counsel on Aging

Healthy Changes- National Counsel on Aging

Healthy Eating for Successful Living- National Counsel on Aging

Evidence Based Prevention Program for Bexar County- Alamo Area Council of Governments, San Antonio, TX

Women Take PRIDE (Problem Identification, Researching one's routine, Identifying a management goal, Developing a plan, Expressing one's reaction/establishing rewards for making process in Managing Heart Disease-Senior Service Centers of the Albany, NY area

Healthy Eating for Successful Living in Older Adults- Montachusett Opportunity Council

Telephone based counseling program that aims to increase physical activity in midlife and older adults through local organizations Designed to increase physical activity and improve physical fitness through the use of care managers and volunteer coaches. The program targets frail, homebound, low-income older adults

IDEAS- Identifying Depression, Empowering Activities for Seniors. The program detects and reduces the severity of depressive symptoms of older homebound adults. The program utilizes screening and assessment, education, referral, and behavioral action to decrease depressive symptoms

Diabetes self-management program for older adults that focuses on nutrition and physical activity. Trained volunteers conduct weekly meetings with nutrition and exercise components.

The program is designed to increase nutrition self-management to enhance heart and bone health. Participants increase knowledge in "how to" set goals, solve problems, and utilize available community resources

Community based intervention, designed to prevent or delay Type 2 diabetes in Hispanic older adults. Program focuses on nutrition education and physical activity programs. The intervention is replicated from the Diabetes Prevention Program.

Community based intervention which focuses on women aged 60+ who have CHD. The four week program is education and behavior modification driven. The intervention is based upon the original research of "Women Take Pride" on physical functioning, symptom experience, and psychosocial status.

Works with older adults to develop positive nutrition strategies, which are education and management based. Stresses heart and bone health to decrease chronic disease disability. Based upon the NCOA model, Healthy Eating for Successful Living in Older Adults.

Robert Wood Johnson Foundation [51]

John A. Hartford Foundation through the National Counsel on Aging, Center for Healthy Aging [52]

John A. Hartford Foundation through the National Counsel on Aging, Center for Healthy Aging [52]

John A. Hartford Foundation through the National Counsel on Aging, Center for Healthy Aging [52]

John A. Hartford Foundation through the National Counsel on Aging, Center for Healthy Aging [52]

Administration on Aging [53, 54]

Administration on Aging [53, 55]

Administration on Aging [52, 53]

Healthy Changes: A Community-Based Self-Type 2 Diabetes self management program Administration on Aging Management Program for Older Adults with uses volunteers to provide one on one [12, 53, 56] Type 2 Diabetes- Elders in Action, Portland, OR counseling to participants to identify explore locate problems, solutions. resources, and communicate with health care providers. Primarily based upon the Chronic Self-management Disease Program developed by Stanford University. Increasing Physical Activity for Sedentary Designed to increase physical activity by Administration on Aging providing weekly one-hour behavior change Older Adults in Los Angeles- City of LA [53, 57, 58] instruction along with a 90 minute light to Department of Aging, CA moderate physical activity class offered at the local OASIS center. Program is based upon work conducted at the Cooper Institute along with the "Stages of Change" model. Preventive Nutrition Cardiovascular Disease Group sessions led by a dietitian focusing on Administration on Aging Program- Little Havana Activities & Nutrition education and counseling with interactive [53, 59, 60] Centers of Dade County, FL activities, goal setting, and monitoring for Hispanic older adults at local senior centers. Based upon the 2000 American Heart Association dietary guidelines. Evidence Based Fall Prevention in Senior A fall prevention program for older adults. Administration on Aging, Donaghue Centers- North Central Area Agency on Aging, Focuses on preventing falls by enhancing fall Foundation [53, 61] Hartford, CT prevention knowledge, while building collaborations community between organizations which can enhance the program. Based upon the Yale Frailty and Injuries Cooperative Studies of Intervention Trials (FICSIT) Neighborhood Centers Inc. Activity Centers for The program focuses on increasing physical Administration on Aging Seniors- Neighborhood Centers Inc., Houston, activity in older adults. Primary focus in on [53, 62] minority residents in predominantly low ΤX income areas. Structured physical activity classes are offered 3 days/wk and taught by qualified instructors. Based upon the Lifetime Fitness Program module. The program is focusing on elderly home Administration on Aging A Community Based Medication Management Intervention- Partners in Care Foundation, patients with chronic conditions to improve [53, 63] Burbank, CA use of medications by identifying and eliminating errors. Program is based upon Vanderbilt University Medication Management Model. Chronic Disease Self-Management for African The program targets African Americans who Administration on Aging Urban have at least one chronic disease. It will be American Elders-Philadelphia [12, 53, 56] Corporation for the Aging, Philadelphia, PA implemented over 6-8 weeks at area senior centers. This program is based upon the Chronic Disease Self Management (CDSM) Program developed at Stanford University. Healthy IDEAS: Evidence-Based Disease Self-The program will target all women of racial Administration on Aging Management for Depression- Sheltering Arms backgrounds with a low income, based upon [52, 53]the replication of the Healthy IDEAS Senior Services of Houston, TX

program

Programs- Illinois Department of Public Health,

Springfield, IL

Improving Self Management of Chronic Disease The program is targeted towards older adults Administration on Aging in the Elderly- Area Agency on Aging of 60+ who have at least one chronic disease. [12, 53, 56] Western Michigan, Grand Rapids, MI Program will be implemented over 6-8 weeks at area senior centers. It will be implemented in both urban and rural settings. This program is based upon the CDSMP. The program utilizes no professionals called Healthy Moves for Aging Well- Partners in Administration on Aging Care Foundation "Care Managers" who will teach exercises to [53,64] home bound older adults. Care Managers will also coach and monitor participants via telephone. This is based upon the LifeSpan: A Physical Assessment Study Benefiting Older Adults developed at California State University, Fullerton. A Matter of Balance- Southern Maine Area The program utilizes lay persons as Administration on Aging Agency on Aging, Portland, ME "volunteer lay leaders" instead of health [51, 53] professionals to facilitate classes and activities to reduce the fear of falling and stop the fear of falling cycle. Based upon the original MOB model. Arkansas Empowering Older Adults Project-The program is designed around the CDSM Administration on Aging Arkansas Department of Health and Human and the Active Living Every Day programs. Services, Little Rock, AR Arizona on the Move for Healthy Aging-The program is designed around the CDSM Administration on Aging Arizona Department of Health Sciences, and the EF programs. It is targeted towards Phoenix, AZ adults 60+. California Initiative to Empower Older Adults The program is designed around the CDSM Administration on Aging to Better Manage Their Chronic Health and the MOB programs. Targets adults 60+ [65] Conditions Through Evidence Based Prevention primarily in five diverse underserved Programs- California Department of Aging, communities Sacramento, CA Healthy Aging Partnership Project- Colorado The program is designed around the CDSM Administration on Aging Department of Public Health & Environment, and the MOB programs. Targeted for Denver, CO traditionally underserved racial/ethnic minorities. Empowering Older People- State of Connecticut The program is designed around the CDSM Administration on Aging Department of Social Services, Hartford, CT and the Step by Step programs. Focus is on African American and Hispanic older adults at risk for falls. Implementation of Evidence Based Prevention The program is designed around the CDSM Administration on Aging Programs- Florida Department of Health, and the Spanish Arthritis Self Management Tallahassee, FL programs. Focus is on adults 60+ who are at risk for chronic diseases. Healthy Aging Partnership- Empowering Elders The program is designed around the CDSM Administration on Aging (HAP-EE)- Executive Office on Aging Hawaii and the EF programs. It will work with 40 State Department of Health, Honolulu, HI aging network partners to target all adults with chronic diseases. The program is designed around the CDSM, Idaho Lifestyle Interventions for the Elderly Administration on Aging Fit and Fall Proof, Healthy Eating for (LIFE)- Idaho department of Health & Welfare, [65, 66]Successful Living in Older Adults programs. Boise, ID Focus will be on older adults in rural underserved areas. The program is designed around the CDSM Arthritis and Chronic Disease Management Administration on Aging

are the target population.

and the Strong for Life programs. Adults 60+

[65, 67]

Empowering Older People to Take More Control of their Health and Reduce their Risk of Disease and Disability- Maine Office of Elder Services, Augusta, ME

Living Well- Take Charge of Your Health-Maryland Department of Aging, Baltimore, MD

Empowering Older People- Massachusetts Executive Office of Elder Affairs, Boston, MA

Partners on the PATH (Personal Action Toward Health) to Evidence-Base Disease Prevention-Michigan Office of Services to the Aging, Lansing, MI

Minnesota's Evidence Based Health Promotion Initiative- Minnesota Board on Aging- St. Paul, MN

Establishing Local and State Partnerships for the Delivery of Evidence Based Prevention Programs for Older Adults- New Jersey Department of Health and Senior Services, Trenton, NJ

Ohio's Evidence Based Prevention Program Initiatives- Ohio Department of Aging, Columbus, OH

Living Longer, Living Stronger: the Oklahoma Project- Oklahoma Department of Human Services, Aging Services Division, Oklahoma, OK

Implementing Evidence Based Prevention Programs for Older Adults- Department of Human Services, Seniors & People with Disabilities, Salem, OR

Texas Healthy Lifestyles- Texas Department of Aging and Disability Services, Austin, TX

Living Well in Wisconsin- Wisconsin Division of Disability & Elder Services, Madison, WI

The program is designed around the CDSM and MOB programs. Focus will be on developing four new "Enhance Fitness" sites for older adults with chronic conditions.

The program is designed around the CDSM and Active for Life programs. Focus will be to implement six "Planning Service Areas" to increase participation of older adults especially African Americans, Hispanics, and Asians.

The program is designed around the CDSMP, MOB and Healthy Eating for Successful Living in Older Adults programs. Will be implemented in the Boston metro area for all older adults with chronic disabilities.

The program is designed around the MOB, EF, and CDSM programs. It will build upon the PATH program to enhance infrastructure for older adults in underserved urban and rural areas.

The program is designed around the CDSM, MOB, and EF programs. Outcomes will focus on increasing quality of life and independence through chronic disease management.

The program is designed around the CDSM and IDEAS programs. Focuses on frail individuals of low socio-economic groups to decrease barriers in these communities.

This program is designed around the CDSM, MOB programs. Targets older adults in low to moderate income and rural populations, and will also evaluate program effectiveness using the POMP Social and Physical Functioning Survey.

The program is designed around the EF and CDSM programs. Focuses on adults 60+ including American Indians, African Americans, Hispanics, and persons in rural communities.

The program is designed around the CDSM, MOB, and EF programs. Implementation is in four diverse areas in Oregon. Evaluation will be done using the CDC six step framework.

The program focuses on managing chronic diseases in adults 60+ through the Aging Texas Well (ATW) Initiative. The program evaluation will follow the RE-AIM model.

The program is designed around the CDSM and Stepping On programs. Targets adults 60+ focusing on Hispanics and Native Americans

Administration on Aging [65]

Administration on Aging [65, 68]

Administration on Aging [52, 65]

Administration on Aging [65]

Administration on Aging [65]

Administration on Aging [65]

Administration on Aging [65, 69]

Administration on Aging [65]

Administration on Aging [65, 70]

Administration on Aging [51, 65]

Administration on Aging [65]

The CDC has also embarked on two new initiatives to advance the future of prevention and healthy aging research, The Healthy Brain Initiative and End of Life Issues Initiative are the latest frontiers.

The Healthy Brain Initiative is looking to address brain health, specifically looking to identify, define, and assess ways to better address cognitive health as a public health goal. The formative research will focus on assessing perceptions about cognitive health and associated risk factors [46].

The End of Life Issues Initiative has come to the forefront do to medical advancements in technology and treatment. Maintaining a high quality of life at the end of life has become a major concern and now a priority issue for society and the public health community. The burden and impact of dying persons, their family members, and society, increase the need to prevent suffering. The future steps are to identify end of life surveillance measures, educate public health professionals about end of life issues, and educate the public in regards to improving the dying experience [46].

#### 1.4 FUTURE DIRECTION OF PREVENTION RESEARCH

Successful public health campaigns, in the past, have changed health behaviors and outcomes [14, 44, 71-76]. Life expectancy has increased largely due to the use of preventive health care, better medical care, and improved sanitation [1, 2]. Chronic diseases including heart disease, cancer, and stroke are now the leading causes of death in the United States [1]. The challenge is how to implement quality preventive public health programs for older individuals. Unfortunately, effective preventive medicine and public health programs for older individuals are

lacking, resulting in unnecessary excessive morbidity, especially as related to congestive heart failure, stroke, myocardial infarction, osteoporotic fractures, muscle weakness and sarcopenia, peripheral vascular disease, breast and colon cancer [3]. If prevention programs are successful, they will improve quality of life; reduce health care utilization and costs [36].

Present day clinical preventive services are performed in public health clinics or in physician offices. These services include screening for high risk conditions such as elevated blood pressure, elevated serum cholesterol, immunizations, and counseling to reduce risky behaviors. Medicare has begun to cover some clinical preventive services such as mammography, colonoscopy, bone density, pneumococcal and influenza vaccinations as well as exercise programs such as the national Silver Sneakers exercise program. Community based prevention programs that benefit an entire geographic area are also on the rise. In the past, public health services have been provided to communities by government public health agencies. Within the last decade other public and private organizations whose missions are to promote physical and mental health and prevent disease, injury and disability have also contributed to the prevention efforts (American Cancer Society, American heart Association, etc) [77].

The future of prevention lies in the hands of public health agencies. As public health agencies focus on current public health problems, they will need to work more closely with managed care organizations. By forming partnerships, managed care organizations can realize the benefits of allocating resources to community-based prevention programs. Due to the fact that the level of funding for prevention is inadequate, more governmental funds will also be needed [14, 30, 78]. The CDC and collaborating partners believe the following strategies are key to preserving health and quality of life for older adults [46].

✓ Provide data on the health status and health behaviors of caregivers and develop measures to assess the care provided by caregivers [46].

- ✓ Identify and synthesize existing evidence-based information on interventions and policies that may help promote and protect older adult health, and create an inventory of recommendations [46].
- ✓ Develop the ability of health professional to use data for action, implement evidencebased interventions, and communicate the importance of healthy lifestyles and advance care planning to older adults [46].

Along with the previous strategies, academics will play a crucial role in framing how society views "healthy lifestyle". Academics will help reframe public policies in regards to recreation, transportation, and urban development to increase physical activity. Also by researching causes of lifestyle choices will help to direct the future of prevention research and health promotion [23, 79].

Another important avenue will be to actively engage more constituencies. Health departments, health care providers, faith groups, community organizations, employers, labor unions, elected officials, universities, and social movements will help to restructure health as an economic, environmental, social justice, and moral issue. By employing this restructure health professionals will have the ability to analyze health problems at the various social levels, enabling them to create more multidisciplinary effective strategies [14, 23, 80, 81].

#### 1.5 DISCUSSION/CONCLUSION

Adults 65 and older are the fastest growing sector of the population and have received a great deal of attention over the past couple of decades due to increased costs of acute medical and long-term care and the interpreted rise in these costs, compete for prevention research funds.

Continuous hurdles and challenges need to be overcome before prevention of chronic diseases is made top priority. Prevention researchers and health professionals have the

knowledge and know-how to significantly increase health gains. Prevention research programs need to be marketed in a more appealing package; we are competing with industries that spend billions each year to sell products. Changing society's perception of healthy living and aging is a monumental task. The role of government agencies (local, state, and federal), academic institutions, health organizations, etc. play a crucial role in initiating these changes to reframe our nations health. Economic incentives for individuals and businesses have the potential for significant health gains and reduce the prevalence of chronic diseases. Governments need to promote and support the transformation of health systems to accommodate primary prevention efforts in health systems; this will help to reduce rising medical costs for all. Raising excise tax to levels that will reduce consumption of unhealthy habits (ex: tobacco), increases revenue that can be used for prevention research programs along with decreasing the burden of disease.

The future burden of chronic diseases depends on the willingness for researchers and health professionals to become more diverse and view disease prevention research as multifactorial and multidisciplinary. Hippocrates said it best "The function of protecting and developing health must rank even above that of restoring it when it is impaired".

#### 1.6 FIGURES:

## INTEGRATING PREVENTION SCIENCE STRATEGIES



Figure 1.1: Integrating Prevention-Science Strategies. [30]

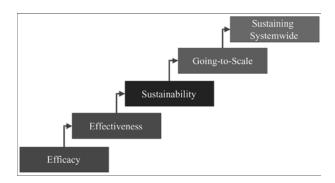


Figure 1.2: Phases of Prevention Research. [30]

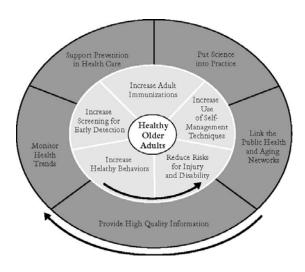


Figure 1.3: The CDC Healthy Aging Program's Approach to Health Promotion and Disease Prevention for Older Adults

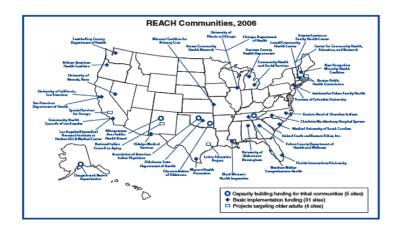


Figure 1.4: Racial and Ethnic Approaches to Community Health (REACH) 2006 U.S. Funded Sites

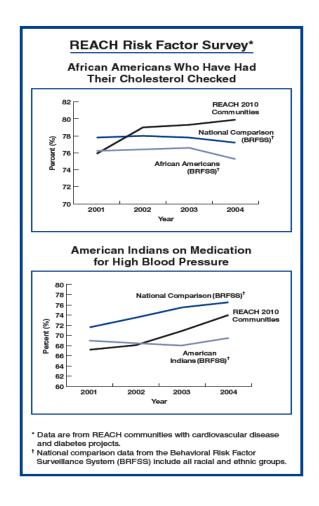


Figure 1.5: REACH Risk Factor Survey for Racial and Ethnic Groups

# 2.0 RESEARCH ARTICLE ONE: RECRUITMENT STRATEGIES FOR THE CENTER FOR HEALTHY AGING DEMONSTRATION PROGRAM

#### To be submitted for Publication

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#### 2.1 ABSTRACT

**Objectives**: The purpose of this report was to analyze the effectiveness of different approaches to improve recruitment of high-risk, hard to reach older adults, and the reasons for non-response. In order to evaluate the process of recruitment, we did a very detailed evaluation in the initial sample of 300 participants for a prevention demonstration clinical trial for older individuals.

Methods: The Center for Healthy Aging (CHA) recruited a population of healthy, at risk, older adults in southwestern Pennsylvania for a community based demonstration program. The program targeted adults aged ≥65, based upon "10 Keys"<sup>TM</sup> to Healthy Aging. Recruitment strategies included a direct mail campaign using voter registration lists and telephone follow-up and home visits.

**Results:** A total of 951 households responded (8.2% response rate). 541 participants from 444 households were enrolled. A sub-study (n=25) showed that most non-responding households were ineligible.

**Discussion:** The combination of direct mailing, telephone interviews and "10 Keys"<sup>TM</sup> to Healthy Aging public health campaign, allowed for successful recruitment of participants needed for the study, but not a representative sample of people living in the targeted community. More intensive recruitment efforts, including home visits, did not greatly enhance the recruitment efforts beyond direct mailing.

**Key Word s**: Community Health Education, Health Promotion, Response Rate, High Risk, Healthy Older Adults

#### 2.2 INTRODUCTION

Approximately 12% of the United States (US) population is aged 65 or above, with over 80% having one or more chronic conditions or diseases. The number of older adults continues to rise rapidly and statistics show that this population is expected to double to approximately 72 million by 2030, making older adults nearly 20% of the entire US population [1, 2]. There is an increased emphasis on decreasing preventable diseases/conditions and maintaining a higher quality of life with functional independence. As the number of older adults continues to increase, it is important for researchers to test the effectiveness of interventions that show promise for preventing and/or decreasing disease or disability [3]. The Center for Healthy Aging (CHA) recognized the need to design a broad innovative campaign that would address the most common causes of disease, death, and disability in older adults that could be prevented or delayed if risk reduction programs were emphasized.

The success of prevention programs in the community depends on the ability to reach at risk individuals and then to do an intervention that is both successful in modifying morbidity and mortality and is acceptable to these at risk participants[4, 5]. Lower socioeconomic and education communities have higher morbidity and mortality even at older age groups. This is due, in part, to both higher levels of risk factors, such as blood pressure, smoking, lipids, etc. as well as adherence to therapies, screening and availability and utilization of medical care[6-13]. The purpose of this article is to report and document strategies used to recruit volunteers ≥65 to the CHA community based demonstration program and clinical trial in a higher risk community.

Many clinical trials such as the Women's Health Initiative [14] recruit subjects by large scale mass mailings with relatively low response rates. The participants are not a random sample of the community. However, the efficacy of the interventions, such as hormone therapy or diet,

can still be evaluated because of unlikely finding that the trial intervention is only efficacious in the selected population. The measure of the effectiveness of the intervention, i.e. can a proven successful intervention from a clinical trial be applied in a defined community, requires an attempt to have a defined sample of a community.

Anderson et al. report on the lack of community representativeness of samples enrolled in community based programs [15]. Primarily, the literature focuses on recruiting from closed medical systems [i.e. Health Maintenance Organizations (HMO's), Veterans Affairs Medical Centers Health Centers, Physician Offices etc.]. The translation of clinical trial findings to the community, with an expectation of similar results is not always possible [15]. To adapt the findings of clinical trials to a community setting, it is important to show acceptability of the program, as well as its success of modifying risk factors or other effectiveness outcomes. A research method may be very efficacious in clinical trials but very difficult to implement in populations that might benefit the most.

Recruitment of older adults presents unique challenges and opportunities [14, 16-21]. Success of a community program is dependent upon recruiting and retaining a sufficiently large and representative sample, within a reasonable timeframe and budget to measure critical outcomes of programs [16, 22, 23]. Age, race, gender, socioeconomic status, and the designed specifications of the study play key roles in influencing recruitment success. Additional factors such as lack of time or interest, perceived risks and benefits, and exclusion criteria also factor into recruitment strategy outcomes. Strategies for recruiting older adults alone or in combination with younger individuals have been reported. The general consensus is that experience combined with detailed planning and strategy enhances recruitment efforts. Given the scarcity of program funds, it is very important to consider cost effective recruitment strategies that don't compromise

program integrity. Even successful strategies of the past are more difficult today due to escalation of mailing and printing costs as well as the Health Insurance Portability and Accountability Act (HIPAA) regulations that limit access to "health services populations," caller ID and no call lists. These challenges, while protecting the public, reduce researchers' access to potential participants [24]. The University of Pittsburgh, Graduate School of Public Health (GSPH), has extensive experience in the recruitment of older adults in Randomized Controlled Trials (RCT) and community based programs [3, 14, 17, 25, 26].

Previous literature has also focused on successful strategies for recruiting older adults in the community. These include: mailings (mass and direct), media campaigns (newspaper, television, radio, posters, brochures, presentations etc.), telephone interviews, direct referrals, incentives and recruitment via physician offices or social groups. The following references include only those programs that were somewhat comparable in design and eligibility criteria to our CHA Demonstration Program [3, 15, 18, 19, 22, 25, 27-32]

#### 2.3 METHODS

#### 2.3.1 Study Design

The Center for Healthy Aging, a Centers for Disease Control, Prevention Research Center, initiated a community based demonstration and randomized efficacy trial. Based upon the "10 Keys"<sup>TM</sup> to Healthy Aging, this prevention program was designed to target and motivate a population of ( $\geq$ 65) adults to participate in a series of prevention interventions, that could potentially lead to improved health.

The "10 Keys"<sup>TM</sup> were developed based upon years of collaborative epidemiological, clinical and laboratory studies of the major diseases associated with morbidity, mortality and disability (**Table 2.1**).

#### 2.3.2 Target Population

According to the 2000 U.S. Census Bureau, the city of McKeesport, PA – the focus for CHA recruitment – has 21% of adults aged ≥65 with 47% reporting at least one type of disability. Approximately 64% are female with only 60% graduating high school or beyond. The mean social security income was \$10,904 dollars and the mean retirement income was \$9,355 dollars, with 12.1% of persons aged 65 and over considered below the poverty level. Surrounding Allegheny County, PA has 18% of adults aged 65 and over; the second highest proportion of older adults in a US urban county [33]. Men and women aged ≥65, with no significant disability or difficulty with mobility, were the population of interest. (**Table 2.2**).

#### 2.3.3 Recruitment Strategies

The recruitment of subjects for the majority of studies in the Department of Epidemiology, University of Pittsburgh, is coordinated centrally by an experienced team of nationally recognized personnel who have participated in numerous national studies. At the onset a thorough plan was initiated that included discussions with community partners and with the support of physicians within the region.

A direct mail campaign with telephone follow-up was combined with a community health promotion campaign based on the "10 Keys." The campaign was designed to familiarize residents with the Center for Healthy Aging so that future mailings may initiate interest or recognition with the program.

1. *Direct Mail:* A master list of zip codes and voter registration lists of Allegheny County, PA residents were used to identify random households of potentially eligible participants based on address, age and race. Random household recruitment was chosen because of the goal to recruit residents who represent the ethnic diversity of the target community. A letter was mailed to the resident's home, describing the study along with a returnable card. Residents were asked to return the card requesting a pre-screening telephone interview or refusing further contact. Trained telephone interviewers attempted to contact residents who replied positively to determine their eligibility. If eligible, all other household members were also invited to participate. Residents refusing further contact were not contacted, while those who did not reply at all were called to determine their eligibility. Telephone numbers were identified via the Cole Cross Reference Directory [34]. Up to three phone calls were made to these non-responders.

Residents were contacted by telephone and asked to participate in a screening assessment interview to determine whether they were willing and eligible to participate in the program. Informed consent was obtained and three successive health assessment visits were scheduled. The first visit was conducted by a Health Counselor in the resident's home. Volunteers were then scheduled for two CHA visits no more than one month apart. Transportation was offered if needed and parking was validated for those who drove themselves. Each health assessment

ranged from 0.5 hour – 1.5 hours in length. Following health assessments, volunteers were randomized by household into either: (1) a Brief Education and Counseling Program or (2) a Brief Education and Counseling Program that included an intensive physical activity intervention for all participants and a dietary intervention for participants with hypertension (**Figure 2.1**). Health status and physical function of all participants were reassessed every 6 months for 24 months. Interim follow-up phone calls were made to all participants by a trained health counselor to encourage adherence to the "10 Keys."<sup>TM</sup>

2. Health Promotion Campaign: Efforts to introduce the "10 Keys" campaign centered on contacting faith-based organizations, schools, community organizations, medical facilities and businesses to establish community partnerships. Letters were sent to these organizations describing the CHA and its proposed demonstration program. The CHA outreach coordinator conducted personalized contacts to encourage community partnerships. This process was key to establishing community support and in reinforcing preventative health goals throughout the community. CHA also participated in health fairs, ethnic fairs, and senior community events.

#### 2.4 RESULTS

#### 2.4.1 Population Sample

A total of 19 sets of household mailing, or cohorts, (approximately 300 mailings/cohort) were mailed (10,388 households) in McKeesport PA, and 4 cohorts in the Oakland area of

Pittsburgh PA (1,200 households) from April 2002 through August 2003. This paper will focus on recruitment efforts in McKeesport PA, a population with a greater number of older, high risk residents. Four part-time telephone recruiters conducted 1654 telephone interviews. These efforts yielded 541 individuals from 444 households who consented and eventually were randomized into the demonstration program (**Figure 2.2**). The population recruited was predominantly white (94.1%) and female (60.1%). The mean age of the participants was 74.5 years (SD 5.6), 60.4% were married, and 53.1% of the participants had greater than a high school education (**Table 2.3**).

#### 2.4.2 Recruitment by Mail

The CHA mailed 11,588 letters with a total of 951 household responses (8.2%). Out of the 951 household responses, a total of 389 (3.4%) households identified at least one eligible person for the program (**Figure 2.3**).

#### 2.4.3 Recruitment Sub-Study

To improve recruitment of "harder to reach" residents from the targeted community, a sub-study, Cohort #1 (n=292 total) mailing, was conducted to determine why households were not responding to our recruitment methods and to learn whether household members were eligible and if not why they were not eligible.

Multiple telephone efforts to contact these households were followed by door to door household visits. The purposes of these visits were to provide a more personalized approach, determine whether the residence was occupied, and reasons for their disinterest. Mean age for

Cohort #1 was 78.4 yrs (SD 8.6), with 178 (61%) females and 169 (58%) Caucasians. Of those households who received telephone contact (n=292) only 156 (53%) residents were reached. From this effort, 74 (25%) residents provided oral consent to complete the pre-screening telephone interview. After completion of all telephone interviews, 34 (12%) individuals were eligible and 9 (3%) were able to be scheduled for a Home Visit. Of the 9 scheduled for the Home Visit, 6 (2%) were later randomized into the program.

From the group of households that had not responded to repeat telephone contacts, (n=136 of 292), households (n=25) were randomly sampled to be further interviewed by a CHA staff member through direct house to house contact. Only 1 person was identified as eligible for the demonstration program (Figure 2.4). We learned that residents had either moved to another residence or a skilled nursing facility (n=2), that the house no longer existed [empty lots] (n=3), or that the individual was deceased (n=5) or did not answer the door (n=6). Of the households that answered the door (n=9), some people were currently employed (n=2), and others refused to answer interview questions (n=3). The remaining households (n=4) from the randomly selected sub-study of 25 were repeatedly contacted by telephone, and asked to complete a telephone interview. Of the four interviews that were completed, 3 people were found ineligible based on exclusion criteria (used a cane or walker for assistance) while only 1 person was eligible for the program.

#### 2.5 DISCUSSION

The recruitment process was successful in obtaining the number of subjects for the study in a reasonable period of time. It was not successful, however, in obtaining a random or representative sample of the population of older individuals in McKeesport, PA. More intensive efforts, such as multiple telephone calls and home visits, had an extremely low yield and are not cost effective. We had access to the entire age-eligible population in McKeesport so identification of the potential eligible population was therefore not a problem. We obtained the support of the physicians and the major medical center within the community as well as active support of community groups and the political structure in McKeesport, PA. At this time there were no similar programs in McKeesport, PA that would be competing for participants.

We could have enhanced the recruitment of participants through the use of community (senior) centers and perhaps physicians' offices. However, such approaches would have further limited the representativeness of the population. The Rural Health Promotion Project [3] was much more successful in recruiting participants but offered a unique incentive, i.e. Medicare benefits, to the population. Major recruitment efforts may depend on the ability to offer a unique and important incentive with substantial financial benefit to the population at risk.

Recruitment of older adults to a community based intervention involves experience, commitment, resources, adequate time and detailed planning/monitoring. Simultaneous direct mailings and follow-up phone calls combined with a community health promotion campaign resulted in the recruitment of 541 healthy older adults. Mailing response rate for the current study was 8.2%, with 3.4% of households having at least one eligible person. Previous studies have reported higher response rates only when recruiting volunteers with the use of purchased or

closed medical system lists. Higher recruitment yields have been reported but not in community intervention programs where specific eligibility criteria were required to participate.

Our sub-study findings are significant given our goal to recruit individuals who had not responded to initial mail and phone call attempts, hypothesizing that there was likely a larger sample available in need of our program services. Yet 25 randomly-selected households yielded only 1 additional eligible participant for the program. Assuming that each eligible person decided to participate, it would take approximately 12,500 household visits to recruit 500 participants. The resources required to staff and fund this effort would be extensive and likely prohibitive, due to funding limitations.

This sub-study enabled us to try out a more ambitious recruitment effort to learn why the response rate was lower in these households. We learned that some of the lack of response was dependent on factors beyond our control such as more advanced disease, relocation or disability. Many potential participants were excluded due to use of a walker or cane, or inability to walk a quarter mile. These eligibility criteria were established to identify individuals able to undertake the physical activity intervention.

It is possible that the unique history of the region may have contributed to the low eligibility rate. The city of McKeesport, PA has been experiencing economic decline for years, and has a median household income of \$23,715 dollars and an unemployment rate of 12.5%, (versus the national average of 5.8%) [33]. Among McKeesport adults, 27% have not obtained at least a high school diploma or equivalency. This lack of education and income likely resulted in regional emigration, leaving residents who are in poorer health.

Recruitment strategies have often focused on senior citizen programs, community health fairs, etc. Unfortunately these strategies select from volunteers who participate in these programs

are not a representative sample. The Medicare population may be the best approach to reach "higher risk" populations. This would require substantial changes to Medicare programs i.e. more attention to prevention in low SES higher risk populations focusing on recruitment and long term adherence to prevention programs.

At present, the percentage and characteristics of eligible Medicare or HMO Medicare Advantage beneficiaries participating in prevention programs such as exercise, and adherence to preventive drug therapies, etc., is not known nor the effectiveness of such programs.

Future studies may want to consider broader incentives to increase participation. It is recommended whenever possible, to emphasize incentives that are not available or are high cost to participants and are likely to provide better health such as prevention interventions and access to health counselors to support participants [35-37]. There also may be the need to broaden project eligibility criteria, where possible, so that more individuals can participate in the intervention. This decision, however, is highly debatable if individuals unlikely to benefit from the programs are included just to increase the sample size.

#### 2.6 AUTHOR'S NOTE

The University of Pittsburgh's Center for Healthy Aging is a member of PRC Program, supported by the Centers for Disease Control and Prevention cooperative agreement number U48 DP000025-04. The Center for Healthy Aging would like to thank all of its volunteers, partner organizations, as well as all of the Center for Healthy Aging staff and students for their assistance and support. We are also grateful to Mary Parker for her countless hours of dedication.

## **Tables and Figures**

## Table 2.1: CHA "10 Keys"TM to Healthy Aging

•	Control Systolic Blood Pressure to <140 mmHg (Optimal <120 mmHg)
•	Stop Smoking
•	Participate in Cancer Screenings
•	Get Regular Immunizations
<b>*</b>	Regulate Blood Glucose (fasting <100 mg/dl)
<b>*</b>	Lower LDL Cholesterol to < 100 mg/dl
<b>*</b>	Be Physically Active
<b>*</b>	Prevent bone loss and muscle weakness
•	Maintain Social Contact
•	Combat depression

### **Table 2.2: CHA Eligibility Criteria**

1.	Age 65+ with medical insurance (Prospective participants must have some form of
	medical insurance for physician's services to avoid barriers in the recommended
	prevention care)
2.	Minimum of "fair health" via self report
	-
3.	Not dependent on a cane or walker
	1
4.	Ability to walk one quarter of a mile
5	Ability to walk up one flight of stairs (equivalent to 10 steps)
	( · · · · · · · · · · · · · · · · · · ·
6	Ability to get out of bed or chair without difficulty
0.	Tromby to got out of ood of chair willout difficulty
7	Not currently under cancer treatment (excluding maintenance treatment and non-
, .	melanoma skin cancer)
Q	Independently baths and dresses
ο.	independently baths and dresses
0	No plane to move outside of western Donney Ivanie in the payt two years
9.	No plans to move outside of western Pennsylvania in the next two years

**Table 2.3: Demonstration Program Participant Socio-Demographics (n = 541\*)** 

Characteristics	Overall	City of McKeesport
	(n=541)	Pennsylvania Demographics
		65 yrs and older
		(2000 Census)
Age		Percentage of persons 65+ in
Mean (SD)	74.5 (5.6)	McKeesport, PA
Median	74.1	20.9%
(low-high)	(65, 95.5)	(N=5,023)
Sex		
Male	216 (39.9%)	36.2%
Female	325 (60.1%)	63.8%
Race		
Non-white	32 (5.9%)	27.6% *
White	509 (94.1%)	72.4% *
Marital Status		
Married	327 (60.4%)	35.4%
Widowed	153 (28.3%)	33.3%
Divorced	28 (5.2%)	7.2%
Separated	5 (0.9%)	1.4%
Single	28 (5.2%)	6.9
		Other 15.7%
Education		
<high school<="" td=""><td>36 (6.7%)</td><td>17.9%</td></high>	36 (6.7%)	17.9%
High School	218 (40.3%)	41.8%
>High School	287 (53.1%)	40.3%

<sup>\*</sup> Percentages are based on the total population for McKeesport Pennsylvania

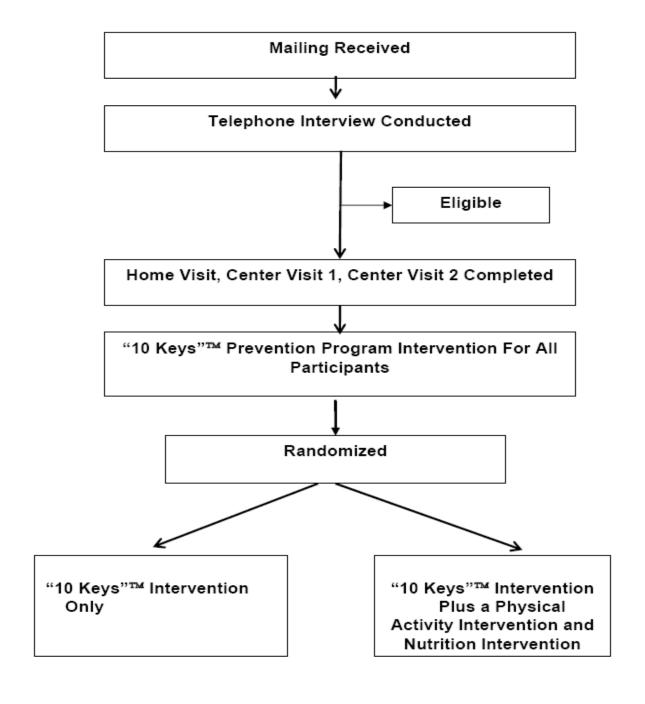


Figure 2.1: Center for Healthy Aging Randomization Flow-chart

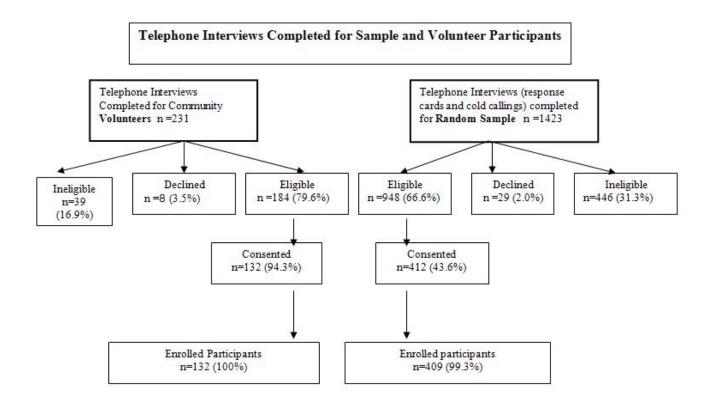


Figure 2.2: CHA Telephone Interview to Randomization Breakdown

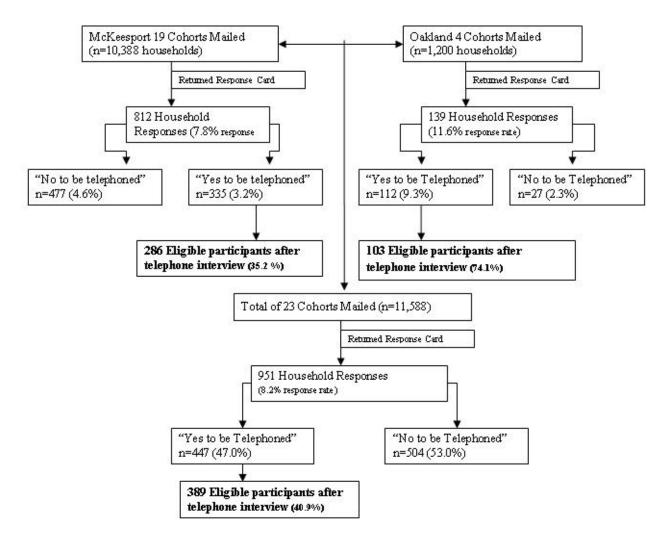


Figure 2.3: CHA Demonstration Project Mailing Response Flow Chart

Randomly selected sample from mailing Cohort 1 (n=292). A randomly selected sample of 25 household eligibility visits was completed for previously nonreachable residence (no-response to mailing/no telephone service). Breakdown of the randomly No longer lives at selected households (n=25) the residence (n=1) Deceased (n=5) Skilled nursing facility Residence no longer (n=1)exists (empty lot) (n=3) Answered Door (n=9) Did not answer the door (n=6) Currently employed Refused to answer questions (n=2)(n=3)Telephone Eligibility Interview Completed (n=4) Eligible for the demonstration project Ineligible for the demonstration project based

on inclusion/exclusion criteria (n=3)

Figure 2.4: CHA Random Selection from Cohort #1

based on inclusion/exclusion criteria

#### 2.7 LITERATURE CITED

- 1. Prohaska, T., Wallace, S., Public Health and Aging, ed. T. Hickey. 1997, Baltimore: The Johns Hopkins University Press. 332.
- 2. He W., S.M., Velkoff V., DeBarros K., 65+ in the United States: 2005 Current Population Reports. 2005. p. 254.
- 3. Ives, D.G., et al., Comparison of recruitment strategies and associated disease prevalence for health promotion in rural elderly. Preventive Medicine, 1992. 21(5): p. 582-91.
- 4. Takahashi, P.Y., et al., Preventive health care in the elderly population: a guide for practicing physicians. Mayo Clinic Proceedings, 2004. 79(3): p. 416-27.
- 5. Veazie, M.A., et al., Taking the initiative: implementing the American Heart Association Guide for Improving Cardiovascular Health at the Community Level: Healthy People 2010 Heart Disease and Stroke Partnership Community Guideline Implementation and Best Practices Workgroup. Circulation, 2005. 112(16): p. 2538-54.
- 6. Bridges, C.B., et al., Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity & Mortality Weekly Report Recommendations & Reports, 2001. 50(RR-4): p. 1-44.
- 7. Cheng, A.Y., et al., Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. Current Opinion in Cardiology, 2006. 21(4): p. 400-4.
- 8. Chia, L.R., et al., Effect of personal and cultural beliefs on medication adherence in the elderly. Drugs & Aging, 2006. 23(3): p. 191-202.
- 9. Chobanian, A.V., et al., Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.[see comment]. Hypertension, 2003. 42(6): p. 1206-52.
- 10. Force, U.S.P.T., Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine, 2008. 149: p. 627-637.
- 11. Force, U.S.P.S.T., Screening for depression: recommendations and rationale.[summary for patients in Ann Intern Med. 2002 May 21;136(10):I56; PMID: 12020161]. Annals of Internal Medicine, 2002. 136(10): p. 760-4.
- 12. Rimer, B.K., et al., The older smoker. Status, challenges and opportunities for intervention.[see comment]. Chest, 1990. 97(3): p. 547-53.
- 13. U.S. Department of Health and Human Services, C.f.D.C.a.P., Advancing the Nation's Health: A Guide to Public Health Research Needs, 2006-2015. 2006.

- 14. The Women's Health Initiative Study Group, Design of the Women's Health Initiative Clinical Trial and Observational Study. Controlled Clinical Trials, 1998. 19: p. 61-109.
- 15. Anderson, L.A., J. Fogler, and R.F. Dedrick, Recruiting from the community: lessons learned from the diabetes care for older adults project. Gerontologist, 1995. 35(3): p. 395-401.
- 16. Souder, J.E., The consumer approach to recruitment of elder subjects. Nursing Research, 1992. 41(5): p. 314-6.
- 17. Tell, G.S., et al., Recruitment of adults 65 years and older as participants in the Cardiovascular Health Study.[see comment]. Annals of Epidemiology, 1993. 3(4): p. 358-66.
- 18. Gavaler, J.S., et al., The Oklahoma Postmenopausal Women's Health Study: recruitment and characteristics of American Indian, Asian, Black, Hispanic, and Caucasian women. Alcoholism: Clinical & Experimental Research, 1999. 23(2): p. 220-3.
- 19. Gilliss, C.L., et al., Recruitment and retention of healthy minority women into community-based longitudinal research. Journal of Womens Health & Gender-Based Medicine, 2001. 10(1): p. 77-85.
- 20. Cohen-Mansfield, J., Recruitment rates in gerontological research: the situation for drug trials in dementia may be worse than previously reported.[see comment]. Alzheimer Disease & Associated Disorders, 2002. 16(4): p. 279-82.
- 21. Warren-Findlow, J., T.R. Prohaska, and D. Freedman, Challenges and Opportunities in Recruiting and Retaining Underrepresented Populations Into Health Promotion Research. 2003. p. 37-46.
- 22. Boult, C., et al., Soliciting defined populations to recruit samples of high-risk older adults. Journals of Gerontology Series A-Biological Sciences & Medical Sciences, 1998. 53(5): p. M379-84.
- 23. Halbert, J.A., et al., Recruitment of older adults for a randomized, controlled trial of exercise advice in a general practice setting. Journal of the American Geriatrics Society, 1999. 47(4): p. 477-81.
- 24. Wipke-Tevis, D.D. and M.A. Pickett, Impact of the Health Insurance Portability and Accountability Act on participant recruitment and retention. Western Journal of Nursing Research, 2008. 30(1): p. 39-53.
- 25. Wing, R.R. and R.W. Jeffery, Benefits of recruiting participants with friends and increasing social support for weight loss and maintenance. Journal of Consulting & Clinical Psychology, 1999. 67(1): p. 132-8.

- 26. Newman, A.B., et al., Strength and muscle quality in a well-functioning cohort of older adults: the Health, Aging and Body Composition Study. Journal of the American Geriatrics Society, 2003. 51(3): p. 323-30.
- 27. Cosgrove, N., et al., Mass mailing and staff experience in a total recruitment program for a clinical trial: the SHEP experience. Systolic Hypertension in the Elderly Program. Cooperative Research Group. Controlled Clinical Trials, 1999. 20(2): p. 133-48.
- 28. Taylor-Davis, S., et al., Time and cost for recruiting older adults. Journal of the American Geriatrics Society, 1998. 46(6): p. 753-7.
- 29. Schoenfeld, E.R., et al., Recruiting participants for community-based research: the Diabetic Retinopathy Awareness Program. Annals of Epidemiology, 2000. 10(7): p. 432-40.
- 30. Adams, J., et al., Recruiting older adults for clinical trials. Controlled Clinical Trials, 1997. 18(1): p. 14-26.
- Whelton, P.K., et al., Recruitment in the Trial of Nonpharmacologic Intervention in the Elderly (TONE). Journal of the American Geriatrics Society, 1997. 45(2): p. 185-93.
- 32. Dillman, D.A., Mail and telephone surveys: the total design method. 1978, New York: John Wiley & Sons.
- 33. U.S. Census Bureau, A.G.a.S., Census 2000 Summary File, McKeesport City, Pennsylvania. 2000.
- 34. 2000 Cole Directory for Pittsburgh- Allegheny County and Vicinity. 2000, Lincoln, NE: Cole Information Services.
- 35. Erlen, J.A., R.J. Sauder, and M.P. Mellors, Incentives in research: ethical issues. Orthopaedic Nursing, 1999. 18(2): p. 84-7.
- 36. Grant, R.W. and J. Sugarman, Ethics in human subjects research: do incentives matter? Journal of Medicine & Philosophy, 2004. 29(6): p. 717-38.
- 37. Alexander, G.L., et al., Effect of incentives and mailing features on online health program enrollment. American Journal of Preventive Medicine, 2008. 34(5): p. 382-8.

# 3.0 RESEARCH ARTICLE TWO: THE KEY TO LIFE NUTRITION PROGRAM: RESULTS FROM A COMMUNITY BASED DIETARY SODIUM REDUCTION TRIAL

# **Submitted for Publication**

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# 3.1 ABSTRACT

**Objective:** Evaluation of a Dietary Sodium Reduction Trial, in a community setting.

**Design:** Community-based randomized trial. Ten week nutrition intervention activities focused on lifestyle modification to decrease dietary sodium intake, under the supervision of a registered dietitian. Twenty-four hour sodium urine specimens were collected at baseline and follow-up visits.

**Setting:** The University of Pittsburgh Center for Healthy Aging, Key to Life Nutrition Program.

**Subjects:** Hypertensive adults at least 65 years of age.

**Results:** Mean age of participants was 75 years. Twenty-four hour mean urinary sodium at baseline was 3174mg/day. This reduced to 2944 mg/day (p = .30) and 2875 mg/day (p  $\leq$  0.03) at 6 and 12 month follow-ups respectively. In a sub-sample (urine volume of  $\geq$ 1000ml, baseline to 12 months) mean urinary sodium decreased from 3220 mg/day to 2875 mg/day (p  $\leq$  0.02).

**Conclusion:** Significant reduction in the mean 24 hour urinary sodium were reported, but results fell short of the recommended guidelines of 1500mg/day for at risk individuals. Our results reiterate the difficulty in implementing these guidelines in community based programs. More aggressive public health efforts, food industry support and health policy changes are needed to decrease sodium levels in older adults to the recommended guidelines.

# 3.2 INTRODUCTION

Hypertension afflicts over 60% of adults ≥65 [1]. The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure 7<sup>th</sup> Report (JNCVII), states that persons who are 55 years of age and considered normotensive have a 90% risk of developing hypertension over their continued lifetime [1]. Hypertension increases the risk for cardiovascular disease, stroke and kidney disease. The 2005, Dietary Guidelines for Americans and the Institute of Medicine recommended a sodium intake of ≤2300 mg/day for "normal" individuals and ≤1500 mg/day for individuals considered at increased risk (individuals with hypertension, blacks, middle-aged, and older adults) [2, 3]. Consuming sodium in greater than recommended amounts is considered a risk factor for increasing blood pressure [4-7]. Past trials comparing behavioral interventions have provided scientific evidence that lifestyle modifications such as reducing dietary sodium intake to recommended levels can result in blood pressure reduction and prevention of high blood pressure [8-13].

Sodium is an essential nutrient in the human body used for maintaining cell homeostasis by regulating extracellular fluid. A small amount of natural sodium is found in virtually all foods, with greater amounts added during processing, or added during the cooking process. On average, Americans consume much higher amounts than is physiologically needed. Minimum daily requirements to replace necessary losses have been estimated at 115mg; however the recommended safe minimum level for adults is set at 500mg to accommodate varying levels of activity and environmental conditions [14, 15]. Excess dietary sodium causes water retention, an increase in blood volume and higher systolic blood pressure (SBP) [16, 17].

For decades, there has been sufficient evidence from clinical trials demonstrating the effectiveness of non-pharmacologic interventions including sodium reduction, to treat, manage and prevent hypertension [1, 9-13].

The Dietary Approaches to Stop Hypertension (DASH) trial is a landmark study for sodium intervention in which participants were randomly assigned to one of three groups, each containing 3000 mg of sodium/day with a 500 mg discretionary allowance of daily sodium. Participants had a mean age of 44, 45 and 44 years for the Control Diet, Fruits and Vegetables Diet and Combination DASH Diet, respectively [8, 18]. The DASH diet is high in fruits, vegetables, low-fat dairy products, whole grains, poultry, fish and nuts. This diet is also low in fats, red meat, sweets, ands sugar-containing beverages [18]. All foods were provided for the 11 week intervention and participants were advised not to consume any "outside" foods. All three groups experienced blood pressure reduction. The DASH group showed the greatest average reduction in SBP (6mmHg) and a 3mmHg reduction in diastolic blood pressure (DBP). This reduction was even greater when stratified for persons with stage 1 hypertension (average reduction in SBP was 11mmHg and DBP was 6mmHg) [8].

These reductions sparked an interest to investigate further on how the DASH diet could be utilized for blood pressure control and prevention, with the DASH-Sodium trial, a randomized controlled trial that assessed the effects of multiple sodium levels on hypertensive adults. Mean age was 47 years for the DASH Diet and 49 years for the Control Diet. Utilizing a crossover design participants received controlled feedings with specific sodium levels of 3000mg/day, 2400mg/day and 1500mg/day for 30 days. Results showed blood pressure reduction at all of the sodium levels, but the most effective group was the DASH diet combined with sodium reduction to 1500mg/day. This group had an average reduction of 8.9mmHg/4.5mmHg for SBP/DBP

respectively. In persons with hypertension the reduction was the greatest with an 11.5mmHg/5.7mmHg reduction for SBP/DBP respectively. Persons considered normotensive also had a reduction of 7.1mmHg/3.7mmHg for SBP/DBP [9].

In the PREMIER multi-centered clinical trial, adults with a mean age of 50 years, and above optimal blood pressure were selected to one of three lifestyle interventions. This trial assessed if a randomized controlled trial intervention could be translated with the same outcomes to the "real world." Blood pressure reductions observed in the DASH group were 11.1mmHg/5.1mmHg reductions for SBP/DBP respectively. After group stratification (hypertensives and non-hypertensives) reductions were 14.2mmHg/7.4mmHg and 9.2mmHg/5.8mmHg respectively. Overall conclusions reiterate that multiple lifestyle modifications significantly lower blood pressure and reduce cardiovascular disease risk [10].

The mean age of participants in the Trial of Non-pharmacologic Interventions in the Elderly (TONE) was 66.5 years. The intervention assessed if a non-pharmacologic intervention could take the place of antihypertensive medication. Sodium reduction goals for the intervention were 80mmol (1840mg) or less and were assessed through a 24 hour urine sodium analysis. Long term results (36 months) for this trial demonstrated the effectiveness and sustainability of sodium reduction on blood pressure with a reduction of 4.3mmHg/2.0mmHg, for SBP/DBP respectively. The results also bring to our attention that non-pharmacologic therapy can be used to control hypertension in older adults without the need for medication [11].

In the Treatment of Mild Hypertension Study (TOMHS), the mean age of the participants was 54 years. The study concluded that lifestyle interventions along with pharmacologic therapy in persons with stage 1 hypertension can be effective in reducing blood pressure. The long term result for the lifestyle intervention group was a reduction of 10.6mmHg/8.1mmHg in SBP/DBP

respectively. This group also reported long term success with 74%, 70% and 59% of participants at follow-up years 2, 3, 4 respectively maintaining blood pressure control without the use of medications [12].

The Trials of Hypertension Prevention (TOHP I and II) demonstrated that blood pressure can be significantly reduced through sodium reduction and weight loss. TOHP Phase I tested the feasibility and efficacy of multiple lifestyle interventions. Results from this trial spurred greater interest and TOHP Phase II tested the efficacy of two non-pharmacologic interventions, weight loss, sodium reduction and combination to decrease blood pressure. Mean age was 44 years, and results of Phase II showed that early interventions alone and in combination were effective in decreasing blood pressure in the long term (48 months) [13].

The Minnesota Mount Sinai Hypertension Trial (MSHT) showed that in a cohort of male hypertensives on medication therapy and lower sodium intake, there was no evidence that potassium supplementation reduces blood pressure further. The mean age for this group of participants was 58 years. This 12 week double masked randomized study reinforces the beneficial effects of dietary sodium reduction on blood pressure [19].

Measures to accurately capture dietary sodium intake from all sources poses a considerable challenge. Collecting dietary sodium intake through food questionnaires is often riddled with underreporting [20, 21]. The preferred methodology requires the use of the 24 hour urinary sodium to obtain reliable values. Under normal conditions, approximately 93% of dietary sodium is excreted through the urine, with minimal losses through feces and sweat. Daily sodium retention is approximately 3.4% or 7.4mMol/day [22, 23].

This article reports on the translation of clinical trial research to community practice, with the primary intervention focus on dietary sodium reduction, rather than blood pressure reduction, in hypertensive older adult volunteers (≥65) in the University of Pittsburgh Center for Healthy Aging Key to Life Nutrition Program.

### 3.3 EXPERIMENTAL METHODS

# 3.3.1 Study background

The Center for Healthy Aging, a Centers for Disease Control and Prevention Research Center, Core Demonstration Program was a community based randomized trial based upon the "10 Keys" to Healthy Aging. This program was designed to advocate preventative services in 10 key areas and to monitor whether changes in health behaviors occurred. The keys are based upon epidemiological, clinical and laboratory studies of the major diseases associated with morbidity, mortality and disability (**Table 3.1**), and were developed in 2001 by experts in aging from the University of Pittsburgh and around the country.

Men and women aged  $\geq$ 65, with no significant disability, were the population of interest. The 2000 U.S. Census Bureau reports that the city of McKeesport, PA which was the site of the community based randomized trial, had 21% of adults aged  $\geq$ 65. Residents reported a mean retirement income of \$9,355 dollars along with a mean social security income of \$10,904 dollars. Approximately 12.1% of residents  $\geq$ 65 are living at or below the poverty level. Surrounding Allegheny County, PA has 18% of adults  $\geq$ 65; the second highest proportion of older adults in a US urban county [24].

# 3.3.2 Recruitment of participants

The recruitment of subjects for the majority of studies in the Department of Epidemiology, University of Pittsburgh, is coordinated centrally by an experienced team of nationally recognized personnel who have participated in numerous national studies. At the onset, the thorough plan for the community based randomized trial included conducting discussions with community partners and obtaining the support of physicians within the region. A direct mail campaign with telephone follow-up was combined with a community health promotion campaign based on the "10 Keys"<sup>TM</sup>. The campaign was designed to familiarize residents with the Center for Healthy Aging so that future mailings may initiate interest or recognition with the program.

Potentially eligible volunteers underwent pre-screening in the form of a telephone interview (Table 3.2). If eligible for the program, informed consent was obtained and three successive health assessment visits were scheduled. The first visit scheduled was the Home Visit in which Health Counselors traveled to the individuals' home to conduct the health assessment. These individuals were then scheduled for two "Center" visits no more than one month apart. Transportation was arranged if needed or parking was validated. Health assessments ranged from ½ hour – 1.5 hours in length. Following the completion of all health assessments, eligible and willing individuals were randomized by household into either group: (1) Brief Education and Counseling Intervention or (2) Intensive Education and Counseling Intervention that included a Physical Activity program for all participants and a Dietary intervention for individuals with hypertension. The advantage of two groups is that it makes it possible to compare a brief and less costly intervention (Group 1) to a more costly and intensive one (Group 2).

Health status and physical function of all volunteers in both groups were reassessed bi-annually for 24 months. Trained Health Counselors contacted volunteers regularly by phone to encourage adherence to the "10 Keys" to Healthy Aging.

# 3.3.3 Key to Life Nutrition Program

The Key to Life Nutrition Program was a voluntary 10 week intensive intervention based on the DASH trials. The primary focus of the intervention was to test whether it is possible to translate past clinical trial sodium reduction results to a diverse community setting of older adults ( $\geq$ 65). This intervention did not focus on blood pressure reduction, rather program emphasis was on educating individuals on dietary sodium reduction by increasing fruits and vegetables, low-fat dairy products, and whole grains in the diet, and decreasing the intake of processed foods, and sodium chloride at the table and in food preparation. Weight loss was recommended only when body mass index (BMI) was  $\geq$ 30. Meetings were facilitated by a registered dietitian.

# 3.3.4 Target Population

Following randomization to the more comprehensive intervention (Group 2), volunteers with hypertension were invited to attend the "Key to Life Nutrition Program."

They understood that the opportunity to attend classes and learn about ways to eat less dietary sodium would be an important complement to their usual treatment for hypertension and would likely improve their overall risk factor status. Hypertension was defined as SBP  $\geq$ 140mmHg or on blood pressure medications.

### 3.3.5 Intervention

Intervention activities included components firmly grounded in behavior theory, specifically behavior modification and social learning theory [25, 26]. These theories were utilized in conjunction to maximize efforts to facilitate health behavior changes. The eating pattern for the intervention incorporated nutrient modifications and meal planning recommendations which were effective in reducing sodium in previous trials. Because adaptation to taste preferences for sodium occurs over time, skill development in a group setting was used to support modification of sodium intake to ensure greater acceptance and success of shaping dietary behaviors. Simultaneously, participants were introduced to numerous self-management approaches that reinforced behavioral change such as self monitoring, food label reading, goal setting, budgeting and problem solving. Following the intensive intervention phase (10 weeks) participants were invited to attend monthly follow-up sessions to maintain motivation and adherence.

# 3.3.6 Assessment of dietary sodium

Those who agreed to participate were asked to collect a 24 hour urine specimen at baseline and at successive center visits (6 and 12 months). They understood the need to collect the sample accurately to measure their sodium levels. Efforts were taken to minimize participant burden associated with urine collection. To help improve completeness of the 24 hour urine, volunteers were contacted and instructions for collection were reviewed.

While multiple collections over several days will improve the accuracy and reliability of urinary sodium measures, data for this study are based upon a single determination due to the feasibility of expecting older adults to collect multiple 24 hour urines for a community based intervention.

A separate analysis was done using data from a sub-sample of our hypertensive group, which included 77 participants who had a 24 hour urine sodium collection volume of  $\geq$ 1000 milliliters. We chose 1000ml since this represents a more normal kidney output for adults  $\geq$ 65. The mean urine volume at baseline was 1956ml compared to 1985ml at the 12 month follow-up visit. In this sub-sample, comparison was done between baseline and 12 month follow-up data.

# 3.3.7 Analyses

Twenty-four hour urinary sodium results were analyzed by Quest Diagnostics Incorporated, Madison NJ using Ion Specific Electrode Methodology. Specimen results were reported as milliMols (mMols) concentration, which was then converted to milligrams (mg) of sodium. This conversion was calculated as 1 mMol concentration = 23 mg of dietary sodium. Matched paired T-tests were run using SPSS version 15.0 statistical software (SPSS Inc. Chicago IL) to assess differences in sodium urine at baseline and consecutive follow-ups.

# 3.4 RESULTS

Baseline characteristics for participants are reported in **Table 3.3.** A total of 115 participants who met the established criteria for hypertension at baseline, were randomized to the healthy lifestyle group (group 2) and completed the 24 hour sodium urine. Average age was 75.1 years (SD 5.3 years).

**Table 3.4** reports 24 hour urine sodium excretions in persons with hypertension at baseline, 6 months and 12 months. At baseline, mean sodium was 3128mg/day (136mMol/day). Comparing baseline and 6 month follow-up 24 hour urinary sodium tests (n = 103 matched pairs), the mean urinary sodium dropped to 2990mg/day (130mMol/day) at the 6 month follow up. This 138mg (6mMol) reduction was not statistically significant (p = 0.30, CI = -5.74, 8.10). When comparing baseline results to 12 month follow-up (n = 90 matched pairs) there was a 299mg (13mMol) sodium reduction. This observed sodium decrease was significant (p = 0.03, CI = 1.16, 25.40). Mean urinary sodium was reduced to 2875mg/day (125mMol).

Table 3.5 refers to a sub-sample of our hypertensive group, and compares 77 individuals at baseline and 12 month follow-up who had a 24 hour urine sodium collection volume of ≥1000 milliliters. The mean urine volume at baseline was 1956ml compared to 1985ml at the 12 month follow-up visit. When comparing sodium at baseline and 12 month follow-up using a matched paired T-test, mean sodium was 3220mg/day (140mMol/day) at baseline and decreased to 2875mg/day (125mMol/day) at the 12 month follow-up. This decrease of 345mg/day (15mMol/day) of sodium was significant (p=0.02, CI = 3.02, 27.76). Refer to Figure 3.1 (stem and leaf plot) for baseline and 12 month 24 hour urinary sodium results for this sub-sample.

# 3.5 DISCUSSION

Blood pressure is one of the major factors in determining the risk for stroke and heart disease. Numerous trials have demonstrated the beneficial effects and importance of reducing dietary sodium to reduce blood pressure and ultimately heart disease and stroke [9-13]. In our demonstration program changes in urine sodium that occurred in persons with hypertension assigned to the Key to Life Nutrition Program intervention were significant, but fell short of the Institute of Medicine and the 2005 Dietary Guidelines recommendations (1500mg/Na/day) for this population. Our results reiterate the importance of how difficult it is to translate these recommended actions into community programs. It is very unlikely that sodium reduction (i.e. 1500 mg/day) can be effective, especially among at risk older individuals who have a decreased ability to excrete sodium and among hypertensives [2].

Past sodium reduction trials have concluded that it is possible to use non-pharmacologic approaches to reduce and prevent blood pressure in older adults. But we have also observed the challenges in maintaining long term outcomes for these interventions. Refer to **Table 3.6** for long term sodium reduction outcomes in past trials. In particular, the large amount of salt (sodium chloride) added during the manufacturing process of foods has been implicated as a factor contributing to the difficulty of maintaining a long term dietary sodium intake reduction of 100mMol/2300mg or even 50mMol/~1200mg a day for at risk populations [27]. This decrease isn't feasible because of the large amount of salt (sodium chloride) added during the manufacturing process of foods.

By imposing more strict policy legislation and the gradual reduction of sodium in food manufacturing, the population would be able to slowly decrease their acquired taste for salt, without altering the taste of foods [28]. This would allow long term reductions in sodium, decreasing the risk for age-related blood pressure increase or hypertension and reducing strokes and CVD morbidity and mortality [1].

The Food Standards Agency (similar to the United States Food and Drug Administration) in the United Kingdom embarked on a major public health campaign to encourage food manufacturers to reduce sodium levels in 2003. Presently reductions can be observed across the board. The Federation of Bakers has reduced salt levels by as much as 30%, and the Association of Cereal Manufacturers reported a 33% reduction in salt levels between 1998 and 2005. The Food and Drink Federation have reduced the salt content of soups and sauces by 30%. Manufactures such as Heinz and Kraft have reduced salt in manufacturing, Heinz claims to have a 11% to 18% reduction and Kraft has reduced sodium in snack products by a third. These reductions will be assessed in 2008 by the FSA for "impact assessment" to survey if further reduction needs to be considered [29].

In contrast, in the United States between 1994 and 2004, despite industry attempts at sodium manufacturing reduction, the average sodium content in foods increased by 6% [30]. Without truly aggressive public health efforts, support from the food industry, and health policy changes, the levels of sodium reduction needed to help reduce blood pressure will be out of reach in the US.

# 3.6 AUTHORS NOTE

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# 3.7 TABLES AND FIGURES

Table 3.1: CHA "10 Keys"TM to Healthy Aging

- 1. Control Systolic Blood Pressure to <140 mmHg (Optimal <120 mmHg)
- 2. Stop Smoking
- 3. Participate in Cancer Screenings
- 4. Get Regular Immunizations
- 5. Regulate Blood Glucose (fasting <100 mg/dl)
- 6. Lower LDL Cholesterol to < 100 mg/dl
- 7. Be Physically Active
- 8. Prevent bone loss and muscle weakness
- 9. Maintain Social Contact
- 10. Combat depression

# Table 3.2: CHA Eligibility Criteria

- 1. Age 65+ with medical insurance (Prospective participants must have some form of medical insurance for physician's services to avoid barriers in the recommended prevention care)
- 2. Minimum of "fair health" via self report
- 3. Not dependent on a cane or walker
- 4. Ability to walk one quarter of a mile
- 5. Ability to walk up one flight of stairs (equivalent to 10 steps)
- 6. Ability to get out of bed or chair without difficulty
- 7. Not currently under cancer treatment (excluding maintenance treatment and non-melanoma skin cancer)
- 8. Independently baths and dresses
- 9. No plans to move outside of western Pennsylvania in the next two years

Table 3.3: CHA Baseline Characteristics for Persons with Hypertension in the Lifestyle Nutrition Intervention Group (N=115)

Age (years)	Mean = 75.1	SD = 5.3
Gender (%)	Male	N = 43 (37.4 %)
. ,	Female	N = 72 (62.6 %)
Race (%)	White/Caucasian	N = 96 (83.5 %)
	Black/African American	N = 19 (16.5 %)
Marital status (%)	Single	N = 3 (2.6 %)
	Married	N=66 (57.4 %)
	Divorced/Separated	N=4 (3.5 %)
	Widowed	N = 42 (36.5 %)
Education Level (%)	< High School	N = 7 (6.1 %)
	High School	N = 57 (49.6 %)
	Some College	N = 16 (13.9 %)
	College Graduate	N = 20 (17.4 %)
	Technical School	N = 2 (1.7 %)
	Other	N = 3 (2.6 %)
Length of residence in Western PA (%)	1-3 years	N = 0 (0 %)
	>3 years	N = 115 (100 %)

**Table 3.4: CHA Urinary Sodium Excretion in Persons with Hypertension** 

	24 hour Urinary Sodium mM/24 hr (mg)	Mean change from baseline in mM (95% CI)	p-value*
Baseline (n= 115)	136 (3128)		
6-months (n=103)	130 (2990)	-6 (-5.74, 8.10)	p = 0.30
12-months (n=90)	125 (2875)	-13 (1.16, 25.40)	p = 0.03

<sup>\*</sup>p-value calculated using a matched paired T-test, indicating statistical significance of the change in urinary sodium from baseline to each of the follow-up points.

Table 3.5: CHA Sub-Sample of Hypertension Group Urinary Sodium Differences

		24 hour Urinary Sodium mM/24 hr (mg)	•	p-value*
Baseline (N=77)	1956	140 (3220)		
12 Months (N=77)	1985	125 (2875)	-15 (3.02, 27.76)	p = 0.02

<sup>\*</sup>p-value calculated using a matched paired T-test, indicating statistical significance of the change in urinary sodium from baseline to each of the follow-up points.

**Table 3.6: Long Term Comparison of Sodium Reduction Trials** 

Study	Author and Year	Study Design	Mean Age (sd)	Urinary Na Reduction (based on 24 hr/urinary sodium excretion)	Duration
Center for Healthy Aging (CHA)		Community Based Randomized Trial	75.1 (5.3)	13 mMol (299mg)	12 months
PREMIER Clinical Trial	Appel et. al. 2003	Randomized Trial	50.0 (8.9)	Advice Only Group 20.6 mmol (474 mg) Established Group 31.6 mMol (726 mg) Established + DASH 32.6 mMol (750 mg)	6 months
Trial of Nonpharmacologic Interventions (TONE)	Appel et. al. 2001	Randomized Trial	65.8 (4.6)	Reduced Sodium Group 45 mMol (1035 mg)	36 months
Trials of Hypertension Prevention II (TOHP II)	Cutler et. al. 1997	Randomized Trial	44	Sodium Reduction Group 35 mMol (805 mg)	36 months
				Combined Group 21 mMol (483 mg)	
Minnesota Mount Sinai Hypertension Trial (MSHT)	Grimm et. al. 1988	Randomized Double Masked Trial	58	55.3 mMol (1271 mg)	12 weeks

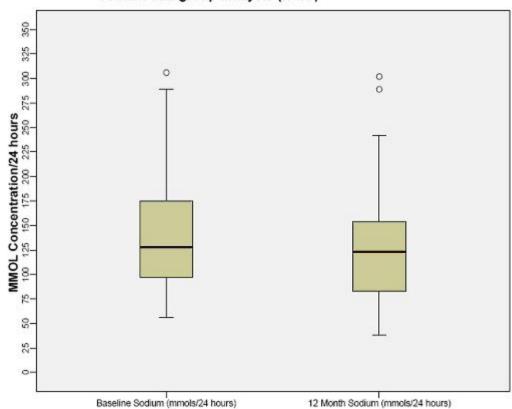


Figure 1: Baseline and 12 month followup 24 hour urinary sodium sub-group analysis (N=77)

Figure 3.1: Baseline and 12 Month Followup 24 Hour Urinary Sodium Sub-Group Analysis (N=77)

# 3.8 LITERATURE CITED

- 1. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report.[see comment][erratum appears in JAMA. 2003 Jul 9;290(2):197]. Jama. 2003 May 21;289(19):2560-72.
- 2. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines for Americans, 2005. In: Services USDoHaH, Agriculture USDo, eds. 6th Edition ed: U.S. Government Printing Office 2005:1-84.
- 3. Food and Nutrition Board IoM. Dietary reference intakes for water, potassium, sodium, chloride, and sulfate,. Washington, D.C.: National Academies Press; 2005.
- 4. Elliott P, Stamler J, Nichols R, Dyer AR, Stamler R, Kesteloot H, et al. Intersalt revisited: further analyses of 24 hour sodium excretion and blood pressure within and across populations. Intersalt Cooperative Research Group.[see comment][erratum appears in BMJ 1997 Aug 23;315(7106):458]. Bmj. 1996 May 18;312(7041):1249-53.
- 5. Cook NR, Kumanyika SK, Cutler JA. Effect of change in sodium excretion on change in blood pressure corrected for measurement error. The Trials of Hypertension Prevention, Phase I. Am J Epidemiol. 1998 Sep 1;148(5):431-44.
- 6. Khaw KT, Barrett-Connor E. The association between blood pressure, age, and dietary sodium and potassium: a population study. Circulation. 1988 Jan;77(1):53-61.
- 7. Dyer AR, Elliott P, Shipley M. Urinary electrolyte excretion in 24 hours and blood pressure in the INTERSALT Study. II. Estimates of electrolyte-blood pressure associations corrected for regression dilution bias. The INTERSALT Cooperative Research Group. Am J Epidemiol. 1994 May 1;139(9):940-51.
- 8. Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group.[see comment]. N Engl J Med. 1997 Apr 17;336(16):1117-24.
- 9. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group.[see comment]. N Engl J Med. 2001 Jan 4;344(1):3-10.
- 10. Appel LJ, Champagne CM, Harsha DW, Cooper LS, Obarzanek E, Elmer PJ, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial.[see comment]. Jama. 2003 Apr 23-30;289(16):2083-93.

- 11. Appel LJ, Espeland MA, Easter L, Wilson AC, Folmar S, Lacy CR. Effects of reduced sodium intake on hypertension control in older individuals: results from the Trial of Nonpharmacologic Interventions in the Elderly (TONE).[see comment]. Arch Intern Med. 2001 Mar 12;161(5):685-93.
- 12. Elmer PJ, Grimm R, Jr., Laing B, Grandits G, Svendsen K, Van Heel N, et al. Lifestyle intervention: results of the Treatment of Mild Hypertension Study (TOMHS). Prev Med. 1995 Jul;24(4):378-88.
- 13. The Trials of Hypertension Prevention Collaborative Research Group. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure. The Trials of Hypertension Prevention, phase II. The Trials of Hypertension Prevention Collaborative Research Group.[see comment]. Arch Intern Med. 1997 Mar 24;157(6):657-67.
- 14. Denton D. The Hunger for Salt; An Anthropological, Physiological and Medical Analysis. New York: Springer-Verlag 1982.
- 15. Stipanuk M. Biochemical and Physiological Aspects of Human Nutrition. Philadelphia: W.B.Saunders Company 2000.
- 16. Kare M, Fregly, M., Bernard, R., , ed. Biological and Behavioral Aspects of Salt Intake. New York: Academic Press 1980.
- 17. Pinto E. Blood pressure and ageing. Postgrad Med J. 2007 Feb;83(976):109-14.
- 18. Karanja N, Erlinger TP, Pao-Hwa L, Miller ER, 3rd, Bray GA. The DASH diet for high blood pressure: from clinical trial to dinner table.[see comment]. Cleve Clin J Med. 2004 Sep;71(9):745-53.
- 19. Grimm RH, Kofron PM, Neaton JD, Svendsen KH, Elmer PJ, Holland L, et al. Effect of potassium supplementation combined with dietary sodium reduction on blood pressure in men taking antihypertensive medication. J Hypertens Suppl. 1988 Dec;6(4):S591-3.
- 20. Moses C, ed. Sodium in Medicine and Health. Baltimore: Reese Press, Inc. 1980.
- 21. Espeland MA, Kumanyika S, Wilson AC, Reboussin DM, Easter L, Self M, et al. Statistical issues in analyzing 24-hour dietary recall and 24-hour urine collection data for sodium and potassium intakes. Am J Epidemiol. 2001 May 15;153(10):996-1006.
- 22. Sanchez-Castillo CP, Branch WJ, James WP. A test of the validity of the lithium-marker technique for monitoring dietary sources of salt in man. Clin Sci (Colch). 1987 Jan;72(1):87-94.
- 23. Liu K, Stamler J. Assessment of sodium intake in epidemiological studies on blood pressure. Ann Clin Res. 1984;16 Suppl 43:49-54.

- 24. U.S. Census Bureau AGaS. Census 2000 Summary File, McKeesport City, Pennsylvania. 2000.
- 25. Bandura A, Adams NE, Beyer J. Cognitive processes mediating behavioral change. J Pers Soc Psychol. 1977 Mar;35(3):125-39.
- 26. Bandura A. Self-efficacy: toward a unifying theory of behavioral change.[see comment]. Psychol Rev. 1977 Mar;84(2):191-215.
- 27. Kuller L. Salt and blood pressure. Population and individual perspectives. American Journal of Hypertension. 1997;10:29S-36S.
- 28. Bertino M, Beauchamp GK, Engelman K. Long-term reduction in dietary sodium alters the taste of salt. Am J Clin Nutr. 1982 Dec;36(6):1134-44.
- 29. Agency FS. New salt reduction targets published as part of FSA campaign to reduce salt in our diets. 2006 [cited; Available from: <a href="www.salt.gov.uk">www.salt.gov.uk</a>
- 30. Jacobson MF. Salt the Forgotten Killer. Washington D.C.: Center for Science in the Public in the Public Interest; 2005

# 4.0 RESEARCH ARTICLE THREE: THE "10 KEYS"<sup>TM</sup> TO HEALTHY AGING: 24 MONTH FOLLOW-UP RESULTS FROM AN INNOVATIVE COMMUNITY BASED PREVENTION PROGRAM

# To be submitted for Publication

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### 4.1 ABSTRACT

**Objective:** To evaluate a prevention program to reduce risk factors for common diseases among older individuals in a lower income community.

**Methods:** This randomized community-based study enrolled older adults into either a Brief Education and Counseling Intervention (BECI) or a Brief Education and Counseling Intervention plus a Physical Activity and (for those with hypertension) a dietary sodium intervention (BECI-plus). Outcomes were collected over 24 months.

**Results:** The sample comprised 389 adults with a mean age of 73.9 years. After 24 months, adherence to the "10 Keys" improved significantly in a number of areas including the proportion meeting goals for LDL cholesterol (+14%), bone mineral density testing (+11%), pneumonia vaccination (+11%), colonoscopy (+14%), and adherence to antihypertensive medication (+9%) among those with hypertension. Physical activity outcomes did not differ between the BECI and BECI-plus interventions. Urinary sodium decreased by 13mmols in individuals with hypertension.

**Discussion:** This program resulted in significant reduction in key risk factors, immunizations and adherence to established prevention guidelines in older adults over two years. Further research is needed to refine the use of community health counselors for translating prevention knowledge into community settings. A more intensive approach to physical activity intervention in older adults may be needed for success.

### 4.2 INTRODUCTION

Adults aged sixty-five and above make up the fastest growing sector of the population. The number of older adults is expected to double to approximately 72 million by 2030, making older adults nearly 20% of the United States population [1, 2]. Older individuals' life expectancy has increased, due to better preventive health care, (including smoking cessation, blood pressure and cholesterol control, and use of low dose aspirin), and better medical treatment, especially for cardiovascular disease (CVD), stroke, diabetes, infectious diseases and some cancers [1, 3].

Epidemiologic studies have helped define the specific risk factors and markers of subclinical disease that contribute substantially to morbidity and mortality among older individuals [4-6]. Clinical trials have documented that interventions can reduce disease risk among older individuals. The challenge now is how to implement preventive health programs which incorporate the knowledge base gained from such efficacy studies. Although it is likely that the translation of preventive knowledge from efficacy studies into community programs for older adults would reduce morbidity and disability and health care costs, well documented effective preventive health programs for older individuals are lacking.

The 10-Keys to Healthy Aging Demonstration Project was based on the principle that community-based prevention programs for older individuals should focus on long term adherence to preventive therapies, screening and immunizations [7]. Furthermore, since many older individuals have multiple chronic diseases, preventive programs focusing on a single condition/disease may be less effective for reducing overall disability, compared with programs focusing on multiple concurrent health concerns. We expected gains to be particularly likely for conditions such as congestive heart failure, stroke, myocardial infarction, osteoporotic fractures,

arthritis, muscle weakness and sarcopenia, peripheral vascular disease, breast and colon cancer and depression, given the high prevalence of these problems among the aged [2, 4-6]. In addition, past research suggests that the substantial burden of clinical disease among older individuals requires fairly aggressive intervention efforts, such as medications for the reduction of BP, blood lipids, control of diabetes, osteoporosis and depression and even surgical therapy for osteoarthritis [4, 8, 9].

The "10 Keys"<sup>TM</sup> to Healthy Aging Demonstration Program focused on specific interventions with scientific evidence for effectiveness, targeting 10 of the major conditions/diseases in older adults living in a low income community. We hypothesized that effective interventions for these 10 conditions/diseases could reduce morbidity, disability and mortality among older individuals. Here, we report on the 24 month evaluation of the program.

# 4.3 METHODS

# 4.3.1 Study Design

The Center for Healthy Aging (CHA) is a Centers for Disease Control and Prevention Research Center, Its Core Demonstration Program was a community-based randomized trial based upon the "10 Keys"<sup>TM</sup> to Healthy Aging. The "10 Keys"<sup>TM</sup> were developed in 2001 by experts in aging from the University of Pittsburgh and received the endorsement of diverse community groups and health care leaders in Allegheny County PA. The keys are based upon

epidemiological, clinical and laboratory studies of the major diseases associated with morbidity and mortality [8, 10-20] (Table 4.1). The interventions they recommend are based on efficacy data demonstrating the potential for decreasing disability, morbidity or mortality. The CHA study focused on the translation of these proven preventive approaches into the community. Given the strong prior efficacy data, we employed no "untreated" control group for the interventions, focusing instead on how best to implement these proven preventive approaches in a "real-world" setting. Support for the program was obtained from the local hospital, Medical community and voluntary health and social service agencies.

# **4.3.2** Target Population

The population of interest included men and women aged  $\geq$ 65, with no significant disability or difficulty with mobility, who were living in McKeesport, Allegheny County, PA. According to the 2000 U.S. Census Bureau, 21% of McKeesport adults were aged  $\geq$ 65 and 47% reported at least one type of disability. Sixty percent of adult residents had finished high school, while approximately 12% of those aged  $\geq$ 65 live at or below the poverty level [21].

# 4.3.3 Recruitment

A detailed description of the recruitment and randomization process is awaiting publication. Over approximately one year, 10, 388 adults aged 65 years or above were identified from voter registration lists and were sent a letter describing the program. Recipients could return a detachable card, either refusing further contact or requesting a screening telephone call. The letter informed them that telephone follow-up would be forthcoming.

Potentially eligible volunteers underwent the pre-screening telephone interview. For those who were preliminarily eligible and interested in the program, informed consent was obtained and three successive health assessment visits were scheduled, each expected to last 0.5 to 1.5 hours in length. During the first visit, health counselors traveled to the individuals' homes to conduct health assessments. Subsequently, two "Center" visits were scheduled at the CHA office in McKeesport, no more than one month apart. If needed, transportation was arranged; otherwise, parking was validated. Following the completion of all health assessments, eligible and willing individuals were randomized by household into either a Brief Education and Counseling Intervention along with interventions for physical activity and (for those with hypertension) nutrition (BECI-plus).

# 4.3.4 Data Collection

At baseline, 12-months and 24-months, study staff collected data on current health problems and preventive practices, including cancer screening status, smoking and immunization histories. Medication names, dosage and adherence were assessed. Blood pressure was measured twice using a standard mercury sphygmomanometer and the average value was recorded. Weight and height were measured in light clothing without shoes. Physical activity level was assessed using the Modified Activity Questionnaire [22], physical function was assessed with standard questionnaires on activities of daily living [23, 24], and mobility [25]. Gait speed, standing balance, and chair stand time were evaluated using the short physical performance battery [26]. Long-distance walking was assessed with a 400 meter walk test [27]. Fasting serum glucose, as well as total and LDL cholesterol, were assessed by a local Quest Diagnostics clinical laboratory. Depression symptoms were assessed using the Centers for the Epidemiologic study of

Depression (CES-D) questionnaire [28]. Social contact was measured by the number of contacts a participant had per week [29]. For those participants with hypertension who were randomized to the BECI-plus group, urinary sodium was collected.

# 4.3.5 Interventions

All participants received a Brief Education and Counseling Intervention designed to educate about the 10-Keys, to encourage adherence to age-appropriate screening procedures and vaccinations, and to work towards the reduction of specific health risk factors. As part of this intervention, each participant was given a "Prevention in Practice Report" which summarized his/her status regarding each of the 10-Keys' goals (**Figure 4.1**). As the study continued, the 10-Keys goals were modified slightly to reflect changing preventive standards for serum glucose or lipid levels [13, 30].

Each participant met individually with a health counselor every six months to review his/her Prevention in Practice report. They identified the Keys that required attention and developed an action plan, including strategies such as knowledge acquisition, skills development, social support, self-monitoring and relapse prevention. This plan was discussed and modified via telephone follow-up calls with one of the study's health counselors at least every three months. Participants were encouraged to take the Prevention in Practice report to their physicians and solicit their support in addressing these goals. Monthly calls were made to participants with concerning (but non-emergent) findings such as elevated blood pressure (SBP >160 mmHg) [12], blood glucose (>130 mg/dL) [31], a positive depression screening score (CESD >16) [32], an absence of physical activity [33], or any current smoking behavior. These calls helped ensure that appropriate medical follow-up was sought, provided support for behavior change and

disseminated information on community resources that could potentially assist with recommended behavior changes. Participants without a primary care physician were encouraged to make a physician appointment, and were given physician names and contact information from the local medical society and hospital. Those with difficulty obtaining or adhering to prescribed medications were provided information on prescription medication benefits and adherence strategies. Counseling calls continued on a monthly basis until active issues were resolved, and then reduced to approximately every three months for the remainder of the program.

Individuals randomized to BECI-plus also received a physical activity intervention (the Key to Life Exercise Intervention) and, for those with a history of hypertension, a dietary sodium nutritional intervention (the Key to Life Nutrition Program). The *Key to Life Exercise Intervention* aimed to increase or maintain physical activity and consisted a walking program and an instructional weight training program, each delivered via a small-group (18 per group) exercise sessions. The program also included stretching, chair exercises along with recreational activities such as basketball and shuffleboard. Participants were encouraged to attend 24 1-hour exercise sessions over 12 weeks, and to exercise on their own at least one other day of the week. A variety of walking resources were provided, including exercise fact sheets, access to indoor locations for walking in inclement weather, pedometers, maps with mileage notations, emergency procedures, exercise logs, hand held weights and a graduation certificate letter and diploma. Walking buttons were awarded monthly as reward for cumulative walking efforts (e.g., "I Walked 10 Miles").

The *Key to Life Nutrition Program* was a voluntary 10 week intensive intervention based on the DASH trials [34, 35], which aimed to translate RCT-proven sodium reduction approaches into a community setting. This intervention focused on educating individuals to

reduce dietary sodium by increasing the intake of fruits and vegetables, low-fat dairy products, and whole grains, and decreasing the intake of processed foods, and sodium chloride. This education was delivered in group sessions, facilitated by a registered dietician. Weight loss was recommended only when body mass index (BMI) was  $\geq 30$ . A more detailed description of the sodium reduction intervention is currently under review [36].

The nutrition counseling was firmly grounded in behavior theory, specifically behavior modification and social learning theory [37-39]. Participants were introduced to numerous self-management approaches such as self-monitoring, food label reading, goal setting, budgeting and problem solving. After 10 initial weekly sessions, monthly follow-up sessions focused on maintaining motivation and adherence.

All interventions were conducted by health counselors with at least a bachelor's level training in health education, nutrition or exercise science with standardized training in research assessment methods and behavior change techniques [39]. Additional health counselor training in behavior change methodology was provided by University of Pittsburgh faculty affiliated with this project.

# 4.3.6 Data Analysis

All data analysis was completed using SAS version 9.1 [40]. We calculated descriptive statistics for the sample, then assessed the proportion of participants that achieved each of the 10-Keys goals at baseline, and 24-months. Because the BECI and BECI-plus interventions were identical regarding most of the 10-Key goals, here we describe analyses for those outcomes pooled across intervention arms.

However, as the two arms differed in terms of physical activity and for a subset of participants sodium reduction counseling, it is important to examine how physical activity changed in each group, and whether the more intensive intervention led to larger effect sizes.

To assess for significance in the change in the proportion successfully completing each of the 10-keys, we used T-tests for continuous variables and Chi-square test for categorical variables. We also assessed for change in continuous measures of several cardiovascular risk factors over the 24 months of the study, using matched paired T-tests. To determine whether outcomes relevant to physical activity changed over time, and to assess for an intervention effect (BECI vs. BECI-plus) we used matched paired T-tests and McNemars test.

### 4.4 **RESULTS**

Overall, 417 individuals enrolled and 93% were retained over 24 months, with 389 individuals completing the 24-month evaluation. Of the 28 individuals who did not complete the 24-month assessment, 8 had died (5 in the BECI group and 3 in the BECI-plus group).

As noted above, here we will first focus on risk factor screening and intervention change from baseline to 24 months for all 389 participants and, second, on comparing randomization groups and performance based measures and levels of physical activity. Analyses of the full 10-Keys according to intervention arm are available in the Appendix.

The sample was predominantly white; 59.44% were female and the average baseline age was 73.9 years (**Table 4.2**). Less than 50% had an education level greater than high school. Chronic diseases were highly prevalent, approximately half reported hypertension, 22.6% with coronary heart disease, 11.6% with diabetes and 7.2% a prior stroke.

The most commonly achieved prevention keys were having the ability to complete 5 chair stands (100%) and maintenance of social contact (99%; see **Table 4.3**). A total of 88% of the sample had CESD scored that were not suggestive of depressive symptoms, while 73% had controlled systolic blood pressure (although only 59% of those with a history of hypertension had values <140 mm Hg). Colon cancer screening rates ranged from 72% to 79%, with a colonoscopy rate of 50%. Influenza and Pneumonia vaccine adherence was 71% and 66% respectively. Only 4% of the individuals were current cigarette smokers at baseline. There was no difference in the baseline characteristics between the two intervention groups.

# 4.4.1 24 Month Results

At 24 months, vaccination rates showed the largest improvement of the 10-Keys under examination (Table 4.3). Among participants without prior influenza or pneumonia vaccination at baseline, 49% had obtained an influenza vaccination and 31% a pneumonia vaccination by the two year follow up. The goal of reducing LDL cholesterol below 100 mg/dL was met by 14% for all participants and 22% of those with a prior CHD diagnosis. There was a 9% increase in the percentage of individuals with systolic blood pressure to less than 140 mm/Hg among those with diagnosed hypertension at baseline. There was little change in the percentage of the sample with blood glucose less than 110 mg/dL (overall, among participants with diabetes, or among those with prescribed antiglycemic agents). Likewise, there was no significant change in the prevalence of depression symptoms. Colonoscopy screening increased 14%. We found an 11% increase in adherence in DEXA bone density screenings

The average level of cardiovascular risk factors at baseline and at 24 months and changes in these values are reported in **Table 4.4**. Overall, the baseline average systolic blood pressure

was 131.9 mm Hg and diastolic blood pressure was 71.3 mmHg. Average blood pressure was slightly higher among participants with diagnosed hypertension. Fasting blood glucose was 97.6 mg/dL for the total sample and 138.8 mg/dL for participants with a history of diabetes. In the whole sample, average LDL cholesterol was 116.3 mg/dL, while among participants with a baseline history of CHD, it was 102.8 mg/dL.

There was a significant decrease in the blood pressure of the total sample (-3.2/-1.9 mmHg) at 24 months; among participants with diagnosed hypertension, an average of -5.1/-2.4 mmHg reduction was found. Blood glucose decreased by 11.2 mg/dL among participants with diabetes. LDL cholesterol decreased -11.7mg/dL overall, including a -15.7 mg/dL reduction for those individuals with a history of CHD. An even greater reduction (-26.6mg/dL) was observed for those individuals whose baseline LDL cholesterol was >130 mm/dL. HDL cholesterol changed minimally overall or in selected subgroups.

# 4.4.2 Results of the Physical Activity Intervention

Table 4.5 reports mean differences within and between intervention groups using specific physical activity performance based measures. For both groups, levels of physical activity generally declined. Within each intervention group, the only physical activity parameters that changed over 24 months were seen in the BECI-plus participants, in whom total physical activity (as measured by the Modified Activity Questionnaire) dropped by 1.6 hours per week and occupational activity which decreased by 1.1 hours per week. However, no statistically significant differences in the mean 24-month change in multiple physical activity-related outcomes were observed between the two intervention groups.

Physical activity adherence data were collected for the first group of 18 participants randomized to receive the physical activity intervention. Overall participation for the 24 sessions averaged 38%.

# 4.4.3 Results of the Sodium Reduction Intervention

Among participants with hypertension, baseline mean sodium excretion was 3128 mg/day (136mmol/day). For those with both baseline and 6-month data (n = 103 matched pairs), the mean urinary sodium dropped to 2990 mg/day (130mmol/day) over 6 months. This 138 mg (6mmol) reduction was not statistically significant (95% CI = -5.74, 8.10). When we compared baseline results to 12 month data (n = 90 matched pairs), we found a statistical significance, -299 mg (-13mmol) sodium reduction (95% CI = 1.16, 25.40), with a final average urinary sodium of 2875mg/day (125mmol).

# 4.5 DISCUSSION

This project demonstrates that older adults in a lower income community can improve their adherence to prevention goals through an evidence-based education and counseling program. Participants successfully improved their adherence to 10-Key goals in areas such as controlling systolic blood pressure (especially those persons with hypertension at baseline), decreasing LDL cholesterol, obtaining colonoscopy for cancer screening and bone mineral density measurement as osteoporosis screening, and influenza and pneumonia vaccinations. A relatively intensive program to promote physical activity was no more effective than brief

counseling in minimizing a loss of physical activity and muscle strength over 2 years, while counseling to reduce sodium intake in a subset of the sample resulted in minimal change in urine sodium excretion over the first year of the study.

To promote sustainability, this intervention complements existing community resources. For example, the study counselors referred participants to the health care system rather than provide them with direct therapy, screening tests or immunizations. Despite relatively low-cost intervention approaches, we achieved considerable success in controlling cardiovascular risk factors. For example, blood pressure control, especially among persons with hypertension (about 70%), was similar to that obtained in the ALLHAT trial [41] and better than in the general U.S. population [12]. Control of serum glucose levels was also better than usually seen in population studies [42-44], and the proportion controlling LDL cholesterol to <100 mg/dL (especially for participants with CAD) was better than typical community values [45].

There are several possible reasons for why the BECI-plus intervention had no significant effect on physical activity, compared to the brief intervention alone. First, the level of physical activity reported was higher than in other elderly samples [46, 47]. Since the participants were well-functioning and active at baseline, there may have been little room for improvement. Second, budget and staffing restrictions resulted in a less-intensive intervention than employed by many physical activity efficacy studies, conducted over a relatively short timeframe. Intervention intensity was likely insufficient to increase subjective measures of physical performance. This idea is supported by controlled data from the Life Study [14, 48] which demonstrate improvement in performance measurements among older individuals with some disability who were enrolled in a much more active physical activity intervention [14]. Other clinical trials have also documented that the performance measures we considered can be

improved by an increase in exercise with physical activity programs [49-52]. Third, attendance at the exercise programs was poor, despite the provision of transportation. Many participants reported already participating in community-based activity programs, and apparently utilized the CHA exercise program primarily as a social outlet. Furthermore, both groups were encouraged to increase their physical activity, by frequent contact from the health counselors; such contact may be sufficient to encourage an increase or maintenance of physical activity in healthy older individuals.

The fact that our program may have lacked sufficiency intensity is particularly concerning as the program was more intensive than typical community programs for promoting physical activity. This highlights the fact that existing community prevention programs for older individuals are often not rigorously evaluated. Many Medicare Advantage programs include access to a gym or other facilities that provide physical activity opportunities [53, 54]. However, program evaluation is often either limited to volunteer samples, incurring the risk of substantial selection bias [54, 55], or focuses on changes in health care costs or utilization of health care services rather than changes in physical performance [53].

While the observed reduction of urinary sodium was significant, it did not approach the goal level of 1500 mg/day. As the level of urine sodium reduction was similar to that in other studies of individuals with hypertension [56, 57], it is very unlikely that more substantial reduction in sodium is feasible without decreasing the amount of sodium in processed foods.

These analyses were limited by a lack of control data. However, given the well-established importance of the 10-Key goals, it would have been unethical to demonstrate that these goals were unmet in control participants without intervening over this two year study.

Since the inception of this project, several major initiatives have underscored the importance of the 10-Key goals, and have suggested possible new "keys." For example, the CDC has identified the reduction of disparities in risk factors for chronic disease among older individuals as a priority issue and recognizes influenza and pneumonia vaccinations, mammography and colorectal screening, cholesterol measurement, and an increase in physical activity as important indicators of preventive health care quality for older individuals [58]. Efforts to reduce hip fracture hospitalizations, via screening and treatment of osteoporosis and fall prevention, are also high priorities [20, 59]. Furthermore, the 10-Keys overlap with most of the older adult prevention priorities that were identified by the Partnership for Prevention [60]. This organization also identified a few areas which the CHA did not emphasize, such as the prescription of aspirin (while not a focus of our interventions, counselors did recommend that the participants discuss aspirin use with their physicians, and the prevalence of daily aspirin use in the sample rose from 33% to 46% over 2 years), the need to avoid heavy alcohol consumption (of very low prevalence in our population), and the need for vision or hearing screening. Future iterations of the 10-Keys<sup>TM</sup> could be expanded to incorporate such sensory screening, and to formally address aspirin therapy. It may also be appropriate to modify the 10-Keys as screening norms for prostate and colon cancer evolve. However, there is still considerable controversy regarding such screening recommendations for older individuals [61, 62].

Few studies have evaluated multifaceted prevention programs among older adults. The Rural Health Promotion Project showed that providing preventive screenings, immunizations and behavioral interventions on smoking, diet and alcohol consumption to Medicare beneficiaries in clinical settings produced no benefit in terms of mortality or Medicare costs, although rates of influenza immunization increased dramatically [63]. More recent studies have evaluated the use

of health counselors or coaches in physician practices, or physician referral to such counselors, particularly for interventions in diet, smoking cessation, exercise [64-66]. However, minimal objective outcome data exists. While Medicare has ongoing demonstrations of how the use of ancillary personnel may improve adherence to recommended therapies in the community, most of these programs focus on higher-risk populations, especially ones with significant chronic disease-related disability. Evidence is lacking regarding the question of how best to promote long-term adherence to recommended preventive therapies in the large population of older individuals with minimal disability but highly prevalent chronic disease. The need for such evidence is underscored by the dropping adherence to therapies for controlling cardiovascular risk factors [67], the under-diagnosis and under-treatment of depression among the elderly [18], and the persistently low colon cancer screening rates among US older adults [68]. Even immunization for pneumonia and influenza remain problematic – while rates are higher than in the past, they do not approach the goal of 80-100% [69, 70].

In light of this translational project, we conclude that the future of prevention research for older individuals should include: 1) testing of new methods to integrate health counselors into the health care delivery system to maximize adherence to prevention programs; 2) empowering older individuals to advocate for their access to the best approaches for preventing disease and disability; and 3) testing interventions to increase physical activity over prolonged time periods, using specific performance-based outcomes. Nutrition programs, such as approaches to increase omega-3 fatty acids in the diet and cognitive training to prevent age-related memory changes also need longer term studies with hard endpoints.

Finally, we need to carefully evaluate new pharmacological and non-pharmacological therapies that may be utilized by large samples of older individuals in the community that are reported to prevent specific chronic diseases, aging and disability.

### 4.6 AUTHORS NOTE

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# 4.7 TABLES AND FIGURES

# Table 4.1: "10 Keys"TM to Healthy Aging

•	Control Systolic Blood Pressure to <140 mmHg (Optimal <120 mmHg)
•	Stop Smoking
•	Participate in Cancer Screenings
•	Get Regular Immunizations
•	Regulate Blood Glucose (fasting <100 mg/dl)
•	Lower LDL Cholesterol to < 100 mg/dl
•	Be Physically Active
•	Prevent bone loss and muscle weakness
•	Maintain Social Contact
•	Combat depression

Table 4.2: Baseline characteristics of the Center for Healthy Aging Demonstration Program Participants (n=389)

Characteristic	
	mean, SD
Age (y)	73.9, 5.4
Gender	N (%)
Men	158 (40.6)
Women	231 (59.4)
Race	
White	369 (94.9)
Black	20 (5.1)
Educational Attainment	
Less than High School	31 (8.2)
High School	184 (48.5)
Greater than High School	164 (43.3)
Marital Status	
Single	21 (5.4)
Married	233 (59.9)
Separated	5 (1.3)
Divorced	14 (3.6)
Widowed	116 (29.8)
Self reported health status	
Excellent / Very Good / Good	351 (90.2)
Fair / Poor	38 (9.8)
Hypertension	209 (53.7)
Coronary Heart Disease*	88 (22.6)
Diabetes	43 (11.1)
Stroke	28 (7.2)

Defined as a reported diagnosis of myocardial infarction (MI), angina, Coronary Artery Bypass Graft (CABG), cardiac stent, or angioplasty.

Table 4.3: Proportion of participants achieving the goals of the "10 Keys" to Healthy Aging at baseline, 24-month follow-up and change

Table: 3 Number and proportion of participants achieving 10 Keys at baseline and 24-month follow-up

	Total (N = 389)				
Key and Goals	N	Baseline	Follow-Up	Difference	
1 Control Systolic Blood Pressure to <140 mmHg	313	73%	76%	3%	
Hypertensive at Baseline	209	59%	68%	9%*	
Prescribed Medications for Hypertension	313	45%	49%	4%	
2 Stop smoking	363	4%	4%	0%	
3 Participate in cancer screenings					
Mammogram	222	79%	79%	0%	
Prostate Cancer Screening	134	72%	70%	-2%	
Colon Cancer Screening	340	79%	79%	0%	
Colonoscopy Alone	349	50%	64%	14%***	
4. Get regular immunizations					
Influenza	363	71%	54%	-17%***	
No Influenza Immunization at Baseline but subsequent shot	104	0%	49%	49%	
Pneumonia	355	66%	77%	11%***	
No Pneumonia Immunization at Baseline but subsequent shot	119	0%	31%	31%	
5 Regulate Blood Glucose to <110 mg/dL	309	86%	81%	-5%**	
Diabetic at Baseline	43	26%	23%	-3%	
Prescribed medications for Diabetes	309	10%	11%	1%	
6 Lower LDLc to <100 mg/dL	306	31%	45%	14%***	
History of CHD at Baseline	75	51%	73%	22%***	
Baseline LDLc > 130	102	0%	16%	16%	
Prescribed Medications for LDLc	306	40%	49%	9% ***	
7 Be physically active at least 2.5 hours per week	338	64%	61%	-3%	
8 Prevent bone loss and muscle weakness					
Bone mineral density test	358	61%	72%	11%***	
Muscle Weakness (chair stands)	297	100%	100%	0%	
9 Maintain social contact at least once per week	363	99%	100%	1%	
10 Combat depression (CES-D <16)	356	88%	88%	0%	

x p ≤ 0.05 xx p ≤ 0.01 xxx p ≤ 0.001

Table 4.4: Means of the "10 Keys" TM Selected Measures for Baseline and 24 Month Follow-up Assessment

Table 4 Means of the 10 Keys Selected Measures for Baseline and 24 Month Follow-Up Assessment

		Total (N = 389)				
	N	Baseline	Follow-Up	Difference		
systolic Blood Pressure	313	130.9	127.7	-3.2 ***		
Persons With Hypertension	209	136.7	131.6	-5.1 ***		
On BP-Controlling Medication	140	134.7	131.3	-3.4 ×		
No BP-Controlling Medication	173	127.9	124.8	-3.1 *		
Diastolic Blood Pressure	313	71.3	69.4	-1.9 **		
Persons With Hypertension	209	72.7	70.3	-2.4***		
On BP-Controlling Medication	140	71.4	69.9	-1.5		
No BP-Controlling Medication	173	71.2	68.9	-2.2 *		
Glucose	309	97.9	98.8	0.9		
Diabetic at Baseline	43	138.8	127.6	-11.2		
On Diabetic Medication	30	140.3	127.8	-12.4		
Non Diabetic	279	93.3	95.6	2.3 **		
LDL Cholesterol	306	117.2	105.5	-11.7 ***		
History of CHD at Baseline	75	102.8	87.1	-15.7 ***		
Baseline LDL > 130	102	155.3	128.7	-26.6***		
On Cholesterol-Lowering Medication	123	101.0	94.8	-6.2 **		
No Cholesterol-Lowering Medication	183	128.1	112.7	-15.4 ***		
HDL Cholesterol	308	54.8	54.3	-0.5		
History of CHD at Baseline	75	48.1	46.9	-1.2		
On Cholesterol-Lowering Medication	125	50.9	49.8	-1.1		
No Cholesterol-Lowering Medication	183	57.4	57.3	-0.2		
Combat Depression (CES-D <16)	356	6.7	7.6	0.95		

<sup>\*</sup>p ≤ 0.05 \*\*p ≤ 0.01 \*\*\*p ≤ 0.001

## Table 4.5: Means of Physical Activity Performance Based Measures by Intervention Group for Baseline and 24 Month Follow-up Assessment

Table 5. Means of Physical Activity Performance Based Measures by Intervention Group for Baseline and 24 Month Follow-Up Assessment

		Lifestyle Plus (N = 188)			Education and Counseling (N = 201)				Intervention
	N	Baseline	Follow-Up Difference		N	Baseline Follow-Up Difference			Comparison p-value
Modified Activity Questionnaire - Total Score	164	7.5	5.9	-1.6 <sup>x</sup>	174	6.5	5.7	-0.8	0.37
Modified Activity Questionnaire - Leisure	164	5.2	4.6	-0.6	174	4.8	4.6	-0.2	0.35
Modified Activity Questionnaire - Occupational	164	2.4	1.3	-1.1 <sup>x</sup>	174	1.7	1.1	-0.6	0.58
Heart Rate									
Pre-Walk Heart Rate	120	76.6	74.9	-1.68	135	75.8	74.5	-1.30	0.79
Post-Walk Heart Rate	120	102.4	100.6	-1.82	135	101.6	101.4	-0.28	0.35
Total Time to Complete 400M Walk (min)	120	5.73	5.81	0.08	135	5.80	5.91	0.11	0.67
Gait Speed (m/sec)	149	1.05	1.03	-0.02	164	1.04	1.02	-0.02	0.72
Lower Extremity Battery Score	148	10.3	10.3	0.06	164	10.4	10.3	-0.10	0.36

<sup>\*</sup>p ≤ 0.05 \*\*p ≤ 0.01

<sup>\*\*\*</sup>p ≤ 0.001



# **Prevention In Practice Report**

The Center for Healthy Aging Graduate School of Public Health University of Pittsburgh Oakland (412-383-1312) www.healthyaging.pitt.edu

## Participant Name:

			Most Recent Height: in.	Weight: Ibs.
10 Keys to Healthy Aging	Center for Healthy Aging Goals	Baseline Status Date:	12 Months Follow-Up Date:	24 Months Follow-Up Date:
Systolic Blood Pressure	Under 140 mm/Hg	BP:	BP:	BP:
Smoking	No Smoking	Cigarettes/day:	Cigarettes/day:	cigarettes/day:
Cancer Screening:				
Breast	Mammogram (2 yr.) (women)	Most Recent:	Most Recent:	Most Recent:
colon	Colonoscopy (10 yr.)	Most Recent:	Most Recent:	Most Recent:
Immunizations	Flu shot (yearly) Pneumonia Vaccine (ever)	Most Recent: Most Recent:	Most Recent: Most Recent:	Most Recent: Most Recent:
Blood Glucose	Under 100 mg/dl Fasting	mg/dl	mg/dl	mg/dl
LDL Cholesterol	Under 100 mg/dl Fasting	mg/dl	mg/dl	mg/dl
Physical Activity	Minimum 2 ½ hrs moderate activity per week	hrs/wk	hrs/wk	hrs/wk
Bone Loss &	Bone Density (women)	Most Recent:	Most Recent:	Most Recent:
Muscle Weakness	Able to sit-to-stand 5 times	Yes/No	Yes/No	Yes/No
Social Contact	Minimum once a week	Yes/No	Yes/No	Yes/No
Depression	Mood Score Satisfactory	Yes/No	Yes/No	Yes/No

Figure 4.1: Prevention In Practice (PIP) Report- "10 Keys" to Healthy Aging Program, Center for Healthy Aging

### 4.8 LITERATURE CITED

- 1. Prohaska T, Wallace, S.,. Public Health and Aging. Baltimore, The Johns Hopkins University Press, 1997.
- 2. He W. SM, Velkoff V., DeBarros K. . 65+ in the United States: 2005 Current Population Reports. In 254; 2005.
- 3. Morbidity and Mortality Weekly Report. Public Health and Aging; United States and Worldwide. In Prevention CfDCa, ed. 52. 101-106; 2003.
- 4. Chaves PH, Kuller LH, O'Leary DH, Manolio TA, Newman AB, Cardiovascular Health S, Subclinical cardiovascular disease in older adults: insights from the Cardiovascular Health Study. American Journal of Geriatric Cardiology 13(3): 137-51, 2004.
- 5. Newman AB, Arnold AM, Naydeck BL, Fried LP, Burke GL, Enright P, Gottdiener J, Hirsch C, O'Leary D, Tracy R, Cardiovascular Health Study Research G. "Successful aging": effect of subclinical cardiovascular disease. Archives of Internal Medicine 163(19): 2315-22, 2003.
- 6. Pinsky JL, Jette AM, Branch LG, Kannel WB, Feinleib M, The Framingham Disability Study: relationship of various coronary heart disease manifestations to disability in older persons living in the community. American Journal of Public Health 80(11): 1363-7, 1990.
- 7. Dunbar-Jacob J, Holmes JL, Sereika S, Kwoh CK, Burke LE, Starz TW, McCall M, Foley SM, Factors associated with attrition of African Americans during the recruitment phase of a clinical trial examining adherence among individuals with rheumatoid arthritis. Arthritis & Rheumatism 51(3): 422-8, 2004.
- 8. Cheng AY, Leiter LA, Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. Current Opinion in Cardiology 21(4): 400-4, 2006.
- 9. Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG, Risk PsgPSoPitEa. Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomized controlled trial.[see comment]. Lancet 360(9346): 1623-30, 2002.

- 10. Kuller LH, Sutton-Tyrrell K. Aging and cardiovascular disease. Use of subclinical measurements. Cardiology Clinics 17(1): 51-65, 1999.
- 11. Anonymous. Sarcopenia and physical performance in old age. Proceedings of a workshop. Bethesda, Maryland, July 9-10, 1996. Muscle & Nerve Supplement 5(S1-120, 1997.
- 12. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr., Jones DW, Materson BJ, Oparil S, Wright JT, Jr., Roccella EJ, Joint National Committee on Prevention DEaToHBPNHLaBI, National High Blood Pressure Education Program Coordinating C. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.[see comment]. Hypertension 42(6): 1206-52, 2003.
- 13. Genuth S, Alberti KG, Bennett P, Buse J, Defronzo R, Kahn R, Kitzmiller J, Knowler WC, Lebovitz H, Lernmark A, Nathan D, Palmer J, Rizza R, Saudek C, Shaw J, Steffes M, Stern M, Tuomilehto J, Zimmet P, Expert Committee on the Diagnosis and Classification of Diabetes M. Follow-up report on the diagnosis of diabetes mellitus.[see comment]. Diabetes Care 26(11): 3160-7, 2003.
- 14. Investigators LS, Pahor M, Blair SN, Espeland M, Fielding R, Gill TM, Guralnik JM, Hadley EC, King AC, Kritchevsky SB, Maraldi C, Miller ME, Newman AB, Rejeski WJ, Romashkan S, Studenski S. Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study.[see comment][erratum appears in J Gerontol A Biol Sci Med Sci. 2007 Mar;62(3):337]. Journals of Gerontology Series A-Biological Sciences & Medical Sciences 61(11): 1157-65, 2006.
- 15. Rimer BK, Orleans CT, Keintz MK, Cristinzio S, Fleisher L, The older smoker. Status, challenges and opportunities for intervention.[see comment]. Chest 97(3): 547-53, 1990.
- 16. Fillit HM, Butler RN, O'Connell AW, Albert MS, Birren JE, Cotman CW, Greenough WT, Gold PE, Kramer AF, Kuller LH, Perls TT, Sahagan BG, Tully T,. Achieving and maintaining cognitive vitality with aging. Mayo Clinic Proceedings 77(7): 681-96, 2002.
- 17. Smith RA, Cokkinides V, Eyre HJ, American Cancer Society Guidelines for the Early Detection of Cancer, 2005. CA: a Cancer Journal for Clinicians 55(1): 31-44; quiz 55-6, 2005.
- 18. Force USPST, Force USPST. Screening for depression: recommendations and rationale.[summary for patients in Ann Intern Med. 2002 May 21;136(10):I56; PMID: 12020161]. Annals of Internal Medicine 136(10): 760-4, 2002.
- 19. Hak E, Nordin J, Wei F, Mullooly J, Poblete S, Strikas R, Nichol KL. Influence of highrisk medical conditions on the effectiveness of influenza vaccination among elderly members of 3 large managed-care organizations.[see comment]. Clinical Infectious Diseases 35(4): 370-7, 2002.

- 20. Kanis JA, Gluer CC. An update on the diagnosis and assessment of osteoporosis with densitometry. Committee of Scientific Advisors, International Osteoporosis Foundation.[see comment][comment]. Osteoporosis International 11(3): 192-202, 2000.
- 21. U.S. Census Bureau AGaS. Census 2000 Summary File, McKeesport City, Pennsylvania. In 2000.
- 22. Pereira MA, FitzerGerald SJ, Gregg EW, Joswiak ML, Ryan WJ, Suminski RR, Utter AC, Zmuda JM. A collection of Physical Activity Questionnaires for health-related research. Medicine & Science in Sports & Exercise 29(6 Suppl): S1-205, 1997.
- 23. Katz S, Ford AB, Moskowitz RW, Jackson BA, Jaffe MW, STUDIES OF ILLNESS IN THE AGED. THE INDEX OF ADL: A STANDARDIZED MEASURE OF BIOLOGICAL AND PSYCHOSOCIAL FUNCTION. JAMA 185(914-9, 1963.
- 24. Fried LP, Borhani NO, Enright P, Furberg CD, Gardin JM, Kronmal RA, Kuller LH, Manolio TA, Mittelmark MB, Newman A, et al. The Cardiovascular Health Study: design and rationale. Annals of Epidemiology 1(3): 263-76, 1991.
- 25. Simonsick EM, Newman AB, Nevitt MC, Kritchevsky SB, Ferrucci L, Guralnik JM, Harris T, Health ABCSG. Measuring higher level physical function in well-functioning older adults: expanding familiar approaches in the Health ABC study. Journals of Gerontology Series A-Biological Sciences & Medical Sciences 56(10): M644-9, 2001.
- 26. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB. Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability.[see comment]. New England Journal of Medicine 332(9): 556-61, 1995.
- 27. Newman AB, Haggerty CL, Kritchevsky SB, Nevitt MC, Simonsick EM, Health ABCCRG. Walking performance and cardiovascular response: associations with age and morbidity--the Health, Aging and Body Composition Study.[see comment]. Journals of Gerontology Series A-Biological Sciences & Medical Sciences 58(8): 715-20, 2003.
- 28. Orme JG, Reis J, Herz EJ. Factorial and discriminant validity of the Center for Epidemiological Studies Depression (CES-D) scale. Journal of Clinical Psychology 42(1): 28-33, 1986.
- 29. Heitzmann CA, Kaplan RM. Assessment of methods for measuring social support. Health Psychology 7(1): 75-109, 1988.
- 30. National Cholesterol Education Program Expert Panel on Detection EaToHBCiA. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report.[see comment]. Circulation 106(25): 3143-421, 2002.
- 31. Expert Committee on the Diagnosis and Classification of Diabetes M. Report of the expert committee on the diagnosis and classification of diabetes mellitus. Diabetes Care 26 Suppl 1(S5-20, 2003.

- 32. The American Geriatrics Society and American Association for Geriatric Psychiatry Recommendations for Policies in Support of Quality Mental Health Care in U.S. Nursing Homes. Journal of the American Geriatrics Society 51(9): 1299-1304, 2003.
- 33. Nelson ME, Rejeski WJ, Blair SN, Duncan PW, Judge JO, King AC, Macera CA, Castaneda-Sceppa C, American College of Sports M, American Heart A. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. Circulation 116(9): 1094-105, 2007.
- 34. Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, Bray GA, Vogt TM, Cutler JA, Windhauser MM, Lin PH, Karanja N. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group.[see comment]. New England Journal of Medicine 336(16): 1117-24, 1997.
- 35. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, Obarzanek E, Conlin PR, Miller ER, 3rd, Simons-Morton DG, Karanja N, Lin PH, Group DA-SCR. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group.[see comment]. New England Journal of Medicine 344(1): 3-10, 2001.
- 36. Robare JF, Milas, N. Carole, Bayles, Constance M., Williams, Kathy, Newman, Anne B., Lovalekar, Mita T., Boudreau, Robert, McTigue, Kathleen, Albert, Steven M., Kuller, Lewis H. . The Key to Life Nutrition Program: Results from a Community-Based Dietary Sodium Reduction Trial. Currently Under Review in Public Health Nutrition 2008.
- 37. Bandura A, Adams NE, Beyer J. Cognitive processes mediating behavioral change. Journal of Personality & Social Psychology 35(3): 125-39, 1977.
- 38. Bandura A. Self-efficacy: toward a unifying theory of behavioral change.[see comment]. Psychological Review 84(2): 191-215, 1977.
- 39. Botelho RJ, Skinner H. Motivating change in health behavior. Implications for health promotion and disease prevention. Primary Care; Clinics in Office Practice 22(4): 565-89, 1995.
- 40. SAS Institute Inc. SAS Version 9.1. In Cary, NC 27513,
- 41. Davis BR, Cutler JA, Furberg CD, Wright JT, Farber MA, Felicetta JV, Stokes JD, Allhat Collaborative Research Group. Relationship of antihypertensive treatment regimens and change in blood pressure to risk for heart failure in hypertensive patients randomly assigned to doxazosin or chlorthalidone: further analyses from the Antihypertensive and Lipid-Lowering treatment to prevent Heart Attack Trial.[summary for patients in Ann Intern Med. 2002 Sep 3;137(5 Part 1):138; PMID: 12204046]. Annals of Internal Medicine 137(5 Part 1): 313-20, 2002.

- 42. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM, Group DPPR. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.[see comment]. New England Journal of Medicine 346(6): 393-403, 2002.
- 43. Herman WH, Hoerger TJ, Brandle M, Hicks K, Sorensen S, Zhang P, Hamman RF, Ackermann RT, Engelgau MM, Ratner RE, Diabetes Prevention Program Research G, The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance.[see comment]. Annals of Internal Medicine 142(5): 323-32, 2005.
- 44. Engelgau MM, Geiss LS, Saaddine JB, Boyle JP, Benjamin SM, Gregg EW, Tierney EF, Rios-Burrows N, Mokdad AH, Ford ES, Imperatore G, Narayan KM, The evolving diabetes burden in the United States.[see comment]. Annals of Internal Medicine 140(11): 945-50, 2004.
- 45. Veazie MA, Galloway JM, Matson-Koffman D, LaBarthe DR, Brownstein JN, Emr M, Bolton E, Freund E, Jr., Fulwood R, Guyton-Krishnan J, Hong Y, Lebowitz M, Ochiai E, Schoeberl M, Robertson RM, American Heart A, Taking the initiative: implementing the American Heart Association Guide for Improving Cardiovascular Health at the Community Level: Healthy People 2010 Heart Disease and Stroke Partnership Community Guideline Implementation and Best Practices Workgroup. Circulation 112(16): 2538-54, 2005.
- 46. Brach JS, Simonsick EM, Kritchevsky S, Yaffe K, Newman AB. The association between physical function and lifestyle activity and exercise in the health, aging and body composition study. Journal of the American Geriatrics Society 52(4): 502-9, 2004.
- 47. Visser M, Simonsick EM, Colbert LH, Brach J, Rubin SM, Kritchevsky SB, Newman AB, Harris TB, for the Health ABCS. Type and intensity of activity and risk of mobility limitation: the mediating role of muscle parameters. Journal of the American Geriatrics Society 53(5): 762-70, 2005.
- 48. Rejeski WJ, Miller ME, King AC, Studenski SA, Katula JA, Fielding RA, Glynn NW, Walkup MP, Ashmore JA, Investigators L, Investigators L. Predictors of adherence to physical activity in the Lifestyle Interventions and Independence for Elders pilot study (LIFE-P). Clinical Interventions In Aging 2(3): 485-94, 2007.
- 49. Blair SN, Blair SN. Physical activity, clinical medicine, and public health. Current Sports Medicine Reports 6(2): 71-2, 2007.
- 50. Blair SN, Haskell WL, Blair SN, Haskell WL. Objectively measured physical activity and mortality in older adults. [comment]. JAMA 296(2): 216-8, 2006.

- 51. Investigators LS, Pahor M, Blair SN, Espeland M, Fielding R, Gill TM, Guralnik JM, Hadley EC, King AC, Kritchevsky SB, Maraldi C, Miller ME, Newman AB, Rejeski WJ, Romashkan S, Studenski S, Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study.[see comment][erratum appears in J Gerontol A Biol Sci Med Sci. 2007 Mar;62(3):337]. Journals of Gerontology Series A-Biological Sciences & Medical Sciences 61(11): 1157-65, 2006.
- 52. Wilcox S, Dowda M, Leviton LC, Bartlett-Prescott J, Bazzarre T, Campbell-Voytal K, Carpenter RA, Castro CM, Dowdy D, Dunn AL, Griffin SF, Guerra M, King AC, Ory MG, Rheaume C, Tobnick J, Wegley S, Active for life: final results from the translation of two physical activity programs. American Journal of Preventive Medicine 35(4): 340-51, 2008.
- 53. Ackermann RT, Williams B, Nguyen HQ, Berke EM, Maciejewski ML, LoGerfo JP, Healthcare cost differences with participation in a community-based group physical activity benefit for medicare managed care health plan members. Journal of the American Geriatrics Society 56(8): 1459-65, 2008.
- 54. Nguyen HQ, Ackermann RT, Maciejewski M, Berke E, Patrick M, Williams B, LoGerfo JP, Managed-Medicare health club benefit and reduced health care costs among older adults. Preventing Chronic Disease 5(1): A14, 2008.
- 55. Nguyen HQ, Ackermann RT, Berke EM, Cheadle A, Williams B, Lin E, Maciejewski ML, LoGerfo JP, Impact of a managed-Medicare physical activity benefit on health care utilization and costs in older adults with diabetes. Diabetes Care 30(1): 43-8, 2007.
- 56. Cutler JA, Follmann D, Allender PS. Randomized trials of sodium reduction: an overview. American Journal of Clinical Nutrition 65(2 Suppl): 643S-651S, 1997.
- 57. Appel LJ, Espeland MA, Easter L, Wilson AC, Folmar S, Lacy CR. Effects of reduced sodium intake on hypertension control in older individuals: results from the Trial of Nonpharmacologic Interventions in the Elderly (TONE).[see comment]. Archives of Internal Medicine 161(5): 685-93, 2001.
- 58. U.S. Department of Health and Human Services CfDCaP. Advancing the Nation's Health: A Guide to Public Health Research Needs, 2006-2015. In 2006.
- 59. Ensrud KE, Barrett-Connor EL, Schwartz A, Santora AC, Bauer DC, Suryawanshi S, Feldstein A, Haskell WL, Hochberg MC, Torner JC, Lombardi A, Black DM, Fracture Intervention Trial Long-Term Extension Research Group. Randomized trial of effect of alendronate continuation versus discontinuation in women with low BMD: results from the Fracture Intervention Trial long-term extension.[see comment]. Journal of Bone & Mineral Research 19(8): 1259-69, 2004.
- 60. Partnership for Prevention. <a href="www.prevent.org">www.prevent.org</a> Community Preventive Services. In Washington D.C., 2008.

- 61. Force USPST. Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine 149(185-191), 2008.
- 62. Force USPT. Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine 149(627-637), 2008.
- 63. Ives DG, Kuller LH, Traven ND. Use and outcomes of a cholesterol-lowering intervention for rural elderly subjects. American Journal of Preventive Medicine 9(5): 274-81, 1993.
- 64. Binks M, O'Neil MP, Referral sources to a weight management program: relation to outcome. Journal of General Internal Medicine 17(8): 596-603, 2002.
- 65. Sesney JW, Kreher NE, Hickner JM, Webb S, Smoking cessation interventions in rural family practices: an UPRNet study. Journal of Family Practice 44(6): 578-85, 1997.
- 66. Clark DO, Clark DO. Physical activity efficacy and effectiveness among older adults and minorities. [see comment]. Diabetes Care 20(7): 1176-82, 1997.
- 67. Chia LR, Schlenk EA, Dunbar-Jacob J, Effect of personal and cultural beliefs on medication adherence in the elderly. Drugs & Aging 23(3): 191-202, 2006.
- 68. Cooper GS, Doug Kou T, Under use of colorectal cancer screening in a cohort of Medicare beneficiaries. Cancer 112(2): 293-9, 2008.
- 69. Nichol KL. The efficacy, effectiveness and cost-effectiveness of inactivated influenza virus vaccines. Vaccine 21(16): 1769-75, 2003.
- 70. Artz AS, Ershler WB, Longo DL. Pneumococcal vaccination and revaccination of older adults. Clinical Microbiology Reviews 16(2): 308-18, 2003.

#### 5.0 DISCUSSION

Adults aged sixty-five and older continually make up the fastest growing population in the United States. This population is expected to double to approximately 72 million by 2030, nearly 20% of the United States population. We have seen an epidemiologic transition from infectious diseases like pneumonia, influenza and tuberculosis to chronic diseases such as heart disease, cancer and stroke. With this shift, life expectancy in the United States has steadily increased over the past decades due to better preventive health care, (including smoking cessation, blood pressure and cholesterol control, and use of low dose aspirin), better medical treatment, especially for cardiovascular disease (CVD), stroke, diabetes, infectious diseases and some cancers. Currently over 80% of older adults in the U.S. population have one or more chronic condition(s) or disease(s) [1-3].

As modern medicine becomes more expensive and continues to exacerbate healthcare resources, the public health field is transitioning to the need to prevent chronic diseases. There is an increased emphasis on decreasing the risk for chronic diseases and maintaining a higher quality of life with functional independence. Epidemiologic studies have helped define specific risk factors and markers of sub-clinical disease that contribute substantially to morbidity and mortality among older individuals [4-6]. The main challenge now is how to implement preventive health programs which incorporate the knowledge base gained from past epidemiological studies.

Although it is likely that the translation of preventive knowledge from efficacy studies into community programs for older adults would reduce morbidity and disability and health care costs, well documented effective preventive health programs for older individuals are lacking.

The "10-Keys"<sup>TM</sup> to Healthy Aging Demonstration Project was based on the principle that community-based prevention programs for older individuals should focus on long term adherence to preventive therapies, screening and immunizations. Furthermore, since many older individuals have multiple chronic diseases, preventive programs focusing on a single condition/disease may be less effective for reducing overall disability, compared with programs focusing on multiple concurrent health concerns. We expected gains to be particularly likely for conditions such as congestive heart failure, stroke, myocardial infarction, osteoporotic fractures, arthritis, muscle weakness and sarcopenia, peripheral vascular disease, breast and colon cancer and depression, given the high prevalence of these problems among the aged [2, 4-6 Article 3]. In addition, past research suggests that the substantial burden of clinical disease among older individuals requires fairly aggressive intervention efforts, such as medications for the reduction of BP, blood lipids, control of diabetes, osteoporosis and depression and even surgical therapy for osteoarthritis [4, 8, 9 Article 3].

Our scientifically based interventions targeted 10 of the major conditions/diseases in older adults living in a low income community. We hypothesized that effective interventions for these 10 conditions/diseases could reduce morbidity, disability and mortality among older individuals.

#### 5.1 RESEARCH ARTICLE ONE

The purpose of research article one was to analyze the effectiveness of different approaches to improve recruitment of high-risk, hard to reach older adults, and the reasons for non-response. In order to evaluate this recruitment process, we did a very detailed evaluation in the initial sample of 300 participants.

A population of healthy, at risk, older adults in southwestern Pennsylvania were recruited for a community based demonstration project between 2001-2003. The project targeted adults aged  $\geq$ 65 and was based upon the "10 Keys"<sup>TM</sup> to Healthy Aging. Recruitment strategies included a direct mail campaign using voter registration lists with telephone follow-up and home visits. A total of 951 households responded (8.2% response rate). 541 participants from 444 households were enrolled.

The combination of direct mailing, telephone interviews and "10 Keys"<sup>TM</sup> to Healthy Aging public health campaign, allowed for successful recruitment of participants needed for the study, but not a representative sample of people living in the targeted community. More intensive recruitment efforts, including home visits, did not greatly enhance the recruitment efforts beyond direct mailing.

## 5.2 RESEARCH ARTICLE TWO

The aim of the second research article was the evaluation of a Dietary Sodium Reduction Trial, in a community setting. This sub-study population consisted of hypertensive adults at least 65 years of age who were randomized to the University of Pittsburgh Center for Healthy Aging,

Key to Life Nutrition Program between 2002-2003. This ten week nutrition intervention focused on lifestyle modification to decrease dietary sodium intake, under the supervision of a registered dietitian. Twenty-four hour sodium urine specimens were collected at baseline and follow-up health assessment visits.

Mean age of this cohort was 75 years. Twenty-four hour mean urinary sodium at baseline was 3174mg/day. This reduced to 2944 mg/day (p = .30) and 2875 mg/day (p  $\leq$  0.03) at 6 and 12 month follow-ups respectively. In a sub-sample (urine volume of  $\geq$ 1000ml, baseline to 12 months) mean urinary sodium decreased from 3220 mg/day to 2875 mg/day (p  $\leq$  0.02).

Significant reduction in the mean 24 hour urinary sodium were reported, but results fell short of the recommended guidelines of 1500mg/day for at risk individuals.

These results reiterate the difficulty of reproducing results reported in clinical trials when implemented in the community setting. More aggressive public health efforts, food industry support and health policy changes are needed to decrease sodium levels in older adults to the recommended guidelines.

#### 5.3 RESEARCH ARTICLE THREE

The aim of research article three was to evaluate the final outcomes of the Center for Healthy Aging Demonstration Project, a prevention program to reduce risk factors for common diseases among older individuals in a lower income community.

This randomized community-based study enrolled older adults into either a Brief Education and Counseling Intervention (BECI) or a Brief Education and Counseling Intervention plus a Physical Activity and (for those with hypertension) a dietary sodium intervention (BECI-plus). Outcomes were collected over 24 months.

Our cohort was comprised of 389 adults (men and women) with a mean age of 73.9 years. After 24 months, adherence to the "10 Keys"<sup>TM</sup> improved significantly in a number of areas including the proportion meeting goals for LDL cholesterol (+14%), bone mineral density testing (+11%), pneumonia vaccination (+11%), colonoscopy (+14%), and adherence to antihypertensive medication (+9%) among those with hypertension. Physical activity outcomes did not differ between the BECI and BECI-plus interventions. Urinary sodium decreased by 13mMols in individuals with hypertension.

This program resulted in significant reduction in key risk factors, immunizations and adherence to established prevention guidelines in older adults over two years.

#### 5.4 CONCLUSION

This project demonstrated that older adults in a lower income community can improve their adherence to prevention goals through an evidence-based education and counseling program. Participants successfully improved their adherence to "10 Keys" goals in areas such as controlling systolic blood pressure (especially those persons with hypertension at baseline), decreasing LDL cholesterol, obtaining colonoscopy for cancer screening and bone mineral density measurement as osteoporosis screening, and influenza and pneumonia vaccinations.

A relatively intensive program to promote physical activity was no more effective than brief counseling in minimizing a loss of physical activity and muscle strength over 2 years, while counseling to reduce sodium intake in a sub-cohort resulted in minimal change in urine sodium excretion over the first year of the study.

Adults 65 and older are the fastest growing population in the United States and have received a great deal of attention over the past couple of decades due to increased costs of acute medical and long-term care and the interpreted rise in these costs, compete for prevention research funds.

Continuous hurdles and challenges need to be overcome before prevention of chronic diseases is made top priority. Prevention researchers and health professionals have the knowledge and know-how to significantly increase health gains.

#### 5.5 FUTURE DIRECTIONS

In light of this translational project, the future of prevention research for older individuals should include: 1) testing of new methods to integrate health counselors into the health care delivery system to maximize adherence to prevention programs; 2) empowering older individuals to advocate for their access to the best approaches for preventing disease and disability; and 3) testing interventions to increase physical activity over prolonged time periods, using specific performance-based outcomes.

Nutrition programs, such as approaches to increase omega-3 fatty acids in the diet and cognitive training to prevent age-related memory changes also need longer term studies with hard endpoints.

Finally, we need to carefully evaluate new pharmacological and non-pharmacological therapies that may be utilized by large samples of older individuals in the community that are reported to prevent specific chronic diseases, aging and disability.

Along with the previous strategies, government agencies (local, state, and federal), academics, health departments, healthcare providers, faith groups, community organizations, employers, labor unions, and social movements need to help restructure health as an economic, environmental, social justice, and moral issue. By employing this restructure health professionals will have the ability to analyze health problems at the various social levels, enabling the possibility to create more multidisciplinary effective strategies to be further evaluated.

By further evaluating and reframing how society views "healthy lifestyle" will help to direct the future of prevention research and health promotion.

#### 6.0 PUBLIC HEALTH SIGNIFICANCE

As the number of older adults continues to increase it is imperative that prevention research be at the forefront to decrease the public health burden of chronic diseases. The Center for Healthy Aging recognized the need and designed a broad innovative health campaign that addressed the most common causes of disease, death and disability in older adults that could be prevented or delayed if risk reduction programs were emphasized. This project made significant contributions to the public health field in three key areas, successful recruitment of older adults, translating research to practice and demonstrating older individuals can improve adherence to evidence based prevention goals, through a multifactor prevention project, the "10 Keys" to Healthy Aging.

We concluded that empowering individuals regarding their own risk factor status for screenings, immunizations, and lifestyle changes using the Prevention In Practice Report as a education and counseling vehicle could successfully impact the quality of health in community settings. We promoted sustainability of this program through collaboration with existing community resources. And continue the second phase of the program with the design, implementation and evaluation of the Center for Healthy Aging, Community Ambassador Program.

This community based program targeting adults ≥ 50 years in southwestern Allegheny County, Pennsylvania offers a free six week (12 hour) multidisciplinary disease prevention

course. Community dwelling adults are certified as "Community Health Ambassadors". These certified Ambassadors now have the ability, knowledge and skills to disseminate the "10 Keys" to Healthy Aging to their peers in their communities.

#### **BIBLIOGRAPHY**

- 1. Morbidity and Mortality Weekly Report. Public Health and Aging; United States and Worldwide. In: Prevention CfDCa, ed, 2003:101-106.
- 2. Prohaska T, Wallace, S., Public Health and Aging. Baltimore: The Johns Hopkins University Press, 1997.
- 3. He W. SM, Velkoff V., DeBarros K. . 65+ in the United States: 2005 Current Population Reports, 2005.
- 4. Scrimshaw SC, White L, Koplan JP. The meaning and value of prevention research. *Public Health Reports* 2001; **116 Suppl 1**:4-9.
- 5. Gordon RL, Baker EL, Roper WL, Omenn GS. Prevention and the reforming U.S. health care system: changing roles and responsibilities for public health. *Annual Review of Public Health* 1996; **17**:489-509.
- 6. Shattuck L. Report of the Commission of Massachusetts. 1850.
- 7. Fee E. The origins and development of public health in the United States. . Oxford University Press 3rd Edition 1991.
- 8. Snider DE, Thacker SB. Fifty years of applied population-based prevention research at the Centers for Disease Control and Prevention. *American Journal of Preventive Medicine* 1998; **14**:308-16.
- 9. Riley PL, Kaplan JP. Prevention research centers. The academic and community partnership. *American Journal of Preventive Medicine* 1999; **16**:5-6.
- 10. Griffith HM, Rabin DL. Commentary on the federal role in clinical prevention research. *American Journal of Preventive Medicine* 1998; **14**:293-9.
- 11. Adler NE, Boyce WT, Chesney MA, Folkman S, Syme SL. Socioeconomic inequalities in health. No easy solution. *JAMA* 1993; **269**:3140-5.
- 12. Lorig KR, Ritter P, Stewart AL, Sobel DS, Brown BW, Jr., Bandura A, Gonzalez VM, Laurent DD, Holman HR. Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Medical Care* 2001; **39**:1217-23.

- 13. Harlan WR. Prevention research at the National Institutes of Health. *American Journal of Preventive Medicine* 1998; **14**:302-7.
- 14. Botvin GJ. Advancing prevention science and practice: challenges, critical issues, and future directions. *Prevention Science* 2004; **5**:69-72.
- 15. U.S. Preventative Services Task Force: Guide to Clinical Preventative Services,. Baltimore: Williams and Wilkins, 1996.
- 16. Center for Medicare and Medicaid Services. www.cms.hhs.gov/statistics/nhe/projections2003/t5.asp.
- 17. Center for Medicare and Medicaid Office of the Actuary NHSG. An Overview of the U.S. Healthcare System: Two Decades of Change 1980-2000. 2000.
- 18. Chattopadhyay SK, Carande-Kulis VG. Economics of prevention: the public health research agenda. *Journal of Public Health Management & Practice* 2004; **10**:467-71.
- 19. Kuller LH. Prevention research strategies. *Nutrition Reviews* 2006; **64**:S2-8.
- 20. Liburd LC, Sniezek JE, Changing times: new possibilities for community health and well-being. *Preventing Chronic Disease* 2007; **4**:A73.
- 21. Weed DL, Weed DL. Methods in epidemiology and public health: does practice match theory? *Journal of Epidemiology & Community Health* 2001; **55**:104-10.
- 22. Rogers WA, Ethical issues in public health: a qualitative study of public health practice in Scotland. *Journal of Epidemiology & Community Health* 2004; **58**:446-50.
- 23. Freudenberg N. From Lifestyle to social determinants: new directions for community health promotion research and practice. *Preventing Chronic Disease* 2007; **4**.
- 24. Reynolds M, Leahy E, Developing a public health training institute through public health improvement efforts: Montana's story.[see comment]. *Journal of Public Health Management & Practice* 2002; **8**:83-91.
- Wiesner PJ, Bonta D, Ford MJ, Kwalick D, Melton R, Noonan AS, Stefanak M, Taking training seriously: a policy statement on public health training by the Joint Council of Governmental Public Health Agencies. *Journal of Public Health Management & Practice* 1995; 1:60-9.
- 26. Navarro A. VK, Liburd L., Bezold C., Rhea M., Recommendations For Future Efforts In Community Health Promotion, Report of the National Expert Panel on Community Health Promotion: Community Health and Program Services Branch, Division of Adult and Community Health Office of the Director, National Center for Chronic Disease Prevention and Health Promotion, Institute for Alternative Futures., 2002.

- Weed DL, McKeown RE, Science, ethics, and professional public health practice. *Journal of Epidemiology & Community Health* 2003; **57**:4-5.
- 28. Caira NM, Lachenmayr S, Sheinfeld J, Goodhart FW, Cancialosi L, Lewis C, The health educator's role in advocacy and policy: principles, processes, programs, and partnerships. *Health Promotion Practice* 2003; 4:303-13.
- 29. Institute of Medicine of the National Academies. Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century. Washington, D.C.: The National Academies Press, 2003.
- 30. Kellam SG, Langevin DJ. A framework for understanding "evidence" in prevention research and programs. *Prevention Science* 2003; **4**:137-53.
- 31. Kellam SG, Koretz D, Moscicki EK. Core elements of developmental epidemiologically based prevention research. *American Journal of Community Psychology* 1999; **27**:463-82.
- 32. Brownson RC, Simoes EJ. Measuring the impact of prevention research on public health practice. *American Journal of Preventive Medicine* 1999; **16**:72-9.
- 33. Ozminkowski RJ, Goetzel RZ, Santoro J, Saenz BJ, Eley C, Gorsky B. Estimating risk reduction required to break even in a health promotion program. *American Journal of Health Promotion* 2004; **18**:316-25.
- 34. Bonneux L, Birnie E, The discount rate in the economic evaluation of prevention: a thought experiment. *Journal of Epidemiology & Community Health* 2001; **55**:123-5.
- 35. Weinstein MC, Stason WB, Foundations of cost-effectiveness analysis for health and medical practices. *New England Journal of Medicine* 1977; **296**:716-21.
- 36. Tengs TO, Adams ME, Pliskin JS, Safran DG, Siegel JE, Weinstein MC, Graham JD, Five-hundred life-saving interventions and their cost-effectiveness.[see comment]. *Risk Analysis* 1995; **15**:369-90.
- 37. Furberg CD. Challenges to the funding of prevention research. *Preventive Medicine* 1994; **23**:599-601.
- 38. Blumenthal DS. A community coalition board creates a set of values for community-based research. *Preventing Chronic Disease* 2006; **3**:A16.
- 39. Evans JG, Beck P, Evans JG, Beck P. Informed consent in medical research. *Clinical Medicine* 2002; **2**:267-72.

- 40. Lefor AT, Scientific misconduct and unethical human experimentation: historic parallels and moral implications.[see comment]. *Nutrition* 2005; **21**:878-82.
- 41. Weindling P, The origins of informed consent: the International Scientific Commission on Medical War Crimes, and the Nuremburg code. *Bulletin of the History of Medicine* 2001; **75**:37-71.
- 42. Wedeen RP, Consent in epidemiology: implications of history for public policy. *Archives of Environmental Health* 2000; **55**:231-9.
- 43. Lang JE, Benson WF, Anderson LA. Aging and public health: partnerships that can affect cardiovascular health programs. *American Journal of Preventive Medicine* 2005; **29**:158-63.
- 44. Lang JE, Moore MJ, Harris AC, Anderson LA. Healthy aging: priorities and programs of the Centers for Disease Control and Prevention. *Generations* 2005; **29**:24-9.
- 45. Division of Adult and Community Health NCfCDPaHP. Aging- CDC Funded Organizations- Healthy Aging for Older Adults, 2007.
- 46. (NCCDPHP) NCfCDPaHP. Information on arthritis, cancer, cardiovascular disease, diabetes and oral diseases and conditions. Atlanta, 2007.
- 47. Airhihenbuwa CO, Laveist TA. Racial and ethnic approaches to community health (REACH) 2010. *Health Promotion Practice* 2006; 7:174S-5S.
- 48. Tucker P, Liao Y, Giles WH, Liburd L. The REACH 2010 logic model: an illustration of expected performance. *Preventing Chronic Disease* 2006; **3**:A21.
- 49. Shenson D. Putting prevention in its place: the shift from clinic to community. *Health Affairs* 2006; **25**:1012-5.
- 50. U.S. Department of Health and Human Services CfDCaP. Prevention Research Centers, Core Research, Intervention and Non-Intervention Research to Reduce Disease Risk. 2006:1-51.
- 51. Belza B. and the PRC-HAN Physical Activity Conference Planning Workgroup. Moving Ahead: Strategies and Tools to Plan, Conduct, and Maintain Effective Community-Based Physical Activity Programs for Older Adults. Atlanta, Georgia: Centers for Disease Control and Prevention, 2007.
- 52. Beattie L, Altpeter, M.,. Using the Evidence Base to Promote Healthy Aging, The Model Programs Project. In: Aging TNCot, ed, 2005.
- 53. Administration on Aging. Evidence Based Disease Prevention Programs, Community Level. In: Aging Ao, ed, 2006.

- 54. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM, Diabetes Prevention Program Research G. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.[see comment]. *New England Journal of Medicine* 2002; **346**:393-403.
- 55. Clark NM, Janz NK, Dodge JA, Schork MA, Fingerlin TE, Wheeler JR, Liang J, Keteyian SJ, Santinga JT. Changes in functional health status of older women with heart disease: evaluation of a program based on self-regulation. *Journals of Gerontology Series B-Psychological Sciences & Social Sciences* 2000; **55**:S117-26.
- 56. Lorig KR, Mazonson PD, Holman HR. Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health care costs. *Arthritis & Rheumatism* 1993; **36**:439-46.
- 57. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. *American Psychologist* 1992; **47**:1102-14.
- 58. Smolander J, Blair SN, Kohl HW, 3rd, Work ability, physical activity, and cardiorespiratory fitness: 2-year results from Project Active. *Journal of Occupational & Environmental Medicine* 2000; **42**:906-10.
- 59. Carleton RA, Bazzarre T, Drake J, Dunn A, Fisher EB, Jr., Grundy SM, Hayman L, Hill MN, Maibach EW, Prochaska J, Schmid T, Smith SC, Jr., Susser MW, Worden JW. Report of the Expert Panel on Awareness and Behavior Change to the Board of Directors, American Heart Association. *Circulation* 1996; **93**:1768-72.
- 60. The American Heart Association. Eating Plan for Healthy Americans, 2000.
- 61. Tinetti ME, Baker DI, Garrett PA, Gottschalk M, Koch ML, Horwitz RI. Yale FICSIT: risk factor abatement strategy for fall prevention. *Journal of the American Geriatrics Society* 1993; **41**:315-20.
- Wallace J.I. BDM, Grothaus L., Leveille S., LaCroix A.Z., Wagner E.H. Implementation and Effectiveness of a Community-Based Health Promotion Program for Older Adults. . *Journal of Gerontology* 1998; **33A**:301-306.
- 63. Meredith S, Feldman P, Frey D, Giammarco L, Hall K, Arnold K, Brown NJ, Ray WA. Improving medication use in newly admitted home healthcare patients: a randomized controlled trial.[see comment]. *Journal of the American Geriatrics Society* 2002; **50**:1484-91.
- 64. Jones J, Rikli, R. LifeSpan: Tools to help you stay strong and Independent.
- 65. Administration on Aging. Evidence-Based Disease Prevention Programs- State Level, 2006.

- 66. Idaho Department of Health and Welfare. Fit and Fall Proof Program. In: District EIPH, ed, 2005.
- 67. Jette AM, Lachman M, Giorgetti MM, Assmann SF, Harris BA, Levenson C, Wernick M, Krebs D, Jack L, Jr. Exercise--it's never too late: the strong-for-life program. *American Journal of Public Health* 1999; **89**:66-72.
- 68. Mitchell RL. Health Science Center Active for Life program receives Cornerstone Award: Texas A&M University System, 2007.
- 69. U.S. Administration on Aging. Performance Outcomes Measures Project for Older Americans Act. In: Aging Ao, ed, 2007.
- 70. Anonymous. Framework for program evaluation in public health. *Morbidity & Mortality Weekly Report Recommendations & Reports* 1999; **48**:1-40.
- 71. Buring JE, Hennekens CH. The contribution of large, simple trials to prevention research. *Preventive Medicine* 1994; **23**:595-8.
- 72. Simons-Morton DG, Cutler JA. Cardiovascular disease prevention research at the National Heart, Lung, and Blood Institute. *American Journal of Preventive Medicine* 1998; **14**:317-30.
- 73. Patterson C, Chambers LW. Preventive health care. *Lancet* 1995; 345:1611-5.
- 74. Prentice RL, Willett WC, Greenwald P, Alberts D, Bernstein L, Boyd NF, Byers T, Clinton SK, Fraser G, Freedman L, Hunter D, Kipnis V, Kolonel LN, Kristal BS, Kristal A, Lampe JW, McTiernan A, Milner J, Patterson RE, Potter JD, Riboli E, Schatzkin A, Yates A, Yetley E. Nutrition and physical activity and chronic disease prevention: research strategies and recommendations. *Journal of the National Cancer Institute* 2004; 96:1276-87.
- 75. Wynder EL, Andres R. Disease prevention research at NIH: An Agenda for All. Workshop A: Diet and nutrition research as it relates to aging and chronic diseases. *Preventive Medicine* 1994; **23**:549-51.
- 76. Jack L, Jr., Mukhtar Q, Martin M, Rivera M, Lavinghouze SR, Jernigan J, Siegel PZ, Heath G, Murphy D. Program evaluation and chronic diseases: methods, approaches, and implications for public health. *Preventing Chronic Disease* 2006; **3**:A02.
- 77. Baker EL, Melton RJ, Stange PV, Fields ML, Koplan JP, Guerra FA, Satcher D. Health reform and the health of the public. Forging community health partnerships.[see comment]. *JAMA* 1994; **272**:1276-82.

- 78. Gostin LO, Boufford JI, Martinez RM. The future of the public's health: vision, values, and strategies.[see comment]. *Health Affairs* 2004; **23**:96-107.
- 79. Formoso G, Marata AM, Magrini N, Social marketing: should it be used to promote evidence-based health information? *Social Science & Medicine* 2007; **64**:949-53.
- 80. Collins JL. GH, Holmes-Chaves A., Old Dilemmas, New Commitments: Toward a 21st Century strategy for Community Health Promotion. *Preventing Chronic Disease* 2007; **4**.
- 81. Yach D, Hawkes C, Gould CL, Hofman KJ. The global burden of chronic diseases: overcoming impediments to prevention and control. *JAMA* 2004; **291**:2616-22.