



Report of the

Surgeon General's Workshop on Osteoporosis and Bone Health

December 12 – 13, 2002, Washington, D.C.

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Introduction

This nation faces a serious yet largely unknown health problem. More than one in 10 Americans either has or is at risk of developing a bone disease. Yet the vast majority of these individuals remain undiagnosed and untreated. As a result, bone disease exacts a huge toll on the nation. Osteoporosis, by far the most common bone disease, is responsible for approximately 1.5 million fractures each year. As many as 300,000 individuals who suffer an osteoporosis-related fracture die as a result of complications from the injury.

Concerns about the large toll that bone diseases are inflicting on the nation has led the Surgeon General to launch a major campaign aimed at improving bone health. A core component of this campaign was the Surgeon General's Workshop on Osteoporosis and Bone Health, held December 12th and 13th of 2002 in Washington, DC. This meeting served as an opportunity for key stakeholders to provide input on the most important priorities for *The Surgeon General's Report on Osteoporosis and Bone Health*, to be released in 2004.

The workshop was preceded by an invitation made through the Surgeon General's Website to the public to share ideas about the priorities for the workshop and the upcoming Surgeon General's Report. These comments emphasized the importance of public education, education and training of health professionals, better access to services, better information (especially for those at risk), and more research and guidelines for prevention, screening, diagnosis, and treatment. (Click here to see a summary of public comments.)

The workshop was designed with these public comments in mind. The goal was to identify the most important issues in bone health from a variety of perspectives, including those of the public, providers, payers, the research community, and industry. It was structured to compile the best evidence from the best minds, with the information being used as a foundation for the 2004 Surgeon General's Report. To that end, the workshop included presentations from experts in bone research and treatment, health promotion and disease prevention, Federal officials, and advocacy organizations. It also provided an opportunity to hear from people who live with bone disease every day.

Most important, the workshop included time for attendees to break into groups to discuss the challenges and opportunities for action to improve bone health within six discrete areas: 1) public awareness and marketing, 2) health care professional knowledge and attitudes, 3) research on health promotion, 4) early prevention through healthy lifestyles and awareness, 5) access to diagnosis, screening, and treatment, and 6) state and local strategies. The results from these small group discussions will help to set priorities for the writing of *The Surgeon General's Report on Osteoporosis and Bone Health*.

Workshop Proceedings

This document summarizes the views expressed by invited speakers and discussants at the Surgeon General's Workshop on Osteoporosis and Bone Health.

Welcome

*RADM Kenneth P. Moritsugu, M.D., M.P.H.
U.S. Deputy Surgeon General*

Dr. Moritsugu conveyed regrets on behalf of the Surgeon General, VADM Richard Carmona, M.D., M.P.H., F.A.C.S., who was unable to be at the meeting due to an emergency. Dr. Moritsugu read a statement from Dr. Carmona emphasizing the importance of addressing bone disease, a silent killer that robs too many Americans, especially women, of health throughout their lives. While affecting more than one in 10 Americans, bone diseases such as osteoporosis, Osteogenesis Imperfecta (OI), and Paget's Disease are largely unfamiliar to the majority of Americans. Physicians, who typically know of these diseases, are often unaware of appropriate management and treatment for them. And like many chronic diseases, osteoporosis—the most prevalent bone disease—is largely preventable. Dr. Carmona's top priority as Surgeon General is to prevent debilitation and premature mortality from all causes, including bone disease and injury, in Americans.

Dr. Moritsugu emphasized the importance of taking a public health approach to bone disease. Bone loss usually develops slowly over a lifetime. Only recently has the extent to which it affects Americans (especially women) become clear. An estimated 34 million Americans have reduced bone mass and 10 million have osteoporosis. While 80% of those with osteoporosis are women, men also suffer from bone disease. In fact, half of women and one quarter of men over the age of 50 will have an osteoporosis-related fracture sometime during their lifetime. The disease affects all races and ethnic groups; Asian women, non-Hispanic white women, Hispanic women, and African-American women over the age of 50 are all at risk for osteoporosis, although to varying degrees. Yet despite these statistics, the disease remains little understood by the general public (including those at the greatest risk) and the medical community. The vast majority of women and men with the disease remain undiagnosed and untreated today. As a result, osteoporosis imposes a huge toll on its victims. Roughly 1.5 million individuals will suffer an osteoporosis-related fracture this year. Up to 20% of those suffering hip fractures will die from injury-related complications within a year.

The good news is that the risk factors for osteoporosis are well understood and in many cases controllable. Risk factors include improper diet, lack of exercise, smoking, excessive use of alcohol, being female, being thin or having a small frame, advanced age, a family history of the disease, and a history of anorexia nervosa or low calcium intake. Dr. Moritsugu emphasized the importance of taking all these risk factors into account in developing a prevention strategy, and he highlighted the need for Americans to stop smoking and drinking, to exercise and eat well, and to get the appropriate vitamins and minerals, including calcium, into their diets. These changes will help reduce the incidence of many other diseases as well. This workshop and the upcoming Surgeon General's Report may be seen as evidence of the high priority the Surgeon General is giving to the promotion of bone health and prevention of bone disease.

*Eve Slater, M.D.
Former Assistant Secretary for Health*

Dr. Slater conveyed the gratitude of Tommy Thompson, Secretary of the Department of Health and Human Services (DHHS), to workshop attendees. Dr. Slater noted that Secretary Thompson believes that osteoporosis and bone health are both long overdue for this level of attention (i.e., a Surgeon General's

Report). Since 1964, the Surgeon General has been communicating directly with the public on important health issues. The first report on smoking had a dramatic impact on public perceptions and on smoking rates. A Gallup survey in 1958 found that only 44% of Americans believed that smoking caused cancer. By 1968 (four years after the release of the Surgeon General's Report on smoking), that figure had increased to 78%. (Part of the increase may have been driven by the 1965 Congressional mandate that cigarette packages contain a health warning; this legislation was also a reaction to the report.) More important, perhaps, smoking rates have fallen by roughly 50% since the report was issued.

Other reports by the Surgeon General have also had a major impact. The 1986 report on HIV/AIDS met with great acclaim and instant controversy. It materially affected both the public's and the medical profession's conceptions of the disease, literally changing the mindset of the nation. In closing, Dr. Slater called on workshop attendees to use their collective memories, superb reasoning skills, and imagination in proposing strategies to improve bone health.

Joan A. McGowan, Ph.D.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Dr. McGowan will serve as senior scientific editor for the Surgeon General's Report. She highlighted several of the key challenges facing the bone field, including finding ways to take actions inside and outside of health care settings to promote prevention, screening, and treatment. She called on the field to look outside of bone health for promising models and best practices. She urged workshop attendees to keep in mind the myriad forms of bone disease in their efforts. While osteoporosis is naturally the primary focus (due to its prevalence and the existence of substantial knowledge about prevention and treatment), other, rare bone diseases can also benefit from early diagnosis and intervention. Dr. McGowan noted that the U.S. is now a formal part of the *Decade of the Bone and Joint*, an international effort to raise awareness among the public and the medical community about all musculoskeletal diseases. The Surgeon General's Report will play an important role in this international effort.

Lawrence G. Raisz, M.D.

University of Connecticut Health Center

Dr. Raisz will serve as a scientific editor for the upcoming report. Noting that he and his peers (affectionately known as "bone heads") tend to focus on how to diagnose and treat bone diseases, he is especially enthusiastic and excited about the focus on prevention and public health that will be a centerpiece of the Surgeon General's Report. Dr. Raisz believes that the goal of the report should be to change the mindset about the disease. But because the problems are big, complex, and far-reaching, a simple "here's-what-to-do" prescription will not work. Getting the message out, in fact, will be a challenge. But the workshop is an excellent start, as it will produce immediate action plans. The report will build on the workshop by collating and verifying meaningful, effective strategies that can be implemented to prevent and treat bone disease throughout an individual's life (from "cradle to fracture"). The ultimate goal from this effort should be to enact a vast array of changes that collectively serve to make bone disease a thing of the past. Achieving this goal will require the collective hard work of a variety of different stakeholders.

The Burden of Disease: Bone Health, Osteoporosis, and Related Bone Diseases

The first panel focused on the basics of bone biology as well as the toll that bone disease exacts on society and individuals, in terms of the incidence, prevalence, and costs of the disease. The panel also included personal testimonials from two individuals with first-hand experience of the burdens imposed by bone disease. The panel was chaired by Vivian Pinn, M.D., of the National Institutes of Health's Office of Research on Women's Health.

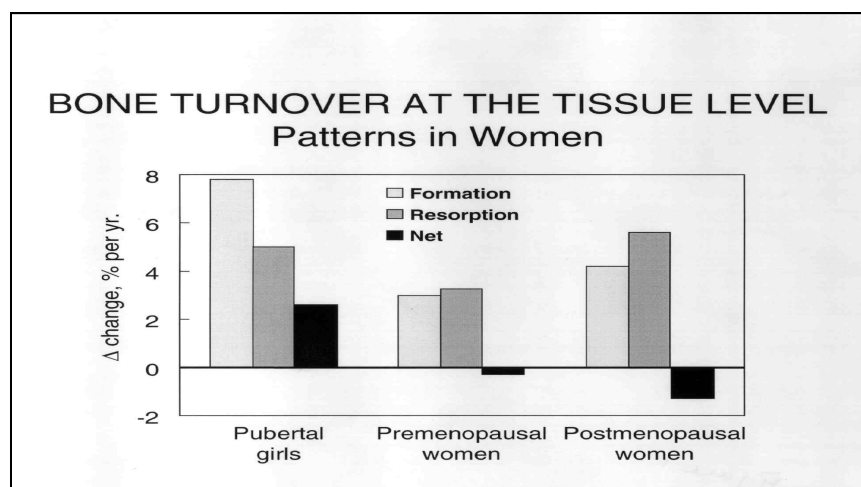
Overview of Bone Health

*B. Lawrence Riggs, M.D.
Mayo Clinic and Foundation*

Dr. Riggs reviewed the challenges and opportunities in the field of bone health. He began by describing the complex and dynamic functions of bone, which include promoting locomotion, protecting internal organs, remodeling in response to mechanical strain, remodeling to repair microdamage, remodeling to support calcium homeostasis, and producing hematologic and immune cells in the bone marrow.

The key to healthy bones is maintaining optimal levels of "bone mass." Bone mass varies over time in individuals, depending upon how much new bone is being formed and how much is being lost (also known as resorption). Bone turnover is a measure of the net rate of formation and resorption in an individual. Both men and women tend to have higher rates of formation than resorption during their childhood years (particularly around puberty). During adulthood, rates of resorption generally equal formation, leading to relatively stable levels of bone mass. After menopause, women experience periods of net bone loss, as demonstrated in Figure 1 below. Men also lose bone after age 50, although on average only half as much as women. One reason for this is that estrogen is as important to bone health for men as it is for women, but, unlike post-menopausal women, elderly men tend not to suffer a rapid decline in estrogen levels. That said, there is evidence that elderly men may face a period of rapid bone loss once they fall below a threshold level of estrogen. Roughly half of men over the age of 75 have fallen below this threshold level.

Figure 1. Bone Turnover at the Tissue Level: Patterns in Women



Source: Lawrence Riggs, Mayo Clinic.

Bone mass is determined by a variety of endogenous factors such as genetics, age, and sex, as well as exogenous factors including nutritional status (e.g., levels of calcium, protein, and Vitamin D), activity levels, environmental risk factors (e.g., smoking, alcohol consumption), presence of certain diseases, and use of certain drugs (e.g., corticosteroids).

The primary bone disease affecting Americans is age-related osteoporosis. Individuals with this disease are more prone to fractures. Fracture risk is increased by the following: low bone density, previous fractures, microstructural damage, high bone turnover, and trauma (e.g., due to a fall). Fortunately, osteoporosis is a preventable and treatable public health problem. Enormous advances have been made in understanding its pathophysiology. Effective drug therapy can help to prevent and treat the disease. The challenge is to implement education and awareness programs oriented toward the public and health care professionals. If these efforts are made, there is a very real opportunity to bring osteoporosis under control within the near future.

Unfortunately, the prospects for preventing other related bone disorders are less bright. These diseases include Paget's Disease, which affects approximately 3% of Americans over the age of 40. This localized bone disease (caused by excessive bone resorption from abnormal osteoclasts (OC) with replacement by abnormal bone) can be painful and deforming. While genetics plays a role in the disease, there is also strong evidence that the measles virus contributes as well. Fortunately, drugs known as bisphosphonates offer the potential for excellent control of (or perhaps even a "cure" for) the disease in many patients.

A rarer but more debilitating genetic bone disease is Osteogenesis Imperfecta or OI. At least six genotypes of the disease have been found, which is characterized by increased bone fragility, ranging from mild to severe. Severe fragility can result in multiple fractures, deformity, and even death before or shortly after birth. Bisphosphonate therapy has recently been shown to reduce fractures in severe cases (even among small children). Gene therapy may offer some hope for the future.

Prevalence and Burden of Illness

L. Joseph Melton, III, M.D.

Mayo Clinic and Foundation

Dr. Melton reviewed the burden caused by the most common of bone diseases, osteoporosis. He began by noting that most people have relatively stable bone mass in mid-life, but lose bone as they get older (particularly women during and after menopause).

Projecting data from the *National Health and Nutrition Examination Survey* (NHANES), it is estimated that more than 10 million Americans over the age of 50 have osteoporosis, including 7.8 million women and 2.3 million men. Another 33.6 million over the age of 50 have low bone mass and thus are at risk for osteoporosis. Looking to the future, the aging of the population will drive rapid increases in these figures, as demonstrated in Table 1.

Table 1. Projected Prevalence of Osteoporosis and/or Low Bone Mass of the Hip in U.S. Women and Men ≥ 50 Years Old

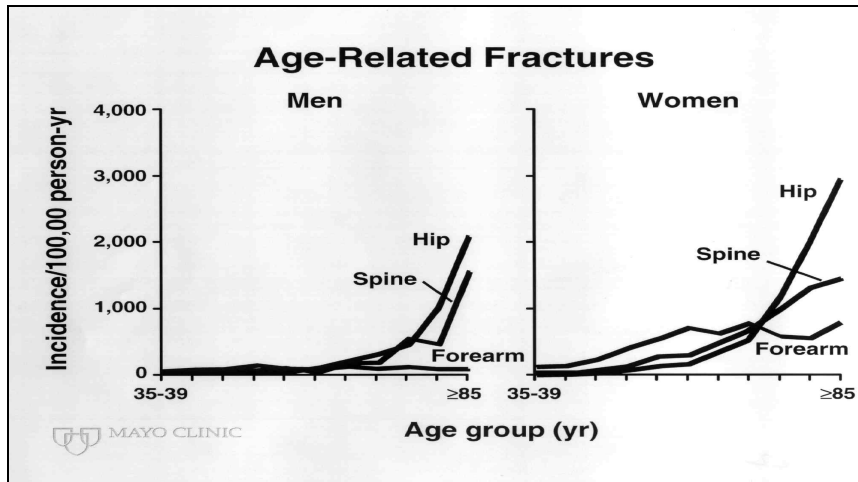
Projected Prevalence of Osteoporosis and/or Low Bone Mass of the Hip in U.S. Women and Men ≥ 50 Years Old			
	2002	2010	2020
Women			
Osteoporosis	7,800,000	9,100,000	10,500,000
Low bone mass	21,800,000	26,000,000	30,400,000
Men			
Osteoporosis	2,300,000	2,800,000	3,300,000
Low bone mass	11,800,000	14,400,000	17,100,000
Both sexes			
Osteoporosis	10,100,000	12,000,000	13,900,000
Low bone mass	33,600,000	40,400,000	47,500,000
Either	43,600,000	52,400,000	61,400,000

MAYO CLINIC America's Bone Health, NOF 2002

Source: America's Bone Health, National Osteoporosis Foundation, 2002.

The big problem with osteoporosis is the risk of a fracture, which grows exponentially as individuals age and bone mass weakens (see Figure 2 below). Dr. Melton believes that virtually all fractures in the elderly are due at least in part to low bone density. In fact, the lifetime risk of a hip, spine, or forearm fracture is nearly 40% among 50-year-old Caucasian women and more than 13% among Caucasian men. Given improving life expectancy and the increasing incidence of hip fractures, data from Sweden suggest that these risks may rise dramatically in the years ahead (see Table 2).

Figure 2. Age-Related Fractures



Source: Cooper C; Melton LJ. Epidemiology of osteoporosis. *TEM* 1992; 3:224-229, with permission from Elsevier.

Table 2. Lifetime Risk of Hip Fracture at Age 50 Years

Lifetime Risk of Hip Fracture at Age 50 Years		
	Women	Men
Current estimate	13.9%	4.6%
Adjusting for improving life expectancy	22.7%	11.1%
Adjusting for increasing hip fracture incidence	34.9%	17.0%

MAYO CLINIC

Source: L. Joseph Melton, using data from a paper by Oden A; Dawson A; Dere W; Johnell O; Jonsson B; Kanis JA. Lifetime risk of hip fractures is underestimated. *Osteoporosis Int* 1998; 8:599-603, Table 3.

Not surprisingly, individuals who suffer fractures frequently lose the ability to perform everyday functions. Dr. Melton shared data showing that roughly one in 10 individuals who suffer a hip fracture becomes functionally dependent as a result of the fracture, while nearly twice that many end up in a nursing home. In fact, 140,000 nursing home admissions each year are the direct result of a hip fracture. More than 4% of spine fracture victims become functionally dependent, while 1.9% end up in a nursing home. A study of women in Rancho Bernardo, California, found that those women suffering hip fractures are more than 11 times more likely to need help cooking meals, 4.6 times more likely to need help shopping, 2.8 times more likely to need help with heavy housework, and 1.6 times more likely to need help putting on their socks than are their peers who have not suffered a hip fracture. (See Table 3 for additional data on the disabling nature of spine and wrist fractures.)

Table 3. Risk of Functional Impairment with Minimal Trauma Fractures Among Women in Rancho Bernardo, CA

Activities	Adjusted odds of impairment		
	Hip	Spine	Wrist
Put socks on	1.6	1.7	1.1
Cook meals	11.1	6.9	10.2
Shop	4.6	5.2	3.3
Heavy housework	2.8	2.1	1.6

MAYO CLINIC
Greendale et al: J Am Geriatr Soc 43:955, 1995

Source: Greendale GA; Barrett-Connor E; Ingles S; Haile R. Late physical and functional effects of osteoporotic fracture in women: the Rancho Bernardo study. *JAGS* 1995 Sept; 43(9):955-961.

And while disability and loss of functional status may be the most common impact from fractures, a small but significant portion of women and men die as a direct result of a fracture. In fact, hip fractures alone result in a 12% to 20% decline in expected survival. Survival rates for men are much worse than for women, especially among very old men.

Dr. Melton concluded his comments by noting that osteoporosis is as prevalent as the most common chronic diseases. The risk of disabling and life-threatening fractures that are related to osteoporosis is high. Looking ahead, the incidence of fractures will increase dramatically with the aging of the population. As a result, greater investments in preventive strategies are urgently needed.

The Costs to Society

Anna Tosteson, Sc.D.

Center for the Evaluative Clinical Sciences at Dartmouth Medical School

Dr. Tosteson reviewed estimates of the economic burden imposed by bone disease. Summarizing the results of several cost-of-illness studies, she noted that the direct costs of osteoporosis in 2001 are between \$11.6 and \$17.1 billion. Data from one study suggest that the vast majority (76%) of these costs are estimated to be the result of white women who have the disease, with another 18% the result of white men. Only 6% of the costs are attributable to nonwhite men and women with osteoporosis. Hip fractures account for 63% of the costs, with other fractures accounting for 37%. Just under two-thirds (63%) of these costs are due to hospital services, with another 28% the result of nursing home care. The government pays for the lion's share of the health care costs of osteoporosis in women over the age of 45, with Medicare paying nearly half (48%) and Medicaid covering nearly a quarter (24%) of the expenses.

Osteoporosis not only imposes direct costs on society, but indirect costs as well, including the costs of morbidity and premature mortality. Moreover, as older Americans remain in the workforce, osteoporosis results in loss of productivity.

While cost-of-illness studies have helped to establish osteoporosis as a public health priority and have identified the high direct costs of the disease, they have not adequately addressed prevention, considered the economic consequences of the disease over a lifetime, or adequately measured indirect costs. To get at some of these issues, Dr. Tosteson shared the results of several cost-effectiveness studies that were designed to assess the relative value of alternative interventions. The rationale behind these types of studies is to ensure that expenditures provide benefits that are worth the additional costs. This type of analysis is especially important in an era of limited financial resources. Most cost-effectiveness studies have focused on postmenopausal women, considering single-age cohorts. These studies have helped to determine the appropriate age of intervention and the expected amount of time before the benefits of treatment are to be realized. This latter calculation can have a significant impact on the perceived benefits for different stakeholders. For example, a private insurer that covers post-menopausal women until they reach the age of 65 (and become eligible for Medicare) will typically have a 10-year time horizon. For these insurers, widespread bone density testing and medication may not be cost-effective, since relatively few fractures are likely to occur during the 10 years of coverage. On the other hand, targeted programs aimed at high-risk individuals are likely to be cost-effective for these insurers. A government insurer such as Medicare, however, may view widespread screening and interventions among postmenopausal women as highly cost-effective, as these early interventions may prevent fractures (and the associated costs of hospitalization and nursing home care) in later years.

Dr. Tosteson concluded by noting that bone diseases result in large economic costs to society, costs which are increasing. Fortunately, opportunities for cost-effective prevention and treatment are also increasing; these approaches must be identified and implemented. Successful implementation requires consideration of the impact of alternative strategies on the health of the entire population.

Personal Perspectives

The panel included presentations by two individuals whose stories demonstrate the personal burden suffered by those who live with osteoporosis and other bone diseases on a daily basis.

Linda Johnson

Linda Johnson, who suffers from osteoporosis, has become a national spokesperson on the disease. Her story is a classic example of the terrible consequences that occur when the medical profession fails to recognize the possibility of osteoporosis in a younger woman.

She began suffering bone fractures while still in her thirties. One of her most vivid memories from this time is when her young sons and daughters would remind each other “not to touch mommy because she will break.” Even as pain levels increased and her quality of life suffered, her doctor blamed her problems on clumsiness. After she turned 40, her internist attributed her problems to being a natural consequence of “getting old.” Finally, after breaking her ankle at the age of 43, an orthopedist diagnosed osteoporosis. At this point she had lost bone mass and was shorter than earlier in life, probably due to spine fractures. The doctor told her there was no treatment available for osteoporosis. He advised her to take calcium supplements and to exercise, although he provided no guidance on what types of exercises would be helpful and safe. While she had a long list of “don’ts” with respect to her life, she did find that exercise made her feel better. Yet she remained paralyzed with fear, particularly after her physician gave her the following advice: “above all else, don’t fall.”

Today at age 55, Ms. Johnson has finally turned the corner on the disease. Thanks to medical treatment, calcium supplements, and exercise, her bone mass has improved. She is no longer considered to have osteoporosis, but rather is classified as osteopenic (i.e., she has low bone mass). She has even regained some height.

As she reflects on her experience, Ms. Johnson is concerned about the millions of other individuals who have osteoporosis or who are at risk of getting it. She reminded the audience that osteoporosis is not necessarily your “grandmother’s disease.” It can affect younger individuals, and therefore it is critical for the public and medical professionals to learn more about the disease. Failure to follow this strategy may mean that the disease of osteoporosis “breaks the bank” with respect to health care costs. As Ms. Johnson noted, “people with osteoporosis do not just die; they slowly break apart.”

“People with osteoporosis do not just die; they slowly break apart.” – Linda Johnson

Jean Mandeville

Jean Mandeville offers the perspective of a parent who has two children with bone disease, a daughter (now 25 years old) with osteoporosis and a son (now 28 years old) with severe OI. Her son suffered nearly a dozen bone fractures at birth. Her instructions from the physicians upon taking him home were to “be careful.” When her son was two months old, she heard the horrible sound of his arm breaking as she turned him over in his crib. To date, he has suffered 140 fractures, some caused by acts as simple as sneezing or being startled. Fractures, however, are not the only health problems he faces. Like many OI sufferers, he also must endure problems such as scoliosis, broken teeth, hernias, kidney stones, and hearing loss. He presently requires full-time oxygen. Only three feet tall, he has never slept through the night.

Yet like many OI patients, Ms. Mandeville's son is highly intelligent and engaging, a true joy to be around. He spoke in complete sentences by the age of one and was reading at the age of two. He showed an interest in politics by age five, querying his mother on whom she was going to vote for in the presidential election, and why. His tremendous intellectual abilities and engaging personality are as much or more a part of him as are his disabilities. Like many OI sufferers, his personality and story make him an excellent spokesperson for the disease. But like all OI sufferers, he would like help as well. With limited treatment options and no possibility for prevention, OI remains a terrible disease that needs to be further researched. To that end, Ms. Mandeville called for the following: better tools to assess the strength of bones in OI patients and to evaluate the relative merits of various therapies for OI; creation of a national center for OI that could serve as a clearinghouse for information on the disease; and increased spending on OI research to reduce the burden of the disease.

The State of the Art Evidence for Diagnosis, Treatment, and Prevention in Individuals Diagnosed with Osteoporosis and Related Bone Diseases

The second panel, chaired by David Atkins, M.D., M.P.H., of the Agency for Healthcare Research and Quality (AHRQ), focused on the latest evidence related to diagnosis, treatment, and secondary prevention (i.e., preventing falls and fractures) in individuals diagnosed with osteoporosis and related bone diseases.

The Problem of Diagnosis

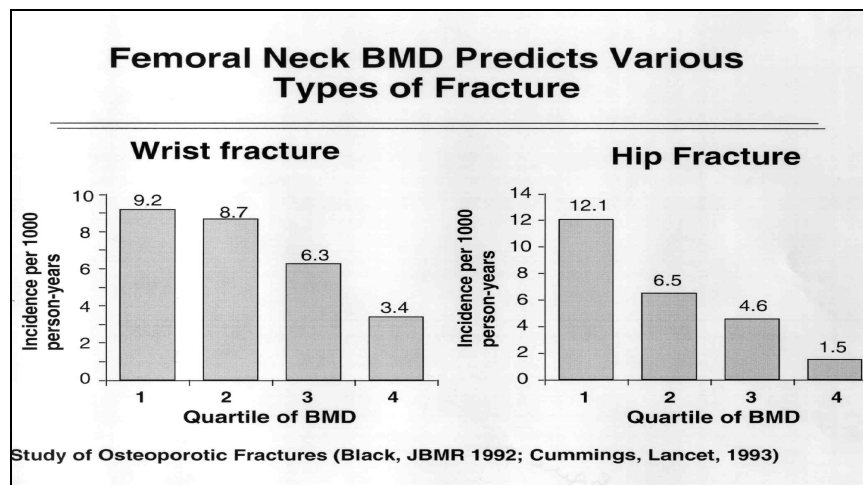
Dennis Black, Ph.D.

University of California, San Francisco

Dr. Black reviewed one of the key issues in diagnosis of osteoporosis—use of bone mineral density (BMD) measurements both as a diagnostic tool and as a risk factor for fracture. He began by describing the technology for measuring BMD. Known as a dual energy x-ray absorptiometry or DXA, this test measures BMD at multiple skeletal sites, including the spine and proximal femur. An office-based procedure that involves minimal exposure to radiation, the DXA test costs roughly \$125 and is in most instances covered by Medicare.

As illustrated in Figure 3, hip BMD is a good predictor of the risk of fractures in Caucasian women over the age of 65. Those individuals in the highest-quartile with respect to hip BMD (i.e., those with the highest levels of bone mass) are at the least risk of a fracture, while those with low hip BMD have significantly higher risk of fracture. In fact, hip BMD is a better predictor of hip fracture than are standard screening tests for other diseases. For example, BMD levels do a better job of predicting the risk of hip fracture than do cholesterol levels at predicting heart disease. That said, measurement of BMD at other parts of the body (e.g., a wrist, a heel) tends to be less predictive of fracture risk, especially hip fractures. While these peripheral tests have some advantages (they are less costly, emit less radiation, and are portable), they also tend to be less reliable as tools for predicting fracture. Because of these problems, the consensus in the field is that central densitometry should be used for a definitive diagnosis whenever possible.

Figure 3. Femoral Neck (Hip) BMD Predicts Various Types of Fractures



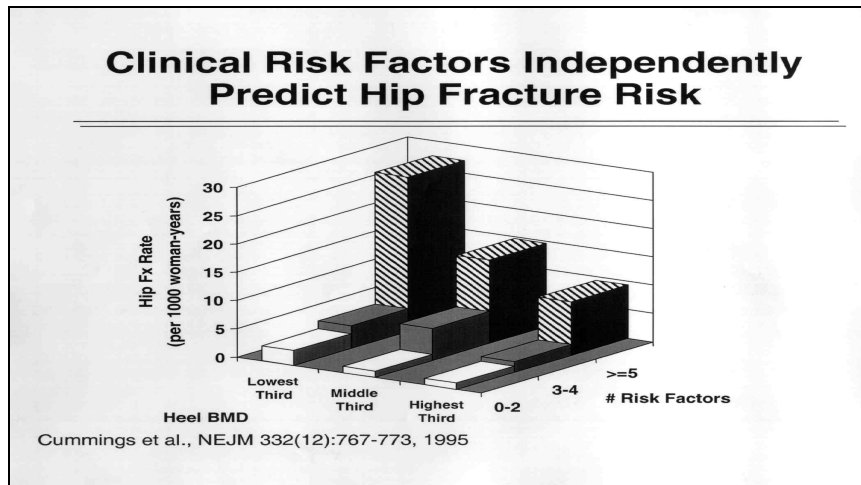
Sources: Black DM, Cummings SR, Genant HK et al. Axial and appendicular bone density predict fractures in older women. *J Bone Mineral Res* 1992; 7(6):633-638.

Cummings SR; Black DM; Nevitt MC; Browner W; Cauley J; Ensrud K, et al. Bone density at various sites for prediction of hip fractures. *Lancet* 1993 Jan; 341(8837):72-5.

Dr. Black noted the development of a classification system that translates BMD scores into diagnosis. This system relates an individual's bone density to that of a normal population of individuals. This comparison uses a "t-score" to indicate the number of standard deviations that an individual falls below or above a standardized normal BMD (0.89 grams per square centimeter, a level that occurs in most individuals around puberty). The World Health Organization (WHO) created three diagnostic categories based on t-scores. Individuals within one standard deviation of peak BMD are considered normal, those one to 2.5 standard deviations below normal are deemed to be osteopenic or have low bone mass, while those 2.5 or more standard deviations below peak BMD are considered to have osteoporosis. The National Osteoporosis Foundation (NOF) recommends that physicians seriously consider prophylactic therapy for individuals with a t-score that is two or more standard deviations below peak BMD. Individuals with known risk factors should be considered for such treatment if t-scores fall 1.5 or more standard deviations below peak BMD.

BMD, however, is not the only risk factor that is predictive of the potential for fractures. While each one-standard-deviation drop in BMD (equivalent to a 10% to 13% decrease) increases the risk of hip fracture by 2.4 times, other risk factors are also strongly predictive of hip fractures, including age (every five-year increase raises the risk of hip fracture by 50%), weight (every 20% decline in weight after the age of 25 increases the risk of hip fracture by 70%), a history of fracture since the age of 50 (which raises the risk of a hip fracture by 50%), having an existing spine fracture, or having a mother who has fractured her hip. (These latter two factors each double the risk of hip fracture.) As illustrated in Figure 4 below, these clinical risk factors are independently predictive of hip fracture risk. In other words, for a given BMD, individuals with more risk factors have a higher likelihood of suffering a hip fracture.

Figure 4. Clinical Risk Factors Independently Predict Hip Fracture Risk



Source: Cummings SR; Nevitt MC; Browner WS; Stone K; Fox KM; Ensrud KE, et al. Risk factors for hip fracture in white women. *N Eng J Med* 332(12):767-773, 1995.

Looking to the future in the field of diagnosis, Dr. Black noted that there is a movement to use fracture risk for diagnosis and to decide whether an individual needs treatment. Using BMD and other risk factors, the risk of fracture can be accurately predicted. Ongoing efforts to redefine diagnosis based on risk are currently underway; they have the potential to unify diagnosis across gender, ethnic groups, and countries. But several challenges remain, including how to integrate the risks and consequences of various fracture types, and how to alter treatment recommendations based on fracture risk. At present, treatments such as bisphosphonates have been shown to prevent nonspine and hip fractures only in those with low BMD. Thus, it is not clear what treatment, if any, will be effective for an individual who has normal BMD but has other risk factors. Other controversial issues in diagnosis include how to apply t-score categories to men and non-Caucasian women, determining optimal BMD values for treatment and optimal use of fracture risk for diagnosis, and determining the proper role (if any) for peripheral densitometry. On this latter point, Dr. Black suggested that peripheral BMD measurement could be used as a pre-screening device to raise awareness among the public.

Current and Upcoming Treatments for Fracture Prevention

Susan Greenspan, M.D.

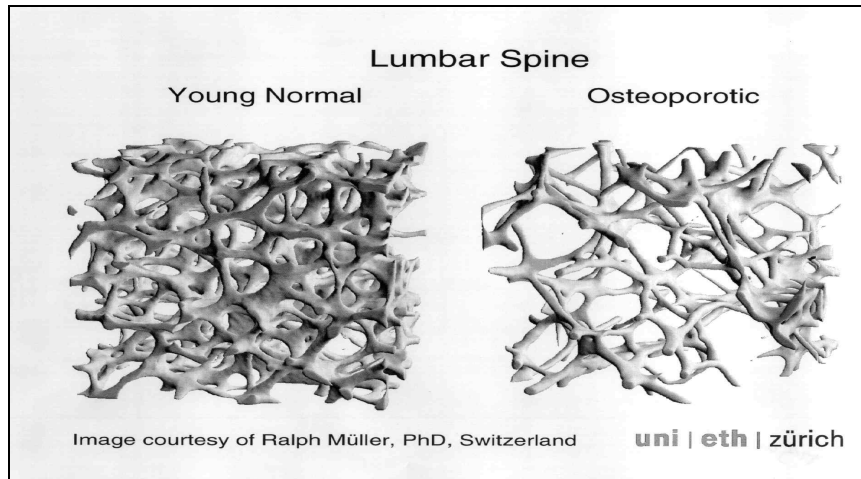
Osteoporosis Prevention and Treatment Center

Clifford Rosen, M.D.

St. Joseph Hospital

Dr. Greenspan illustrated the challenge in preventing fractures. As shown in the chart below, the goal is to prevent the young, normal bone from becoming osteoporotic bone. But when osteoporosis does occur, treatments can help to reverse this evolution, making a previously brittle bone stronger. These treatments include antiresorptive therapy that helps prevent bone loss, anabolic therapy that helps build bone, and combinations of therapies, such as two antiresorptive therapies or an antiresorptive therapy combined with an anabolic therapy. One key issue with combination therapy is whether to use the therapies at the same time (concurrently) or one after the other (sequentially).

Figure 5. Lumbar Spine



Source: Image courtesy of Ralph Müller, Ph.D., Switzerland, ETH and University Zürich.

Dr. Greenspan and Dr. Rosen reviewed the evidence to date on a variety of antiresorptive and anabolic therapies. Dr. Greenspan cautioned that there is little data that allow for head-to-head comparisons between therapies. She also noted that most studies evaluate improvements in BMD, which are not directly correlated with fracture reduction. That said, evidence suggests that the greater the improvement in BMD, the greater the fracture risk reduction (even though changes in BMD account for only about one-third of overall risk).

Antiresorptive Therapies

Antiresorptive therapies prevent bone loss and can stabilize the microarchitecture of the bone, which in turn leads to a decreased risk of fracture. Bisphosphonates such as alendronate and risedronate are among the most common antiresorptive therapies. These drugs have been shown to increase BMD at the hip and the spine, leading to a 40% to 50% reduction in spine and hip fractures over a three-year period. Evidence suggests that the benefits accrue in as little as one year for spine fractures and 18 months for hip fractures, with benefits lasting up to 10 years with alendronate and five years with risedronate. Importantly, higher BMD continues for at least several years following discontinuation of the treatment. Benefits have been shown in post-menopausal women and men with osteoporosis, patients with glucocorticoid-induced bone loss, and patients with Paget's Disease and OI. One problem with bisphosphonate therapy, however, is that the drugs are difficult for the body to absorb. Current therapies involve taking an oral medication once a week. The future may allow for a once-a-year intravenous administration of the drugs.

Hormone replacement therapy (also known as HRT or ERT for estrogen replacement therapy) has also been shown to increase BMD at the spine and hip, and to reduce the risk of spine and hip fracture in older women by 34%. Unfortunately, however, significant bone loss has been found to occur shortly after discontinuation of the therapy. This bone loss may "wipe out" any gains from the treatment. HRT has been used in postmenopausal women and women with glucocorticoid-induced osteoporosis. The key issue with HRT is whether the risks exceed the benefits. The findings from the Women's Health Initiative (WHI) suggest that HRT increases events related to heart disease as well as the risk of stroke and breast cancer. Looking ahead, the development of new types and doses of HRT may address some of these risks. Interestingly, the combination of ERT and alendronate has been found to have a greater impact on BMD in postmenopausal women than either agent used alone, and the benefits appear to continue after the therapy is discontinued. But no data exist on the impact of this combination therapy on fracture reduction. Looking ahead, studies of various combinations of this treatment must be evaluated to determine its impact on fractures and its cost-effectiveness versus other treatments.

Dr. Rosen noted that selective estrogen receptor modulators or SERMs work in a manner similar to estrogen. They have been shown to increase BMD at the hip and spine and to reduce spine fractures by 50% in postmenopausal women (although they appear to have no impact on hip or nonspine fractures). Efficacy begins three years after a treatment begins, but bone loss occurs after discontinuation of treatment. SERMs are an oral therapy that is well absorbed and causes no menstrual bleeding. Like estrogen, SERMs increase the risk of venous thromboembolisms and may result in an increase in hot flashes. But they may actually decrease the risk of breast cancer. Looking ahead, researchers will test SERMs with different risk-benefit ratios, and will further evaluate their impact on nonspine fractures.

Calcitonin is an easy-to-take, well-tolerated medication that has been shown to increase BMD at the spine modestly in postmenopausal women. One dose has been shown to decrease the risk of spine fractures by 36% (although this finding is controversial), with no reduction in the risk of hip fractures.

Anabolic Therapies

Anabolic therapies build bone. PTH (parathyroid hormone) was approved by the Food and Drug Administration (FDA) on November 27, 2002. PTH has been shown after 18 months of treatment to increase BMD at the spine and hip and to reduce the risk of spine fractures by 65% and nonspine fractures by 50%. While definitive evidence is not yet in, the treatment appears to be effective for men and postmenopausal women with osteoporosis, as well as for patients with glucocorticoid-induced osteoporosis who have failed other forms of treatment. Not surprisingly given the newness of the medication, several issues remain to be resolved, including the best way to administer the medication (it is currently injected daily), when and how to check blood calcium levels, and whether to use PTH alone or with other antiresorptive therapy. Looking ahead, other forms of PTH and other modes of administration are likely to be developed. For example, in early 2004 another form of PTH that may offer even greater potential to build bone will likely be submitted to the FDA for review. But since PTH costs \$20 per day (or \$7,200 per year), one critical issue is who to treat. Data suggest that postmenopausal women with a t-score that is two or more standard deviations below peak bone mass (1.5 or more standard deviations if other risk factors exist) can benefit, as can men with diagnosed osteoporosis. PTH is relatively effective versus alternatives in preventing spine fractures in high-risk patients, but like many other treatments has not yet been proven effective in low-risk individuals.

Combinations of Anabolic and Antiresorptive Therapies

A handful of therapies combining anabolic and antiresorptive approaches have been tested, including one that found that use of PTH and HRT is better than HRT alone. A study of PTH combined with bisphosphonate is not yet completed.

Conclusion

Dr. Rosen concluded by noting that there are effective therapies available to increase BMD and reduce spine and hip fractures. That said, the therapies differ in terms of the fracture sites they address, the amount of time that treatment lasts (and when signs of efficacy begin), and the impact on bone mass after discontinuation of therapy. Key issues to be resolved include who needs this type of preventive therapy (including what BMD cut-off should be used for men and nonwhite ethnic groups), how long treatment should last, what bone mass needs to be achieved, and whether the “cycling” of therapy (i.e., a period of treatment, followed by discontinuation for a period of time, followed by treatment again) makes sense. Looking ahead, Dr. Rosen called for the development of better guidelines to address these issues.

Development and Registration of Drugs for Osteoporosis

Henry G. Bone, M.D.

Michigan Bone and Mineral Clinic

Dr. Bone reviewed how drugs for bone disease are developed and approved. He began by describing the key measures that are used to determine a drug's efficacy at various stages of development. Early testing focuses on pharmacology measures, including blood and urine levels that help to estimate drug absorption, metabolism, and excretion. In addition, biochemical markers are measured as a means of determining the drug's impact on bone metabolism. Later in the process, the drug's impact on bone density is measured at multiple sites. This clinical test is considered very important, since bone mass is a major mechanical determinant of strength and, as noted earlier, is highly predictive of fracture. Fracture rates, however, remain the ultimate clinical outcome. Spine, nonspine, and hip fractures are typically considered separately.

Pre-clinical drug development involves the screening of millions of compounds to find one or a few that have an effect on bone. Once a compound with strong potential is discovered, it is tested on animals to determine the impact on pharmacology and toxicology. Assuming these trials suggest that the compound is safe and potentially effective, human clinical trials begin. Phase I testing involves evaluation of short-term pharmacology and safety issues in healthy individuals. The primary goal is to determine if the drug can be safely tolerated. Phase II may be the most important part of the testing, as it focuses on efficacy, dose-finding, tolerability, and the impact of the drug on biochemical markers and BMD. Roughly 1,000 individuals are involved in this phase for a period of approximately one year. Phase III may involve anywhere from 5,000 to 20,000 individuals. These trials focus on making a definitive determination of the drug's efficacy and safety, including its three-year impact on BMD and fracture rates at different skeletal sites.

Looking ahead, Dr. Bone urged drug companies and regulators to make sure that drug evaluation is as efficient as possible while still maintaining reliability. He emphasized the importance of rigor during phase II trials designed to determine the appropriate dose, and urged reconsideration of statistical requirements for evaluation of the impact of drugs on secondary fracture sites (if the drug has been proven successful at a primary site). He also called for greater coordination between the U.S. and EU regulatory authorities, and reminded drug developers and regulators not to forget about drug treatments for bone diseases other than osteoporosis.

Diagnostic and Treatment Issues for Men and Minorities

Eric Orwoll, M.D.

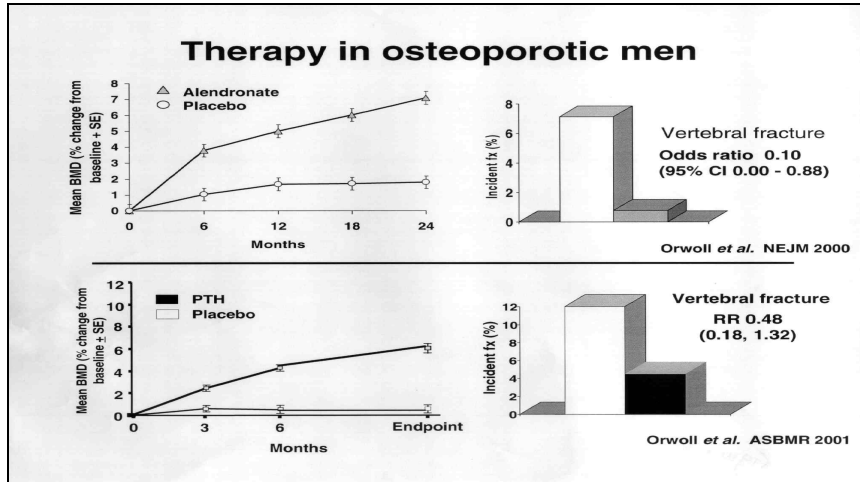
Oregon Health Sciences University

Despite the conventional wisdom that osteoporosis is a "woman's disease," many men are affected as well. Just over 13% of men aged 50 will have a fracture sometime in their life. While BMD is a good predictor of fracture risk in men, there are no set criteria for determining when men have osteoporosis and therefore need treatment. Using the same criteria that define osteoporosis in women, roughly one in seven men over the age of 80 has the disease.

Men get osteoporosis for a variety of reasons, although one-third to one-half of the cases are primarily the result of genetics. Environmental factors also play a role, including alcoholism. Men with prostate cancer who are being treated with androgen deprivation therapy are also at greater risk of bone loss.

Treatments such as alendronate and PTH have been shown to markedly increase BMD and reduce the risks of fracture in men (see Figure 6). But men are much less likely to have the disease diagnosed and treated, even after a fracture occurs (see Figure 7).

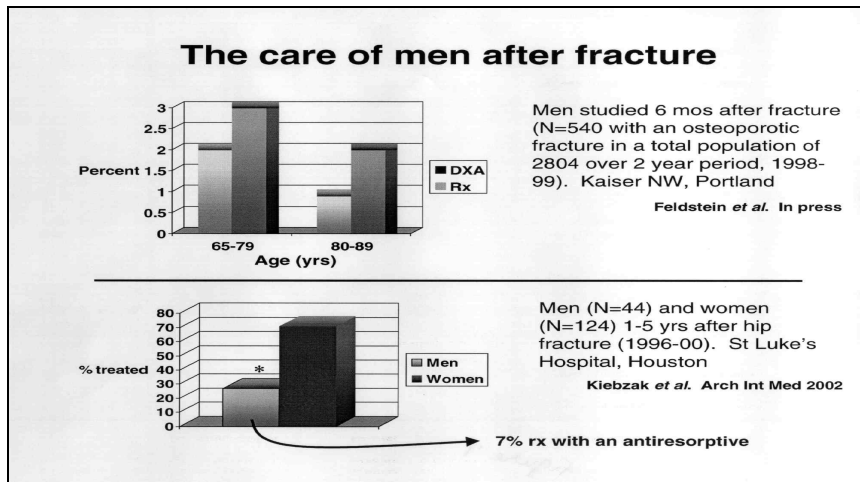
Figure 6. Therapy in Osteoporotic Men



Sources: Orwoll E; Ettinger M; Weiss S; Miller P; Kendler D; Graham J, et al. Alendronate for the treatment of osteoporosis in men. *N Engl J Med* 2000 Aug 31; 343(9):604-10.

Orwoll E; Belknap JK; Stein RK. Gender specificity in the genetic determinants of peak bone mass. *J Bone Miner Res* 2001 Nov; 16(11):1962-71.

Figure 7. The Care of Men After Fracture



Sources: Feldstein et al. In press.

Kiebzak GM; Beinart GA; Perser K; Ambrose CG; Siff SJ; Heggeness MH. Undertreatment of osteoporosis in men with hip fracture. *Arch Intern Med* 2002 Oct 28; 162 (19):2217-22.

Jane Cauley, Ph.D.
University of Pittsburgh

Caucasian women have higher rates of osteoporosis than do African-Americans and Asians, but the rate of bone loss in all ethnic groups increases with age. (Differences in body weight and the length of the hip axis appear to be important factors in explaining differences in BMD across ethnic groups.)

African-American women are more likely than Caucasian women to die from a fracture. Risk factors for African-American women are similar to those for Caucasians and include having low body weight in

relation to height (a condition known as low body mass index or low BMI—a reading below 22.6 raises the risk of hip fracture by 13.5 times), alcoholism (consuming more than seven drinks a week raises the risk of hip fracture by 4.6 times), a history of stroke (which raises the risk of hip fracture by 3.6 times), and use of ambulatory aids (which raises the risk of stroke by 5.6 times). Each one-standard-deviation decrease in BMD in African-American women raises the risk of fracture by 80%, compared to 40% for Caucasian women. Fortunately, treatments for osteoporosis appear to be effective in African-American women. A study of alendronate, for example, found that the benefits of the drug to African-American women were similar to the benefits for Caucasian women. Dr. Cauley noted that further study is needed on the efficacy of various therapeutic agents across ethnic groups.

Increasing Access to Screening and Treatment

Nelson Watts, M.D.

Osteoporosis Center, University of Cincinnati

Bone diseases are often silent conditions that exist for years before any obvious signs manifest (e.g., a fracture). The only way to definitively diagnose the disease is through a bone density test. One of the barriers to testing is coverage, since the cost of the test is relatively high. Since July 1, 1998, Medicare has covered baseline bone density testing for certain individuals that are deemed to be at risk for bone disease (e.g., estrogen-deficient women, patients with abnormalities of the spine, patients receiving long-term glucocorticoids, and patients with primary hyperparathyroidism). Payment is based on diagnoses, which are conveyed by a complex set of codes that are used inconsistently. Along with a lack of insurance coverage, the inability to travel to a testing center may also limit access to diagnostic testing. While the nation has an adequate number of central DXA machines to adequately meet the needs of the 35 million Americans—including 20.5 million women over the age of 65 and 10 million men over the age of 70—who likely need to be screened on a regular basis, the geographic distribution of these machines may make it difficult for individuals in rural regions to get access to a test.

Assuming that individuals are screened, effective pharmacologic therapies for osteoporosis are available. But coverage of these therapies by private insurance is inconsistent, while none of these drugs is covered by Medicare in the outpatient setting. Nonpharmacologic treatments such as calcium and vitamin D, physical therapy, and hip protectors, are also not typically covered.

Dr. Watts noted that the limits to access to screening and treatment for osteoporosis are similar to problems in financing and delivering care for the prevention of other chronic diseases. Looking ahead, he hopes for the development of new diagnostic strategies that are less costly, and for changes in coding and reimbursement to improve access to testing and treatment.

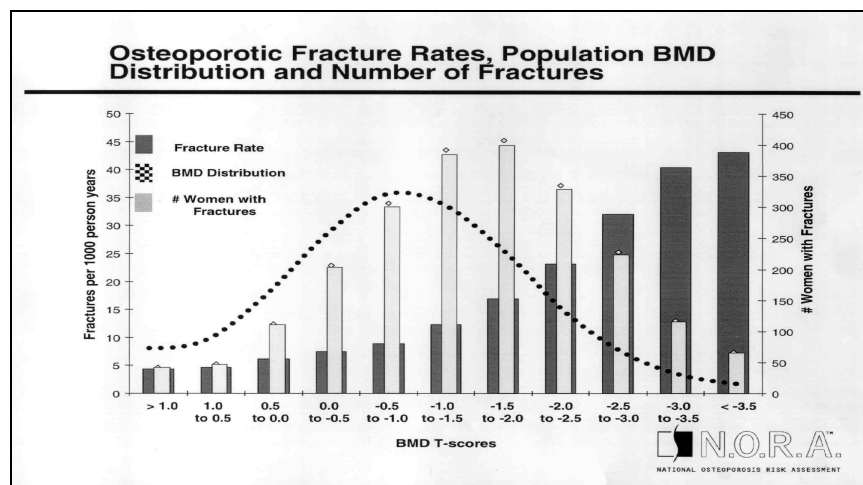
Ethel Siris, M.D.

Columbia University

Access to screening and treatment for osteoporosis begins with awareness of the problem. Dr. Siris shared data from the National Osteoporosis Risk Assessment (NORA) study, which assessed the scope of the problem of osteoporosis and osteopenia in women. This study evaluated 200,000 postmenopausal women without known osteoporosis. All women completed questionnaires on risk factors and had a BMD performed at a single peripheral site (the heel, forearm, or finger) at baseline. The study found that 7.2% of the study population had osteoporosis (defined as a t-score 2.5 or more standard deviations below peak bone mass), while 36.9% had low bone mass (defined as between 1.0 and 2.49 standard deviations below peak bone mass). Bone mass scores declined with age in all ethnic groups, including Caucasians, Asians, African-Americans, Native Americans, and Hispanics. Similarly, fracture rates were significantly higher for those with the lowest t-scores in all ethnic groups (see Figure 8). Perhaps the most interesting finding from

the study was that even though the risk of fracture is much higher in individuals with osteoporosis, the greatest absolute number of fractures occurred in individuals with low bone mass (since there are roughly five times more individuals with low bone mass than with osteoporosis). Dr. Siris emphasized the importance of finding ways to diagnose and help these individuals as well as those with osteoporosis.

Figure 8. Osteoporotic Fracture Rates, Population BMD Distribution and Number of Fractures



Source: Siris ES, Miller PD, Abbott TA, Chen Y, Faulkner K, Barrett-Connor E, Berger M, Santora A, Sherwood L. *J Bone Miner Res* 2001; 16:Suppl 1, S337.

Personal Perspectives

The panel included a presentation from an individual whose personal story highlights the need for better tools for diagnosing and treating osteoporosis.

Annie Lorigan

Ms. Lorigan is a 73-year-old woman with a long history of osteoporosis. She suffered her first fracture 18 years ago, and since that time has had eight additional fractures, each of which caused tremendous pain and required hospital stays and long periods on various medications. Unfortunately, Ms. Lorigan does not tolerate many osteoporosis medications very well. As a result, her treatment consists primarily of estrogen, Vitamin D, and calcium supplements.

Osteoporosis affects every part of her life. She must limit the time she spends with her grandchildren, as well as the types of activities she can enjoy with them. (She has fractured her back three times while playing with her grandchildren.) She finds it impossible to lie down on her back or right side, and finds it difficult to get in and out of bed or a chair. She has had to give up dancing, one of her favorite activities, and feels she has become a “drag” on family members who must slow down to accommodate her limitations.

Ms. Lorigan called for the following actions: a national education campaign focusing on early diagnosis of osteoporosis and other bone diseases (modeled after the diabetes campaign), development of new medications that are easier to tolerate, and greater understanding, patience, and compassion among doctors.

***“I had planned to spend these years enjoying my grandchildren, but I’ve really had to curtail my activities with them. I’ve fractured my back three times while playing with them”
– Annie Lorigan***

Promoting Awareness and Action

The third panel and the luncheon presentation and discussion focused on ways to promote awareness and action among the public and health care professionals. The panel was chaired by Lynne Wilcox, M.D., M.P.H., of the Centers for Disease Control and Prevention (CDC).

Promoting Public Awareness through Social Marketing

Edward Maibach, Ph.D., M.P.H.

Porter Novelli

Dr. Maibach summarized three decades of experience on education programs and behavior change with five key observations:

First, public education works, as suggested by massive secular trends in smoking rates, use of seat belts and child safety seats, cancer screening rates (e.g., mammography), and incidence of sudden infant death syndrome or SIDS. But he cautioned that public education tends to work slowly (over a period of 5 to 10 years) and that some health behaviors are more easily influenced than others through public education. For example, the SIDS campaign was effective because it targeted a highly motivated audience (parents concerned about the safety of their infant children) and because the requested behavior change was easy (putting the child to sleep on his or her back). Changing physical activity levels is a much more complex and challenging task that may take decades to achieve.

Second, the “general public” is not a valid definition of the target audience. Different people have different educational needs, and those embarking on a public education campaign must segment the audience into homogenous subsets of people, tailoring educational efforts to the extent possible to each group’s unique needs.

Third, education is not equivalent to motivation or behavior change. Knowledge gained through education does not automatically result in a change in attitude or behavior. Education requires the development and delivery of simple, clear messages that are frequently repeated. Motivation requires finding the “difference that makes a difference.” Behavior change is more likely to occur with education, motivation, and the ability to make change.

Fourth, the process works best when three critical assets are used: campaigns that are based on evidence of proven effective interventions, behaviors, or procedures; behavioral science that helps understand why people do what they do and what can be done to help them change; and consumer research that ensures that programs are relevant, credible, and motivating. Dr. Maibach warned against getting ahead of the evidence base, and cautioned that failure to conduct consumer research may cause a campaign to fail.

Fifth, the most effective campaigns are “big, messy” programs that include contributions from all sectors of society (e.g., government, nonprofit, and for-profit organizations) and a multitude of communication vehicles and program elements. That said, leadership often comes from one or a few organizations, as evidenced by the successful educational campaign on blood pressure spearheaded by the National Heart, Lung, and Blood Institute (NHLBI).

Disseminating New Information

David Chambers, Ph.D., M.Sc.

National Institute of Mental Health

Dr. Chambers reviewed key issues in disseminating new information to the public. First and foremost, he reiterated the point made by other speakers—that information presented to an audience will not necessarily lead to behavior change. Everyone does not interpret information in the same way, and the importance of

information will be related to the context in which it is disseminated. Information may evolve over time, and many individuals might choose to challenge the information being presented. Developers of education campaigns should keep tabs on changes in the field and be prepared to respond to any challenges to data or other information that is included in an awareness campaign.

Questions to be considered when developing a campaign to disseminate new information include the following:

- How was the information created? Answering this question effectively can help in responding to any challenges.
- Who is presenting the information, and how is it being presented?
- Is the information being retained by the audience and is it leading to behavior change? These may be the most critical questions.

Dr. Chambers recommended that those planning an information dissemination campaign use active and interactive methods rather than passive ones (e.g., handing out paper); involve target audiences in planning the dissemination campaign; use multiple disciplines in designing the dissemination plan; and track the outcomes of the dissemination campaign (including who received the information and whether knowledge has been gained).

Dr. Chambers also urged campaign developers to take advantage of important contributions from other fields, including social marketing (e.g., for “packaging” of messages), behavioral change (for “using” the information), organizational culture, anthropology (to help determine how different communities will react), organizational change, and finance/economics (to craft economic arguments for behavior change).

Direct-to-Consumer Advertising

Richard Kravitz, M.D., M.S.P.H.

University of California, Davis

Dr. Kravitz believes that the private sector’s financial resources and ability to reach a huge market can be brought to bear on the public health issue of bone health. Spending on direct-to-consumer (DTC) advertising reached roughly \$7.5 billion in 2000, and is expected to continue growing rapidly. DTC apparently works—drugs with the largest DTC budgets enjoy the highest sales increases, while several studies show that DTC ads are read and acted upon. For example, a random digit dial survey in Sacramento found that 56% of respondents had read an entire DTC ad. More than a third (35%) asked their physicians for more information on the drug, while 19% asked for a prescription. A binational clinic survey suggests that patients who request a prescription have an 8.7 times higher chance of getting one, even though physicians are much more ambivalent about the need for the drugs their patients request (versus those they prescribe without patient input).

Dr. Kravitz sees potential harms and benefits in DTC advertising. On the positive side, DTC advertising encourages patients to seek care when needed and allows for more informed decision making, more active involvement in care planning, and a greater understanding among patients of their conditions. At the same time, however, DTC advertising may encourage the “over-medicalization” of certain conditions and lead to too-low thresholds for when a condition requires treatment. Most important, perhaps, physicians who are inundated with questions from patients may find themselves with inadequate time to address other, more pressing clinical needs among patients.

But both the critics and the proponents of DTC advertising agree that the benefits will outweigh the risks for conditions which are under-diagnosed and under-treated, and when the net benefits of treatment are evident even among less severely affected individuals. Osteoporosis is clearly under-diagnosed and is under-treated among certain populations, including men. But the absolute benefits of treatment are clearly dependent upon the baseline risk, with high-risk individuals benefiting much more from treatment than those at lower risk. As a result, the educational value of DTC advertising can be enhanced by targeting those groups with the highest absolute risk of osteoporosis, such as elderly women and those with a previous fracture. The educational value can also be enhanced by describing benefits and risks in understandable, quantitative terms (many DTC ads do not do this at present), and by portraying drugs as playing an important role in an overall package of care for osteoporosis, a package that may also include calcium, vitamin D, exercise, and hip protectors.

Stage-Matched Interventions for Behavior Change

Sara S. Johnson, Ph.D.

Dr. Johnson presented a transtheoretical (TTM) model for behavior change that emphasizes the importance of matching interventions to an individual’s readiness for change. There are five stages of change in this model—pre-contemplation, contemplation, preparation, action, and maintenance. In other words, behavior change is a process. While an education campaign can initiate this process, it cannot sustain it. Stage-matched interventions and campaigns are needed for all levels, including those directed at individuals, providers, and communities.

Dr. Johnson shared the results of a study that applied the TTM to osteoporosis prevention and management. This survey found that 25% to 57% of individuals were in the pre-action stage with respect to key behaviors related to osteoporosis and bone health. Among these individuals, 34% to 57% were in the pre-contemplation stage. The implications from this study are clear—while a large proportion of the population may be at risk of osteoporosis and bone disease, many of these individuals are not currently contemplating behavior changes that could reduce this risk.

Changing behavior to reduce the risk of osteoporosis and bone disease is a multivariate problem requiring multivariate solutions. The process can be accelerated by matching interventions to the target audience’s readiness for change. Scientifically valid assessments can be created to measure stage, thus allowing interventions to be targeted appropriately. As a result, tailored messages can be delivered to diverse populations. But the challenge is to go beyond education to develop population-based programs for each of the behavior changes that are important to improving bone health.

Educating Health Care Professionals

Deborah Gold, Ph.D.

Duke University Medical Center

As increased life expectancy puts more people at risk for osteoporosis, the need for early, accurate diagnosis becomes more critical. While osteoporosis can be reliably diagnosed, treated, and prevented, it often goes unnoticed in patients, leading to severe physical, social, functional, and psychological consequences, including increased mortality and morbidity. Thus, improving the diagnosis and treatment of osteoporosis is a major challenge and priority for health care professionals.

Unfortunately, physicians and other professionals receive relatively little training about osteoporosis and bone health. At the undergraduate level, pre-clinical training may cover osteoporosis during study of the pathophysiology of the endocrine and/or musculoskeletal system. Osteoporosis may also be touched upon in a case presentation or standardized patient interview, and may be included in certain rotations. But overall, health professions students spend less than an hour studying osteoporosis during their undergraduate days.

The situation is little better during residencies and fellowships. Residents and fellows in most specialty areas rarely see a patient with osteoporosis. Primary care residents have little opportunity to treat osteoporosis and fractures (especially spine fractures), since most spine compression fractures are treated on an outpatient basis outside of academic teaching centers, and hip fractures are treated by orthopedic surgeons. Even residents and fellows in endocrinology and rheumatology have little exposure to the disease.

Once a physician finishes his or her formal education, continuing professional education on osteoporosis is available from a variety of sources in a variety of formats, including through provider web sites that link to the sponsors of such programs (e.g., the National Osteoporosis Foundation). Many courses are funded by unrestricted grants from corporate sponsors. While some health professionals are uncomfortable with such funding, Dr. Gold believes that these programs are generally of high quality.

Looking ahead, Dr. Gold cautioned against relying on information alone. While many health professionals have inadequate knowledge about osteoporosis and how to identify and treat it, an additional problem is the failure to apply what knowledge they do have in patient care settings. Thus, both information and application need to be stressed in all training of health professionals.

Learning from Other Campaigns

Edward Roccella, Ph.D., M.P.H.

National High Blood Pressure Education Campaign

Dr. Roccella shared insights from the National Heart, Lung and Blood Institute's (NHLBI) highly successful education campaign on high blood pressure that may be applied to any similar type of campaign on osteoporosis. The NHLBI campaign has been instrumental in dramatically increasing knowledge about blood pressure, which has led to a tripling in blood pressure control rates since the campaign began. Lessons of relevance to bone health include the following:

- Develop a focused program with reasonable, achievable objectives. Campaigns that try to do everything end up accomplishing nothing.
- Develop partnerships with other organizations that may have unique ideas and/or access to the target audience. Noting that a "rising tide lifts all ships," Dr. Roccella urged the formation of broad coalitions.

- Constantly monitor and evaluate the campaign, and make mid-course corrections as needed. Program objectives may need to shift over time.
- Knowledge alone is not enough. Rather the focus should be on application and action. In other words, as other speakers also suggested, mass media campaigns and continuing medical education alone will not spur behavior change.
- Campaigns must focus on the many “late adopters” to behavior change. Dr. Rocella urged the formation of partnerships with other organizations that may have unique access to those at greatest risk for bone disease. The same type of approach worked in developing a campaign to reduce salt use; organizers partnered with the food processing industry, which produces products that account for 80% of salt intake.

Personal Perspectives

The panel included two presentations from individuals whose illnesses illustrate the real need for greater awareness about bone disease among the public and the medical profession.

Judge Jewel Lewis

In the late 1970s, Judge Lewis was diagnosed with Paget’s Disease, a disease that affects bones by causing calcium loss in the spine (the calcium is redeposited elsewhere in the body, often the skull). At the time of her diagnosis, Judge Lewis was 5'8" tall. She was informed by doctors that there was no treatment for the disease, and that her fate was to become “a little old lady with bowed legs.” Today she is 84 years old and a foot shorter, but has not yet developed bowed legs. She has suffered a series of spine fractures, however. After finding that none of the treatments she tried as an NIH research subject worked, her primary treatment today is exercise, calcium, and vitamin D.

Paget’s Disease has had a profound impact on Judge Lewis’ life. Because she traveled for her job as a Federal administrative judge, she was forced during her time as part of the NIH research trial to carry around a refrigerated bag with her medications. Having access to this bag at all times was critical to complying with NIH’s rigid medication schedule. She is presently being treated for angina and hearing loss, both of which are a result of Paget’s Disease. Looking ahead, she urged the development of education campaigns for both the general public and the medical community on this terrible disease. She also called for frequent testing and early treatment for those with the disease.

Thomas G. Carskadon

A psychology professor and an advocate for research and screening for osteoporosis, Dr. Carskadon served as the “token male” on the panel. His story is a classic example of the failure of the medical profession to appreciate the potential for severe osteoporosis in men. When he first sprained his ankle many years ago, the doctor told him he may have a “little osteoporosis” and that he should take calcium so that the bone can “grow back.” It was not until years later, however, that he finally received a bone scan that showed he had severe osteoporosis. At this time, he continues to take bisphosphonates, which have helped him regain a bit of bone density. His BMD is presently stable, albeit at a very low level. Osteoporosis has had a profound effect on his life. He is constantly afraid of falling, and as a result seriously curtails his activities (e.g., he gave up running).

***“Where in the heck were the doctors? I had a slew of warning signs but no one picked it up.”
– Thomas G. Carskadon***

Dr. Carskadon made an impassioned plea to get the word about osteoporosis in men out to the public and to the caregivers on the front lines of medicine, and for the development of formal guidelines for screening and treatment of the disease in men. Noting that it costs only \$150 for a test that can very accurately diagnose osteoporosis, he also called for revisions to existing guidelines to make bone density tests more widely available. The failure to spend \$150 today to diagnose the disease in its early stages will inevitably lead to higher costs later in life when fractures occur. As he noted, “you can pay now or pay me later.”

The Role of the News Media in Educating the Public on Osteoporosis

Susan Dentzer

The NewsHour with Jim Lehrer

During lunch, Ms. Dentzer expanded on the issue of education and awareness by discussing the role of the news media in telling the “hard truth” about osteoporosis. Ms. Dentzer was introduced by Stephen Katz, M.D., Ph.D., Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, who noted that Dr. Elias Zerhouni, director of the National Institutes of Health, often urges his team of institute directors to “communicate, communicate, communicate!”

Ms. Dentzer believes that osteoporosis should be a major story in the media. With 10 million Americans having the disease, another 34 million at risk of developing it, and 1.5 million fractures occurring each year because of it (at a cost of \$15 billion a year), the media should be jumping on this story. If that is not enough to get the media interested, the growing costs of osteoporosis—projected to reach \$50 billion by 2040—and its association with other common conditions such as depression, lack of mobility, social isolation, and disability, should be.

Yet neither the medical community nor the media appear to be paying attention to the disease. Many doctors do not believe that osteoporosis is as big a threat to health as other diseases, such as cardiac disease, cancer, or diabetes. Many physicians, unaware of the death and disability caused by osteoporosis, view the condition as a normal part of aging. Perhaps because of this indifference among the medical community, mainstream media is also not paying much attention to osteoporosis. A review of recent literature suggests a paucity of comprehensive media coverage compared to other major diseases such as heart disease and diabetes. Ms. Dentzer’s own unscientific review of the literature found only 20 stories of a comprehensive nature since January 2001. Much more common are situations where osteoporosis receives a brief mention in a story about general women’s health issues. A good example of this approach can be seen in the recent coverage of the end of the combination hormone replacement therapy trial in the Women’s Health Initiative or WHI.

The big problem with coverage of osteoporosis is that journalists have not yet been able to “put a face” to the disease. The most popular health stories are based on anecdotes about individual patients. But even though osteoporosis affects millions—including well-known individuals like Ronald Reagan and Julia Child—there have not been any “celebrity” spokespersons for the disease, perhaps because of social stigma or the disease’s association with aging. In fact, in an era of “disease by celebrity,” there has been just one public face so far—Lauren Hutton in Wyeth’s commercials for HRT. But even in this instance, osteopenia and osteoporosis are not mentioned by name in the ads.

Ms. Dentzer also noted that it takes systematic coverage over a long period of time to get a story out to the public in a way that they truly understand. For example, a new Partnership for Prevention poll found that 69% of the 1,003 women surveyed (all between the ages of 55 and 70) had heard of or read about the WHI HRT study. Nearly six in 10 (58%) said they were concerned about the risks of HRT. But nearly one-third of the women thought that HRT helped prevent some of the diseases associated with aging, such as

heart disease, stroke, and breast cancer. (The study found that HRT actually increased the chances of getting these diseases.)

To get stories on osteoporosis out to the public, Ms. Dentzer believes that the news media needs to give osteoporosis and osteopenia a face (including a male face). The media needs to profile people with the disease, explaining what has happened to them with respect to lifestyle, disability, and poverty. The media should also graphically discuss what happens during and after a hip fracture or other bone fracture, and should publicize the large costs of these avoidable conditions. But the media must also acknowledge the limits of current knowledge about screening, prevention, and treatment. The public often becomes disenchanted when new findings contradict old ones. Thus it is critical to be honest about the fact that much is not yet known with respect to preventing and treating bone disease, and that new knowledge will be forthcoming in the years ahead.

With those limits acknowledged, the key challenge is to put forth what is believed to be known about prevention, and to clarify that taking calcium alone is likely not sufficient to solve the problem. These messages should include an emphasis on the role of exercise (especially the weight-bearing variety) in prevention, and should also stress the critical role of exercise with respect to a wide variety of health issues. Ms. Dentzer urged the bone health community to work with advocates for other diseases in developing messages on those behaviors—including diet and exercise—that have an impact that cuts across multiple diseases. Too many disease-specific messages can confuse the public. That said, the media also needs to convey specific information about the pros and cons of screening, including those situations where routine screening is recommended (e.g., for women over the age of 65). The media also needs to communicate the benefits and risks of various treatment options, including drug regimens. Finally, the media needs to get information out to physicians. Ms. Dentzer shared the results of a recent study of 114 women whose BMD tests showed osteoporosis or low bone mass. Even though these results were shared with the women's physicians, fewer than one in 10 (9.7%) patients received recommendations from their physicians that were consistent with those of NIH and NOF.

In closing, Ms. Dentzer asked health care professionals to help the media in doing a better job. To that end, she called for the Surgeon General's Report to be written in the clearest language possible. She also suggested that a conference or in-depth briefing be held for journalists in advance of the report's release. Finally, she asked that knowledgeable professionals make themselves available to the media, and that they share stories on the human suffering caused by osteoporosis as well as the research findings documenting the tremendous costs borne by society and the tremendous opportunities to reduce these costs through better prevention, screening, and treatment. But she cautioned that commercial television will always be most interested in brief "sound bites," and urged health professionals to think about these sound bites when addressing the media. She also reiterated the importance of putting a face to the disease, as the public will tend to remember personal stories, not data.

Promising Public Health Prevention Strategies for Individuals and Families in Communities

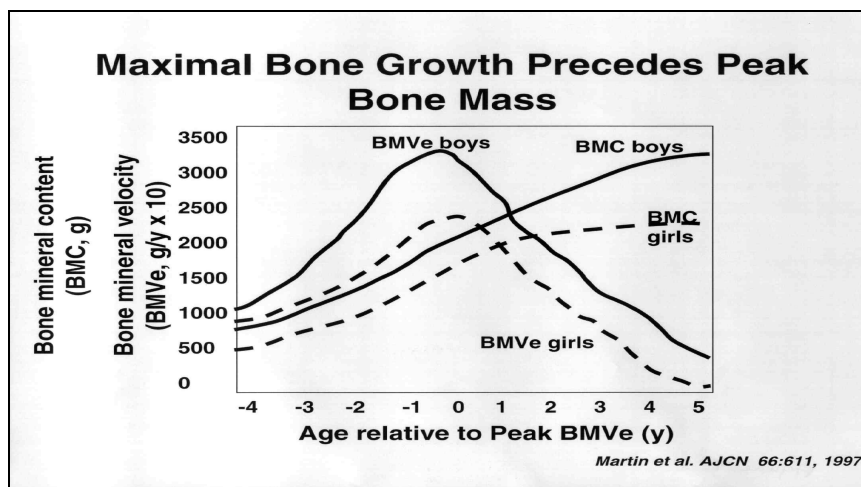
The fourth panel, chaired by CAPT Allan S. Noonan, M.D., M.P.H., of the Office of the Surgeon General, focused on promising public health prevention strategies. In moderating the session, Dr. Noonan emphasized the diversity of the different programs featured, including individual, community, and state and Federal government approaches. Collectively these initiatives provide a roadmap for how people and organizations can participate in preventing bone disease from a variety of perspectives. He also emphasized that a public health approach to preventing bone disease can ultimately help to reduce costs. Yet today the U.S. spends only 1% of its health care dollar on preventive activities. Governments at all levels—Federal, state, and local—need to increase their commitment to prevention, thereby serving as catalysts for bringing together the community to prevent bone disease and its associated complications for individuals of all ages.

What Individuals Can Do to Assure Their Future Bone Health

Connie Weaver, Ph.D.
Purdue University

Dr. Weaver reviewed the importance of good diet to building bone and to keeping bones strong. She emphasized the importance of developing healthy behaviors early in life, both because early habits carry on into later life and because there is a narrow opportunity during youth to build bone. Figure 9 illustrates this latter point, showing that the rate of accumulation in both boys and girls rises rapidly until puberty, but then falls off dramatically. Total bone mass continues to grow until later in life. Boys tend to have a steeper accumulation curve than girls, and African Americans tend to accumulate bone at a faster rate than do Caucasians.

Figure 9. Maximal Bone Growth Precedes Peak Bone Mass

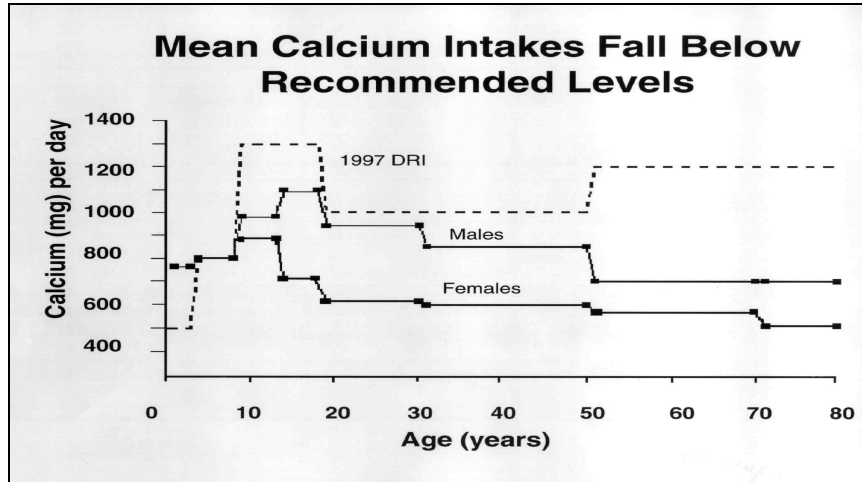


Source: Martin AD; Bailey DA; McKay HA; Whiting S. Bone mineral and calcium accretion during puberty. *Am J Clin Nutr* 1997 Sep; 66(3):611-5.

Nutrients and dietary habits help to promote calcium retention and strong bones. By getting enough calcium, vitamin D (vitamin D promotes absorption of the calcium), and other nutrients including phosphates and magnesium, individuals are more likely to build strong bones. A diet that is low in salt and full of fruits and vegetables can help to minimize the amount of calcium loss from the bone via the urine. The

net result should be a maximization of peak bone mass, minimal bone loss, and good body weight management. Unfortunately, however, most individuals are not getting adequate levels of calcium. In fact, after age 11, males, and to a greater extent females, fall below recommended levels, as exhibited in Figure 10.

Figure 10. Mean Calcium Intakes Fall Below Recommended Levels



Source: Connie Weaver.

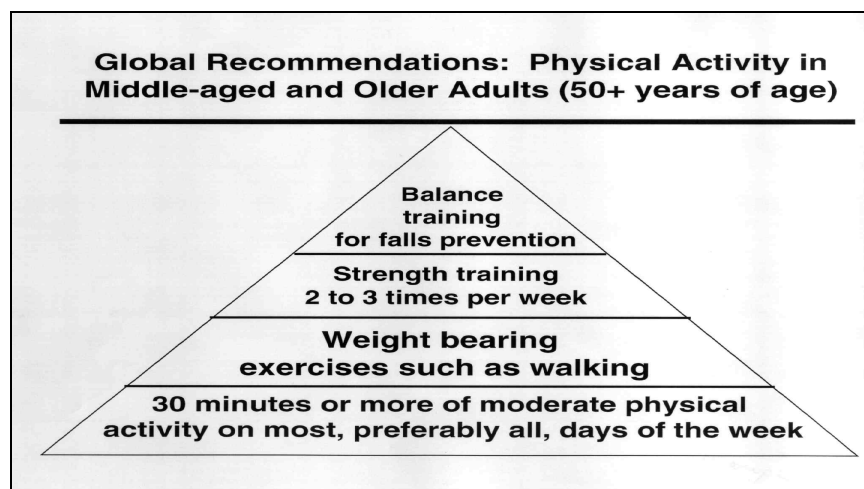
Christine M. Snow, Ph.D.
Oregon State University

Dr. Snow reviewed the unique role that exercise can play in building bone, preventing falls, and reducing fracture risk. She focused primarily upon exercise during youth and early adulthood (e.g., pre-menopause for women). Load-bearing exercises are central to bone development and maintenance. Bone-building exercises need to be site specific (i.e., they will help build bone in those areas that are the focus of the exercise) and involve “overloading” the bone through increased force and loading rates, which occurs in exercises such as jumping and aerobics. The bone-building benefits of exercise are particularly large in youth. Both impact and resistance exercises have been shown to increase bone mass by 3% to 5% and to alter bone geometry in boys and girls before adolescence. Exercise early in life appears to provide lasting benefits, as adults who engage in impact exercise during their youth have greater bone mass than those who do not.

Adults can benefit from exercise as well. Studies of premenopausal women show that spine loading exercise (e.g., rowing, upper-body lifting) increases bone density by 2% to 3%; use of a weighted vest combined with impact exercise increases hip BMD by 2% to 3% and also improves lower body strength, balance, and power; controlled impact exercises such as jumping increase hip BMD by 3%; and step aerobics and jumping increase spine and hip BMD by 1% to 2%. In some cases, these benefits can accrue with as little as 5 to 10 minutes of exercise, 5 days a week. That said, adults must continue exercising if they want to maintain these benefits. Studies show that adults lose 1% to 3% of bone mass within three to six months of ending an exercise regimen. As Dr. Snow noted, “if adults don’t use it (bone mass), they lose it.”

Dr. Nelson expanded upon Dr. Snow's comments by reviewing the benefits of physical activity in adults over the age of 50. She believes that adequate evidence exists to make the following recommendations to this population: get 30 minutes or more of moderate physical activity on most (preferably all) days of the week; and include a mix of exercises during this physical activity, such as weight-bearing exercises, strength training (two or three times a week), and balance training (to help prevent falls). These recommendations are outlined in Figure 11.

Figure 11. Global Recommendations: Physical Activity in Middle-Aged and Older Adults (50+ Years of Age)



Source: Miriam Nelson, Tufts University.

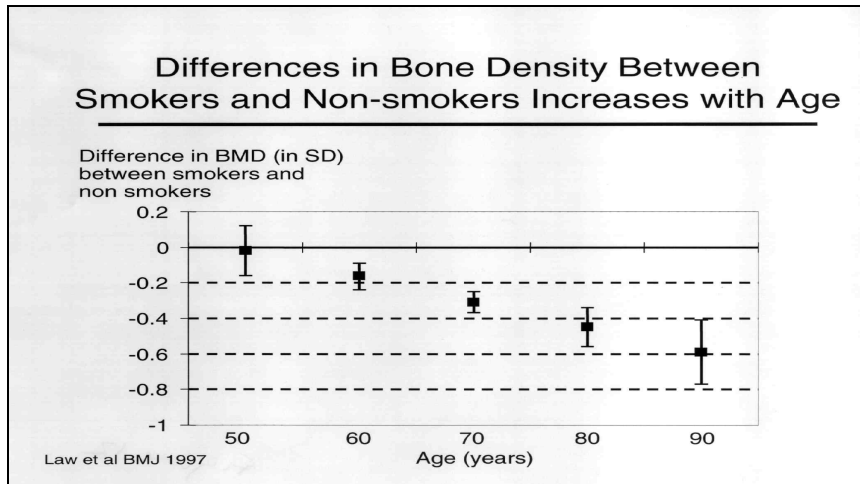
The benefits of these types of activities are significant. For example, weight-bearing exercises such as walking are associated with higher bone density. Walking more than a mile every day over long periods of time is associated with slower bone loss, and older women who walk for exercise are 30% less likely to fracture a hip. Other weight-bearing activities such as tennis and gardening are also associated with higher bone density. On a cautionary note, Dr. Nelson noted that most longitudinal studies of short-term walking—less than 12 months—show little slowing in bone loss; to maximize benefit, walking needs to be long-term and combined with other exercises.

For its part, strength training by older adults is associated with higher bone density and increased muscle strength. Studies indicate that engaging in moderate to strenuous strength-training exercises two or three times a week yields improvements in bone density of 1% to 2%. These exercises can be performed at home or in exercise facilities. Finally (and perhaps most importantly for elderly individuals), balance training helps to improve coordination and balance, and has been shown to reduce falls by 30% to 40%. These exercises can also be performed in the home.

In short, safe, culturally appropriate exercises can be fun and effective. A number of community programs for older women have been developed across the country (e.g., the Growing Stronger Program in Washington, D.C.). These programs—which can be developed wherever seniors congregate—can have a significant impact on bone health, balance, and muscle, which in turn should lead to a reduction in fractures.

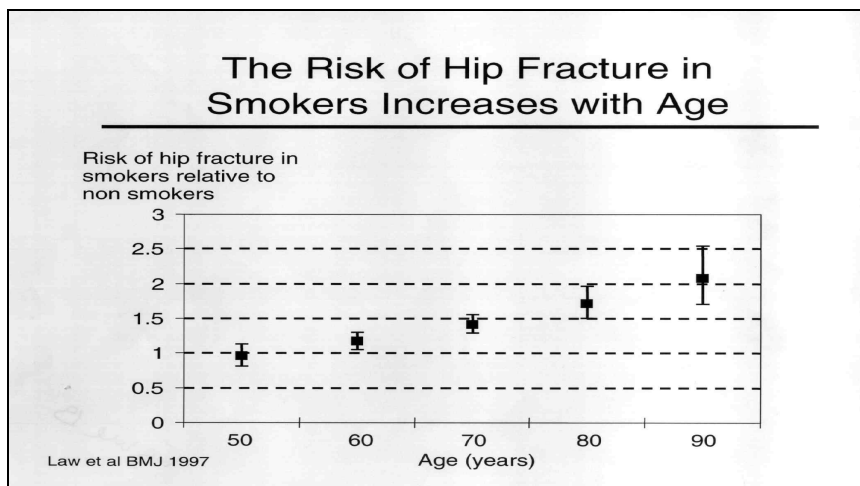
Dr. Kiel reviewed the impact of smoking on bone density and fracture rates. Smoking early in life would not appear to have an effect on bone density in either men or women. After menopause, however, women who smoke lose bone mass at a greater rate than nonsmokers (see Figure 12). The evidence also suggests a causal relationship between smoking and bone density in older men. Smokers also have a greater risk of suffering a hip fracture, particularly as they get older (see Figure 13).

Figure 12. Differences in Bone Density Between Smokers and Non-smokers



Source: Law MR; Hackshaw AK. A meta-analysis of cigarette smoking, bone mineral density and risk of hip fracture. *BMJ* 1997; 315:841-846, with permission from the BMJ Publishing Group.

Figure 13. The Risk of Hip Fracture in Smokers Increases with Age



Source: Law MR; Hackshaw AK. A meta-analysis of cigarette smoking, bone mineral density and risk of hip fracture. *BMJ* 1997; 315:841-846, with permission from the BMJ Publishing Group.

On a different but related note, Dr. Kiel also reviewed the rationale for use of hip protectors by older individuals at high risk of a hip fracture. Most hip fractures occur because of falls to the side. Energy absorption in soft tissue may account for 75% of the total energy transmitted during the fall. A hip protector system—like a car seat belt or bicycle helmet—can help to absorb much of this energy, effectively diverting it from the skeleton. A meta-analysis of six randomized controlled trials showed that hip protectors reduce the risk of hip fractures by as much as 63% to 76%. And unlike pharmacologic therapies that take one or two years before they are effective, hip protectors provide immediate benefits.

Federal Programs to Promote Bone Health for All Ages

Saralyn Mark, M.D.

National Bone Health Campaign, Office of Women's Health, Department of Health and Human Services

Dr. Mark reviewed the *National Bone Health Campaign*, a national social marketing campaign to promote bone health in girls between the ages of 9 and 18 and thus reduce their risk of osteoporosis later in life. The initial focus of the effort is on girls 9 to 12 years of age, an age range that represents a “once-in-a-lifetime” opportunity to build skeletal mass. The campaign’s tailored messages make use of parents and other adults as spokespersons, since they may have influence over the behavior of young girls.

The initiative was based on lessons learned from a series of focus groups designed to understand current knowledge levels and motivating forces among girls and their parents. The focus groups with girls found that they had little knowledge of the health benefits from calcium and physical activity, or of the amount of each they needed to promote bone health. But these girls could be motivated by messages that invoke “power” and “strength”—especially if the spokesperson is a strong, bold, confident, active female who is part of a group. Based on this research, the “Powerful Bones, Powerful Girls” campaign name was developed. For their part, parents had little knowledge of the calcium requirements or physical activity requirements for adolescent girls, although they perceived calcium to be good for overall health. (The parents’ primary concern was having their daughters eat a diet that was good for their overall health.) Barriers to achieving a healthy diet rich in calcium were as follows: a perceived need for a large quantity of food to meet the calcium requirements; a lack of time to prepare healthy, calcium-rich meals; inadequate financial resources to buy groceries and other necessities; and a lack of perceived influence over their daughter’s behavior.

The campaign was launched in September 2001. It consists of a web site for girls (www.cdc.gov/powerfulbones), advertising and promotion to girls and parents, and collateral material for girls (e.g., calendars with stickers, water bottles, and pens). Many organizations, including the Girls Scouts, Girls, Inc., and the National Association of School Nurses, are collaborating on the campaign. A web site and collateral materials for parents are currently under development, while a journal for girls will be available during the winter of 2002-2003.

The campaign appears to be reaching many individuals. During the first year, 24 million print media impressions and 986,000 broadcast impressions had been distributed, along with 1.3 million items related to the campaign. The campaign’s award-winning web site was accessed 579,000 times during the year.

John McGrath, Ph.D.

Milk Matters Program, National Institute of Child Health and Human Development

Milk Matters is a public health education campaign to increase awareness about the importance of calcium in the diets of children and adolescents. It was launched in response to growing evidence on the importance of calcium to health and the failure of children and adolescents to get adequate levels in their diets. The campaign targets health professionals and parents (as gatekeepers that influence children) as well as children and teenagers who consume calcium. The goals of the program are threefold: to create

awareness of the importance of calcium in building strong bones and a healthy body, and of milk as an excellent source of calcium; to increase knowledge about the importance of beginning osteoporosis prevention in childhood; and to change attitudes about the role of milk and other dairy foods in the diet as a source of calcium. The campaign does not make behavior change an explicit goal; the campaign's leaders felt that it was unrealistic to expect an educational campaign to have a significant influence on consumption, since its budget is small and the dairy industry funds major efforts to promote consumption of dairy products.

The primary strategy for reaching these goals is involvement and fun. For parents and health professionals, the campaign has used credible sources to develop informational products to help influence children (and in the case of health professionals, their parents). For children and teens, the campaign includes a variety of fun activities (e.g., a coloring book, a web site geared to young people) as well as educational messages that speak to children in their language through channels that they value.

Bess Dawson-Hughes, M.D.

National Institutes for Health Osteoporosis and Related Bone Diseases-National Resource Center

Founded in 1994, the NIH Osteoporosis and Related Bone Diseases National Resource Center is funded by NIAMS and six other NIH institutes and offices and is operated by NOF in partnership with the Paget and Osteogenesis Imperfecta Foundations. Headquartered in Washington, D.C. in the NOF offices, the center's mission is to increase knowledge about osteoporosis and related bone diseases, including knowledge of primary and secondary prevention strategies, diagnostic tools, and treatment options. Within the past year, the center has received 32,000 requests for information, one-third of which were from doctors.

The center is constantly focused on identifying and addressing gaps in knowledge about osteoporosis. One of the recent challenges has been to understand and reach a new audience—girls and their parents. To that end, the center has been developing culturally appropriate programs and materials targeting Hispanic girls, older Hispanic women, and older Asian women. The center is currently focused on addressing another large gap—the failure to test for (and when appropriate treat) osteoporosis in individuals with osteoporotic fractures. At present only 5% of such individuals receive testing or treatment. Through partnerships with the American Academy of Orthopedic Surgeons and other organizations, the center is distributing educational materials to physicians, patients, and family members. The materials are free of charge and are formatted to allow for easy reproduction (e.g., they can be downloaded from the center's web site).

Dr. Dawson-Hughes expressed her hope that the center could use the upcoming Surgeon General's Report as a new, fresh catalyst for the development and dissemination of effective messages about osteoporosis, including educational materials and model programs. Dr. Noonan endorsed this strategy, noting that the Surgeon General's Report should not be viewed as an end in and of itself, but rather as a foundation on which to build a wide variety of programs to promote bone health.

Suzanne Feetham, Ph.D., R.N., F.A.A.N.

Bureau of Primary Health Care

Dr. Feetham described the role of the Health Resources and Services Administration (HRSA) in addressing two critical, related issues for the future of bone health—increasing access to care and reducing health disparities across ethnic and racial groups. HRSA, also known as the “Access Agency,” seeks to improve the nation's health by assuring equal access to comprehensive, culturally competent, quality health care for all. As a safety net for U.S. health care, HRSA also assures the availability of quality health care that meets the unique needs of low-income, uninsured, isolated, vulnerable, and special-needs populations. To accomplish its goals, HRSA's Bureau of Primary Health Care operates 750 consolidated

health centers or CHCs that collectively serve 10.3 million individuals through more than 3,300 service delivery sites. These centers serve individuals of all ages, roughly two-thirds of whom are racial and/or ethnic minorities and 85% of whom have incomes that are below 200% of the Federal poverty line. President Bush has committed the Federal government to dramatically expanding the CHC program as a means of enhancing access and reducing disparities for the poor. To that end, his five-year plan calls for there to be 1,200 centers serving 16 million individuals by 2006. The challenge facing HRSA is to manage this growth while strengthening existing centers and maintaining quality.

In addition to operating CHCs, HRSA engages in a variety of collaborative initiatives in partnership with other Federal agencies that are designed to reduce health disparities and improve health outcomes by increasing leadership capacity and generating new information. Disease management collaboratives have been developed in the areas of diabetes, cancer, cardiac care, asthma, and depression. Collaboratives oriented at prevention have been launched in diabetes, healthy weight management, tobacco use, blood pressure, immunizations, lead screening, and oral health. Surgeon General Reports and Healthy People 2010 objectives have served as a catalyst for a number of these initiatives. Roughly 70% of CHCs have participated in one or more collaboratives. HRSA has embarked on several osteoporosis prevention and outreach initiatives. For example, HRSA is supporting the North Carolina Primary Care Association in forming a statewide partnership in women's health that includes osteoporosis workshops, exhibits, support groups, and train-the-trainer programs. HRSA has also worked in collaboration with other Federal agencies to support the "Powerful Girls, Powerful Bones" program in collaboration with Northeast Ohio Neighborhood Health Services. Looking ahead, Dr. Feetham sees the prevention collaboratives as a potential prototype for further work in the area of osteoporosis.

State and Community Programs to Promote Bone Health for All Ages

Denise Cyzman
Michigan Public Health Institute

Ms. Cyzman described the Michigan Osteoporosis Project (MOP), which was launched in August 1999 on the basis of an earlier strategic plan developed by the state. The project is overseen by a statewide advisory committee in collaboration with the state public health department, and is funded through a variety of sources (although the bulk of funds comes from the state and CDC, which recently funded a fall prevention program). The MOP engages in a wide variety of activities, including community interventions such as participating in statewide screening and education (including referrals and follow-up), conducting health coaching for risk reduction and school-based programs, and developing brochures for pediatricians. The MOP also offers education and tools for providers, including the development of voluntary quality assurance standards, continuing medical education, journal articles, and fall prevention programs in emergency departments and clinics. An integral part of MOP is a commitment to evaluate the outcomes from all its activities. For example, the MOP conducted an osteoporosis/arthritis behavioral risk factor survey in 2000-2001, and hopes to repeat the survey in 2003. In addition, MOP requires all subcontractors to evaluate the outcomes of individual projects. To date, MOP has been able to document increases in knowledge about osteoporosis, as well as some increase in physical activity in the schools.

Ms. Cyzman raised a concern about the fragility of state funding, which resonated with other state representatives in attendance. The Michigan state government recently terminated all funding for the MOP in response to a state budget crisis caused by the poor economy. Given that the state has historically provided \$400,000 in annual funding (out of a total budget in FY2003 of just over \$700,000), MOP's leadership will have to scramble to find other sources of funding if it is to continue to provide the same level of services. (Following Ms. Cyzman's presentation, several audience members from other states,

including Georgia, Texas, Connecticut, and South Carolina, noted that their legislatures had also reduced funding levels for programs related to bone health.)

Betty Wisner, Ed.D.

North Carolina Department of Health and Human Services

Dr. Wisner reviewed North Carolina's state osteoporosis program, which began in 1994 with an exhibit at a health and aging conference. In 1995, the first statewide osteoporosis workshop was held, with support from the private sector. This workshop proved to be a catalyst that led to a "snowballing" level of interest in osteoporosis. In 1996, the Osteoporosis Coalition of North Carolina was launched; that same year the state legislature began funding for osteoporosis programs, a commitment that continues to this day. In 1997, the legislature allocated \$200,000 for the creation of the Osteoporosis Task Force, and in 1999 expanded coverage of bone density testing for those under the age of 65.

In each of these activities, the state has relied on a coalition consisting of a variety of organizations, including cross-agency collaboration as well as partnerships with women's organizations, civic and faith groups, universities and research centers, and NOF. Over the years, the state osteoporosis program has made a variety of recommendations and has developed strategic plans, fact sheets, and reports related to osteoporosis. More than 50 workshops, 400 statewide and local exhibits, and 17 support groups have been sponsored. The most innovative of these workshops focus on "training-the-trainers"—in other words, they strive to teach community leaders how to educate the public about osteoporosis and how to mobilize support for osteoporosis education in the community. Each year the state holds an Osteoporosis Legislative Day during which free bone density screenings are offered as well as a Best Bones Night sponsored in conjunction with the Girls Scouts. The state has developed a handbook to assist support group leaders and has sponsored an hour-long call-in television program on osteoporosis.

Looking ahead, the state hopes to improve education and awareness for all North Carolinians, focusing in particular on service providers, individuals over the age of 50, and youth. As in Michigan and other states, securing and maintaining funding is an annual challenge, a task that is made easier if the program can be made more accountable for documenting the impact of its activities.

Peggy Lassanske

Elder Floridians Foundation

The Elder Floridians Foundation began its work on osteoporosis in 1997, following the passage the previous year by the state legislature of an unfunded mandate for a state education program on osteoporosis. The state's mandate was a response to evidence suggesting that the public was poorly informed about the disease, in part because physicians were not doing a good job in discussing or treating it. More than three million women in Florida are at risk for osteoporosis. Both the state and the Elder Floridians Foundation felt that greater awareness could lead to increases in screening and treatment rates, which ultimately would save the state money.

Thus, in 1997 the foundation launched *Project Osteoporosis: Be Smart, Be Dense, Know the Difference*. This community-based education and prevention program was designed to create grassroots support and a more knowledgeable public, and to encourage discussions between physicians and patients about osteoporosis. The program included a risk assessment questionnaire, a slide presentation, a free peripheral bone density test (at the wrist), and a follow-up survey. (The density test was considered to be more of an educational tool than a definitive means of diagnosis.) Through outreach and advocacy efforts, the foundation formed partnerships with industry and community groups and secured funding from the state government (\$150,000 in 1998 and \$500,000 in 1999). Since its founding, *Project Osteoporosis* has sponsored

436 programs, educated more than 50,000 individuals, and provided free peripheral screenings to more than 20,000 individuals.

Data from the baseline questionnaire and follow-up survey suggest that the program is making a difference. Between 1998 and 2002, the percentage of surveyed individuals who have discussed osteoporosis with their doctor has increased modestly (from 33% to 37%), the percent who have changed their behavior has increased significantly (from 56% to 77%), the percent who have received a diagnostic test has doubled (from 19% to 38%), and the percent who have discussed results with their doctor has increased slightly (from 53% to 55%).

Jeannie Suarez-Reyes, M.P.H.

Hispanic Girls: Theater Approach to Healthy Bones, National Alliance on Hispanic Health

The National Alliance for Hispanic Health is the oldest and largest national health and human services program oriented at improving the health and well-being of Hispanics. The organization represents all Hispanic groups, and emphasizes the use of theater as a tool for prevention. *Hispanic Girls: Theater Approach to Healthy Bones* is a pilot project funded by the NIH Osteoporosis and Related Bone Diseases National Resource Center (described earlier by Dr. Dawson-Hughes) that is intended to promote bone health among Hispanic girls between the ages of 9 and 19 through theater. The goal is to reach 1,000 girls through the community implementation site (Concilio Latino de Salud in Phoenix, AZ). Theater within the Hispanic community has historically been an effective communications vehicle that appeals to a variety of audiences (girls, parents, grandparents, and siblings) through multiple physical senses (e.g., visual, oral). More important, perhaps, theater empowers participants by transforming youths into the deliverers of messages. A small group of girls develops the script for the program, a script that emphasizes nutrition, exercise, and other healthy lifestyle behaviors. The vehicle of theater allows for the development of a more dramatic and compelling message, while still being flexible enough to adapt to the unique needs and cultures of a local group.

An independent evaluator of the project has found that it has increased knowledge about bone health among all ages, but especially among youth. Motivation levels for changing behavior are moderate to high, although participants are less sure about altering their diets to include foods high in calcium. More information about this approach, including a discussion guide and questionnaire, is available through the National Alliance for Hispanic Health.

Karen Lim

*Living Healthy: The Asian American Women's Osteoporosis Education Initiative,
National Asian Women's Health Organization*

Founded in 1993, the National Asian Women's Health Organization (NAWHO) is a nonprofit, community-based advocacy organization that has a membership of 200 organizations and 4,000 individuals in 24 states and Washington, D.C. Along with osteoporosis, programs cover a variety of issues affecting women, including violence prevention, breast and cervical cancers, diabetes, immunization, mental health, and reproductive health. Key activities include research and education, professional and public education, social marketing, leadership development, and collaboration building. The overall goal is to achieve health equity for the 30 to 50 distinct ethnic groups that make up the Asian-American community.

Postmenopausal Asian-American women are at high risk for osteoporosis due to diets low in calcium (many Asians are lactose intolerant), low weight, and small bones. One in five Asian women over the age of 50 has osteoporosis. While they vary by culture, common barriers to preventive care include language problems (the word osteoporosis does not translate into most Asian languages), low literacy rates, a lack of

orientation to preventive care (talking about a disease is viewed as “asking for it” in many Asian cultures), lack of familiarity with western medicine and health care systems, and financial constraints. In addition, most Asian-American women play the role of caregiver in their families; their own health and well-being often take a back seat.

To address these barriers, NAWHO developed *Living Healthy: The Asian-American Women’s Osteoporosis Education Initiative*. With support from the NIH Osteoporosis and Related Bone Diseases National Resource Center, this initiative involves in-language community education through the development of a culturally competent guide/curriculum for development of localized osteoporosis education seminars for post-menopausal Asian-American women. Because NAWHO cannot independently develop the 30 to 50 different programs that would be needed to reach the various Asian ethnic groups, the group decided to develop a framework that can be tailored to the unique needs of individual communities. The goals of the program are to raise awareness of risk factors and diagnostic and treatment tools for osteoporosis, and to describe the consequences of the disease. The program also encourages prevention through the adoption of positive lifestyle behaviors, including appropriate levels of diet and exercise and periodic consultation with health care providers.

To reach these goals, the *Living Healthy Implementation Kit* provides a step-by-step guide to planning, implementing, and evaluating an effective, culturally competent education seminar on osteoporosis. The kit is divided into three components: messages about osteoporosis (provided in print, orally, and visually); steps for planning, coordinating, and evaluating the seminar; and resources to assist. The kit allows local advocates to customize the seminar using a mix of topics, exercises, languages, speakers, and discussion opportunities that best meet the audience’s unique needs.

To date, the kit has been implemented in three ethnically and geographically diverse California communities through local Asian-American community-based organizations. Highlights from these experiences are as follows: less than half of the participants had heard of osteoporosis before the seminar; those that had heard of the disease thought it was a natural part of aging that could not be prevented; and community forums appear to be highly effective in increasing knowledge and changing attitudes.

Personal Perspectives

The panel included the perspectives of two individuals on the importance of education and awareness campaigns.

Katherine Moy Chin

Ms. Chin, a retired dietician and member of the Maryland Governor’s Commission on Asian Pacific American Affairs, expanded upon Ms. Lim’s remarks by emphasizing the concerns of the Asian-American population, especially for elderly and immigrant women. She reiterated the need for general education on osteoporosis, focusing on such basic questions as: What is it? Why should I care? What should I do about it? She highlighted the language barriers faced by Asian Americans, and called for bilingual educators in the schools and in organizations catering to the elderly. She called on these educators to stress the importance of diet and nutrition, but to keep in mind that many Asian Americans are lactose intolerant. And like Ms. Lim, she highlighted the need for tailored approaches that cater to the unique needs of the many different ethnic groups that comprise the Asian-American population.

Julie Gonzalez

Ms. Gonzalez is a 10-year-old, fifth-grade student who has participated in the *Strong Girls, Strong Bones* program through her *Girls Scouts* troop. Through innovative and engaging activities, this program taught her and her fellow scouts about the make-up of bones and about bone disease, including what osteoporosis is, how it affects people, and how it can be prevented. Noting that she learned a great deal and had lots of fun doing so, she called for more of these types of programs aimed at building awareness among youth.

Opportunities in Behavioral and Social Sciences Research for Addressing Osteoporosis

Raynard S. Kington, M.D., Ph.D.

Former Associate Director, Office of Behavioral and Social Sciences Research

Now Deputy Director, National Institutes of Health

The second day of the conference began with a keynote address by Dr. Kington, who heads up an office at NIH that is charged with developing and expanding the knowledge base in social and behavioral science research. The office was created by Congress eight years ago in response to the perceived need to understand how behavior and social issues relate to health. Behavioral and social sciences' research is relevant to addressing osteoporosis because such research can have an influence on interventions that are designed to elicit behavior changes that will have an impact on osteoporosis, including physical activity, smoking, and diet. Dr. Kington focused most of his remarks on the lessons to be learned from campaigns to increase physical activity and to reduce smoking rates.

With respect to physical activity, the problem facing the country is straightforward—Americans do not exercise enough. Just over 35% of men and 41% of women are physically inactive during leisure time. Only 25% of American adults engage in recommended levels of physical activity (30 minutes of moderately intense activity on five or more days a week or 20 minutes of vigorously intense activity three or more days a week). Physical activity can reduce the risk of osteoporotic fractures by increasing bone strength and by improving muscle strength and balance, which reduces the likelihood of falls. Conversely, a lack of physical activity can lead to greater prevalence of osteoporosis and increased incidence of hip fractures, as demonstrated in Table 4, which shows a clear correlation between levels of physical activity and the incidence of hip fractures.

Table 4. Hip Fracture Incidence and Hours Per Week of Physical Activity

Hip fracture incidence and hours per week of physical activity					
Activity, MET-hours/week					
	<3	3-8.9	9-14.9	15.23.9	≥24
Age-standardized	118.0	82.4	70.2	52.7	46.6
Adjusted*	230	184	155	124	100

Per 100,000 women per year

*Hip fracture incidence estimated for white women 65 years old who have never smoked, do not use postmenopausal hormones, do not drink alcohol, and are at the median level for all other covariates.

SOURCE: Feskanich et al. 2002. JAMA 288:2300-2306.

Source: Feskanich D; Willett W; Colditz G. Walking and leisure-time activity and risk of hip fracture in postmenopausal women. *JAMA* 2002 Nov 13; 288(18):2300-6. Copyrighted 2002, American Medical Association.

The successful campaign to change smoking habits (which has helped to cut the rate of smoking in half since 1964) offers some interesting lessons that can be applied to physical activity and other behaviors that have a direct impact on osteoporosis. These lessons include the following:

- Information about risk is not enough in and of itself to change behavior.
- Interventions need to be targeted at both prevention and treatment.
- It is important to intervene at multiple levels, including society at large, local communities, and individual patients.

As an example of these three lessons, Dr. Kington noted that effective smoking interventions have included efforts targeted at current users (e.g., counseling, pharmacologic therapies) as well as prevention campaigns (e.g., education, clinical information, restricting access, price increases via taxes, restrictions on smoking in public places, counter-advertising, and a stigmatization of the behavior).

But even with smoking, huge challenges remain. First and foremost, more than 20% of the population still smokes. One of the big problems in influencing smoking rates and other behaviors is how to maintain the behavior change over long periods of time. While there are many successful programs for short-term behavioral change for smoking, physical activity, and diet, relapses are very common. Only about one in four smokers who quit on their own is still not smoking after three months. One in five people who exercise regularly reports lapses of three or more months on at least three separate occasions. The average dieter loses 8% to 12% of their baseline weight within six months of beginning their diet. But by four years, the average weight loss is only 4% off the baseline. This failure to maintain behavior change raises two important research questions:

- Are the neurobiological, social/psychological, and other processes involved in adopting a new, short-term behavior change different from those for sustaining a behavior change over time?
- How should the knowledge of factors involved in initiation versus maintenance phases of behavioral change efforts determine the structure of interventions designed to maintain behaviors?

With respect to behavior change related to physical activity, several challenges remain. One relates to the physical environment, including the perceived safety of neighborhoods. Simply stated, individuals are more likely to exercise if they believe they live in a safe community. The reluctance to exercise in communities that are perceived to be unsafe is especially pronounced among older individuals. Other aspects of the physical environment must also support physical activity, including access sidewalks, walking trails, bike paths, malls, school gyms, parks, recreational facilities, and brightly lit stairwells. The U.S. Task Force on Community Preventive Services (USTFCPS) has addressed these issues through a variety of recommendations that combine information (e.g., community-wide campaigns, point-of-decision prompts for stair use), behavioral and social approaches (e.g., school-based physical education, social support interventions in community settings, individually adapted health behavior change), and environmental and policy approaches (e.g., creation of access to places for physical activity combined with informational outreach).

A second challenge involves creating a social environment that promotes physical activity. Dr. Kington noted that the social environment surrounding smoking has changed dramatically over the last 40 years. In the 1950s, smokers happily asked for a cigarette from a fellow smoker (who happily obliged). By the 1970s, smokers began asking nonsmokers for permission to smoke in their presence, and today smokers automatically excuse themselves to go outside to smoke. Attitudes about physical activity today are largely where attitudes about smoking were in the 1950s. Americans still have not made exercise a priority over other leisure-time activities, such as watching television. A social environment that promotes physical

activity must address the time constraints that people face as well as provide the family, cultural, and worksite support that individuals need.

Other research challenges related to community interventions for increasing physical activity include the following:

- New technologies to measure physical activity levels in real-world settings.
- Strategies to increase participation rates.
- Strategies to increase the long-term effectiveness of interventions.
- Better understanding of the differences between interventions for initial behavior change and behavior change maintenance.
- New approaches to increase the effectiveness of self-help interventions.
- Better understanding of how to tailor and deliver exercise programs to children and adolescents.
- Strategies for assisting racial, ethnic, and cultural diversity in populations.

An additional challenge exists for providers in clinical settings. Since the vast majority of individuals have been to a health care provider within the past year, clinical settings offer an excellent opportunity for intervention. Unfortunately, however, the USTFCPS has not found sufficient evidence demonstrating the effectiveness of behavioral counseling on physical activity by physicians (and thus has not included such counseling in its recommendations). The challenge for the research community is to determine which interventions (if any) work in clinical settings, and to create interventions that can be implemented in these settings. Finally, additional challenges facing behavioral and social science researchers in the area of osteoporosis include understanding how genes interact with social and physical environments to influence behaviors and health outcomes, and determining how to promote long-term adherence to treatment regimens. With increased life expectancies, some patients may be treated for 20, 30, even 40 years. Little is known about how to maintain compliance over this long a period of time.

Unfortunately, however, as several audience members pointed out, very few behavioral and social scientists currently work on issues related to osteoporosis. The scientists have difficulty finding funding, while agencies get few applications for funding from behavior and social scientists. To address this issue, Dr. Kington called for “two-way pressure,” with both sides making a concerted effort to find each other. He also called on various government agencies, foundations, and other organizations to form “cross-agency” relationships that focus on identifying needed positions and attracting and retaining behavioral and social scientists to fill them.

“Public health is going to be about behavior change for the next 50 years – if we don’t get this right, we won’t reach our goals on osteoporosis. This is the future of public health, but there is little recognition of this in public health departments.” – Allan S. Noonan, M.D., M.P.H.

Visions for the Future

The final panel, chaired by Dr. McGowan and Dr. Raisz, offered visions for the future of bone health and osteoporosis.

Achieving Healthy People 2010 Goals for Osteoporosis

Anne Looker, Ph.D.

National Center for Health Statistics

Released every 10 years since 1980, the *Healthy People* reports lay out the nation's prevention agenda for the coming decade. To that end, *Healthy People 2010* (HP2010) defines 467 objectives in 28 areas, including osteoporosis. Federal, state, and local governments, along with community-based organizations, use these objectives to set up prevention initiatives. Each objective is not only prevention-oriented, but also measurable; 190 different data sources are used to track the nation's progress toward these goals. More information on the program is available at www.healthypeople.gov.

The HP2010 objectives that directly relate to osteoporosis include the following: reducing cases of osteoporosis, reducing hospitalizations for spine fractures, reducing hip fractures, increasing calcium intake, and increasing physical activity. Other objectives that have relevance to osteoporosis include reducing tobacco use and substance use and abuse, increasing intake of fruits and vegetables, decreasing sodium intake, improving access to quality health services, and increasing education and community-based programs.

Dr. Looker called on audience members to think about ways for using the upcoming Surgeon General's Report to overcome the barriers to increasing the use of the current Healthy People objectives, to identify relevant data for tracking progress toward these objectives (e.g., surveys), and to promote the adoption and/or revision of osteoporosis-related objectives in Healthy People 2020 (the next version of the report, to be released in 2010).

Beyond 2010: Changing the Paradigm for an Aging Population

David Buchner, M.D., M.P.H.

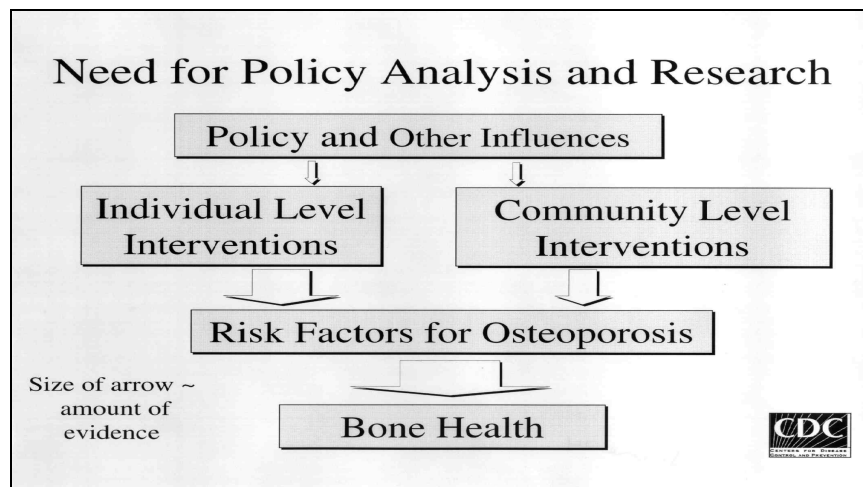
Centers for Disease Control and Prevention

Dr. Buchner emphasized the importance of changing the paradigm for how the nation thinks about public health in an era of an aging population. Noting that behavior choices are among the leading determinants of health (responsible for 40% of early death), he called for development of evidence-based, community-level interventions to promote physical activity. The key is to emphasize interventions that are easy to focus on by individuals, such as prompts to take the stairs, physical education classes in schools, and enhanced access to recreational facilities. Community-level initiatives can also help, including providing greater social support for individually-adapted behavior changes. As evidence of the potential power of this paradigm shift, Dr. Buchner shared the results of studies conducted in New Zealand which found that exercise programs delivered in a variety of settings helped to reduce falls and injuries by 35%, generating a per-fall savings of roughly \$NZ426 (or \$210 U.S.).

Dr. Buchner also believes that society needs to further debate and clarify the role of public health in chronic disease and injury prevention. This role may include surveillance, state-level plans and programs (especially those oriented at environment and policy), guidelines and best practices, partnerships, and evaluation. In this context, it is especially important that initiatives oriented at bone health be well-coordinated with those oriented at other public health problems, since many of the desired behavior changes (more exercise, better diets) cut across diseases.

Finally, Dr. Buchner highlighted the need for policy analysis and further research. As illustrated in Figure 14, relatively little is known about how policy and other influences affect the ability and willingness of individuals and communities to put interventions related to bone health in place. While more is known about how these interventions affect risk factors, and about how the risk factors affect bone health, additional research into some aspects of these causal relationships is needed as well. Finally, Dr. Buchner emphasized the importance of programs to translate research findings into practice, holding out The Robert Wood Johnson Foundation's \$10 million investment in this area as an important initiative.

Figure 14. Need for Policy Analysis and Research



Source: David Buchner, Centers for Disease Control and Prevention.

Policies to Promote Bone Health

Wojtek Chodzko-Zajko, Ph.D.

University of Illinois-Champaign

Dr. Chodzko-Zajko reviewed a collaborative program to increase physical activity among adults aged 50 and older. This initiative, known as the Blueprint Partners Project and launched after the release of the Surgeon General's Report on physical activity, may serve as a useful guide for the nation on how to effectively address osteoporosis and bone health in the future, after the Surgeon General's Report is released.

The project began with release of a national blueprint that laid out goals and objectives for the program, along with 68 strategies for increasing physical activity among older Americans. The strategies cut across five dimensions, including marketing, public policy, medical systems, home/community, and research. (Strategies that cut across these areas comprise a sixth dimension.) Perhaps the most innovative aspect of the program is that it establishes priorities for what is feasible and important to bone health. Within each of the six areas, three high-priority strategies have been identified, with a lead agency designated for leading a coalition to implement the strategy. These organizations are being held accountable for reporting back on their progress in 12 months. For example, within the area of research, the American Geriatrics Society is taking the lead on the development of evidence-based guidelines on the types and amounts of physical activity needed to enhance health and functional outcomes with a special emphasis on chronic illness and disability. The National Council on Aging is leading an effort to conduct research to understand what motivates individuals to participate in community, home-based, and work-site programs. Within the area of home and community, the American College of Sports Medicine has been charged with identifying professionals in the community who can serve as resources for information and assistance, while the National Council on Aging is leading an effort to develop a template for good physical activity programs.

Laura Tosi, M.D.
American Academy of Orthopaedic Surgeons

Dr. Tosi highlighted the need for another major paradigm shift with respect to treating osteoporosis—that is, the need for orthopaedic surgeons to re-evaluate how they traditionally take care of patients with fractures. Orthopaedic surgeons tend to focus on “fixing things” rather than on prevention. And because the bulk of fractures occurs in individuals who do not have osteoporosis, screening and treating the disease is not on most surgeons’ minds on a daily basis.

Dr. Tosi, however, believes that there are compelling arguments for changing this paradigm, arguments that surgeons can relate to. For example, the high risk of re-fracture in patients with metabolic bone disease is something that surgeons should understand and may believe they can “fix.” In addition, compelling evidence that treatment for osteoporosis works should also be a motivating factor for change. To that end, Dr. Tosi called on orthopedic surgeons to do the following: consider the possibility of metabolic bone disorder and/or osteoporosis in every fracture patient; inform the patient or patient’s family of any concerns; ensure that an evaluation is performed and/or partner with other health professionals to do so; participate in establishing clinical pathways for hospitalized patients; and document the evaluation and intervention on the patient’s chart.

“Today is a great day to convince orthopods to change”– Laura Tosi, M.D.

To help promote this major change in behavior among orthopedic surgeons, the Academy is expanding continuing medical education opportunities and publications (e.g., a brochure for orthopedic surgeons on what to do when a fractured patient comes to the office), changing the in-training exam to include questions about osteoporosis, developing a public relation campaign (known as “Breaking Tradition”) for physicians and the public, partnering in the establishment of cost-effective, evidence-based clinical pathways (especially in the area of refracture), and encouraging payers to recognize “fragility fractures” as “pathologic fractures.” Dr. Tosi would also like to see Medicare change its DRG for hip and other types of fracture to cover the costs of BMD testing in the hospital.

Judith Cranford
National Osteoporosis Foundation

NOF is an advocacy organization that works on behalf of the public. The organization operates on three fundamental principles: that advocacy drives policy (and vice versa), that advocacy based on strong scientific evidence is the key to sound, long-lasting policy, and that collaboration can help drive success. As an example of this latter point, Ms. Cranford noted that the National Bone Coalition led the effort to lobby Congress to authorize funding for the Surgeon General’s Workshop and the Surgeon General’s Report on Osteoporosis and Bone Health.

Looking to the future, NOF sees two key imperatives—reducing the prevalence of bone disease across gender and ethnicity, and improving the quality of care and the quality of life for all Americans. Reaching the first objective requires a multifaceted, multigenerational effort that must go beyond a focus on postmenopausal women. Meeting the second goal requires a myriad of activities targeted at promoting access to prevention, screening, diagnosis, treatment, and rehabilitative services. To that end, NOF is proposing a National Framework for Action, a multiyear action plan that represents the organization’s hope and vision for the future. NOF plans to implement this vision in collaboration with lead Federal and

state agencies, advocacy organizations, professional health provider organizations and societies, and other key stakeholders. The specific elements of the plan are as follows:

- Establish guidelines of care accepted nationally by agencies, insurers, facilities, providers, and other organizations that can be used to evaluate the quality of care.
- Shape education messages that resonate with consumers, providers, legislators, insurers, and other key stakeholders. Only through education can the goals be realized.
- Further improve osteoporosis prevention, diagnosis, and treatment.
- Nurture grassroots and state advocacy efforts.
- Increase research funding and encourage/retain scientists.
- Maximize use of databases to track progress. Databases must be able to interact with each other, so that best practices and new learning can quickly be shared.
- Evaluate cost-effectiveness.

In closing, Ms. Cranford urged all stakeholders to use the Surgeon General’s Workshop and subsequent Surgeon General’s Report as a landmark opportunity to come together to develop and implement a national plan of action for osteoporosis and bone health. The opportunity to have a huge influence on millions of Americans has never been greater.

“Osteoporosis may be considered silent, but as advocates, we cannot be silent.”
– Judith Cranford

Break-out Group Recommendations for the Surgeon General's Report

The workshop included time for attendees to break into six small groups to discuss challenges and opportunities to improve bone health. These challenges and recommended actions will help to set priorities and directions for the writing of *The Surgeon General's Report on Osteoporosis and Bone Health*. The groups focused on six key issues related to bone health: public awareness and marketing, health care professional knowledge and attitudes, research on health promotion (surveillance and evaluation), early prevention through healthy lifestyles and awareness, access to diagnosis, screening, and treatment, and state and local strategies.

What follows is a summary of the key insights from these discussions, organized as follows: common challenges identified by the groups, top priority areas for overcoming these challenges, and key action steps within each priority area.

CHALLENGES

- Educating and promoting awareness of bone health among policymakers, health care professionals, other professionals, and the general public, with the goal of making it a compelling issue
- Overcoming cultural pressures to maintain a certain body image
- Promoting exercise and improved eating habits in a technology-driven society that promotes sedentary lifestyles and the choice of fast food
- Clarifying mixed messages about nutritional supplements
- Delivering different messages to different audiences—there are no official mechanisms for information transfer
- Determining—in collaboration with other groups—how to avoid competing messages on healthy lifestyles (and work with complementary ones)
- Empowering patients to obtain and understand health information
- Ensuring adequate access to preventive services and treatment, in part by reducing geographic and cost barriers
- Ensuring that all providers have a strong knowledge of issues and conditions related to bone diseases; current medical education curricula does not focus adequate attention on bone health
- Forging a consensus statement among various stakeholders related to bone health care, prevention, and treatment
- Facilitating effective implementation of--and innovation within--programs to improve bone health

- Increasing basic and translational research on issues such as exercise, diagnostics, nutrition, hormones, and opportunities for prevention and ensuring adherence to recommendations
- Ensuring consistency in coverage and reimbursement at the state level
- Realizing adequate funding for programs, research, and professional education

PRIORITIES

1. Create a base of common knowledge about bones by educating individuals, communities, and society at large about the importance of healthy lifestyles throughout life to promote bone health.
2. Create and disseminate different messages tailored to different audiences.
3. Address access issues (including access to knowledge, diagnosis, and treatment) and all of their implications.
4. Help individuals and communities adopt and maintain behaviors that promote healthy lifestyles for bone health.
5. Educate health professionals to the level necessary for them to prevent, treat, and manage bone diseases.
6. Develop standards and guidelines for individuals, providers, and communities to promote bone health.
7. Create synergies and partnerships among organizations that develop or promote healthy lifestyle messages.
8. Stimulate basic, clinical, and epidemiological research to obtain better data on the surveillance, prevalence, and outcomes of interventions.
9. Raise funding levels for research, intervention programs, and education.

Priority 1: Create a base of common knowledge about bones by educating individuals, communities, and society at large about the importance of healthy lifestyles throughout life to promote bone health.

ACTION STEPS

- Define bone health throughout the life span and elevate bone health to the level of other common health concerns
- Understand the different aspects of bone health in different groups
- Identify lifestyle issues universally applicable to bone health (e.g., smoking, exercise, calcium, nutrition)

Priority 2: Create and disseminate different messages tailored to different audiences.

ACTION STEPS

- Develop both general and targeted messages for osteoporosis and other bone diseases that engage listeners (e.g., through an emotional hook)
- Bring together different perspectives to guide the development and delivery of messages
- Make development of a cohesive message on healthy lifestyles a key objective of *Healthy People 2020*
- Develop ways to evaluate messages' effectiveness and to refine as required
- Promote healthy lifestyles through point-of-decision prompts (e.g., to use the stairs rather than the elevator)
- Develop a national speaker's bureau to disseminate information about bone health and bone disease to health professionals
- Link osteoporosis to issues raised in the Institute of Medicine report on ethnic disparities in health and to the need to develop osteoporosis programs in community health centers
- Develop a modifiable web-based educational tool on bone health from which people can select appropriate levels of information about bone diseases
- Create a National Bone Education Campaign and identify celebrity spokespersons (e.g., public officials, actors) to deliver messages
- Create a clearinghouse for existing educational material

- Create a brand identity, such as a logo that is a visual cue for bone health
- Work with the media

Priority 3: Address access issues (including access to knowledge, diagnosis, and treatment) and all of their implications.

ACTION STEPS

- Develop standards of care for diagnosis and treatment of bone diseases (including for special populations such as children, the disabled, and non-Caucasian men and women) and build public awareness around these standards
- Make standard care available to all who need it, which will require adequate local resources, reimbursement, and commitment
- Promote programs sponsored by pharmaceutical companies that make drugs available to low-income individuals
- Develop less costly treatments and supplements
- Offer better financing of clinical services
- Increase availability of mobile DXA

Priority 4: Help individuals and communities adopt and maintain behaviors that promote healthy lifestyles for bone health.

ACTION STEPS

- Develop tools for volunteers and advocates to take action in local communities
- Encourage schools and work sites to make healthy food available
- Promote activity through accessible and safe indoor and outdoor space (e.g., trails, walkways, stairs)
- Develop multidisciplinary centers that house all aspects of bone health under one roof, including bone density screening, physical therapy, and other services
- Publish best practices in community interventions
- Engage policymakers in discussions of local needs

Priority 5: Educate health professionals to the level necessary for them to prevent, treat, and manage bone diseases.

ACTION STEPS

- Issue a call for inclusion of information about bone health in the curricula of health professionals
- Define basic competencies for all health professionals for the prevention and treatment of osteoporosis and other bone diseases
- Develop a tiered approach to training health professionals about bone health (e.g., use curriculum “bytes” that are appropriate at various levels of education)

Priority 6: Develop standards and guidelines for individuals, providers, and communities to promote bone health

ACTION STEPS

- Develop nutrition and exercise guidelines, curricula, and messages that are gender, age, and culturally appropriate
- Engage patients in the health care decision-making process around bone health
- Develop multidisciplinary, evidence-based protocols to promote bone health and identify and treat patients with bone disease
- Develop a simple uniform policy for the treatment of bone disease
- Identify relevant system components for quality bone health care, including the role of physicians, nurses, and physical therapists
- Identify and promote community best practices
- Expand nutritional labeling to restaurants
- Develop national practice guidelines to assist in the implementation of state-level quality-of-care programs
- Implement performance measures (e.g., HEDIS) to evaluate quality of care of bone diseases

Priority 7: Create synergies and partnerships among organizations that develop or promote healthy lifestyle messages.

ACTION STEPS

- Develop collaborative public-private partnerships to fund research, education, and interventions, and to promote access to policymakers
- Develop a committee of health professional organizations to identify clinical practice priorities and specific treatment objectives for bone disease
- Collaborate with non-medical community entities (e.g., churches and senior centers) to provide consistent information about prevention and treatment of bone disease
- Partner with the food industry on initiatives to improve bone health (e.g., approach fast food restaurants about changing the standard drink in children's meals from soda to milk, work with grocery stores to put signs in the dairy section saying “stop here for bone health”)
- Create interdisciplinary networks to shape an educational and research agenda

Priority 8: Stimulate basic, clinical, and epidemiological research to obtain better data on the surveillance, prevalence, and outcomes of interventions.

ACTION STEPS

- Develop a better understanding of the mechanisms that lead to osteoporosis, with an eye toward early interventions (e.g., for pre-menopausal women)
- Strive to alter the pathophysiology of diseases such as Osteogenesis Imperfecta and fibrous dysplasia
- Conduct further research into restorative therapies and innovative therapeutic strategies (e.g., combination therapies, sequencing of therapies, appropriate duration)
- Increase research on medical and behavioral interventions and outcomes among specific populations including providers
- Evaluate data on positive and negative messages to determine what effect they have on behavior change
- Define optimal nutrition and exercise prescriptions
- Increase research on physical activity strategies for special needs populations
- Increase epidemiological research

- Develop methods to better track trends in data on bone health
- Collect data about bone health on diverse populations to guide treatment practices
- Improve reporting of fracture incidence and develop a state and local public health fracture surveillance network across age spans
- Develop outcome measures as a database for messages to policymakers
- Increase the focus on the development of standardized, measurable objectives to achieve better bone health

Priority 9: Raise funding levels for research, intervention programs, and education.

ACTION STEPS

- Increase funding for national and state partnerships and prevention programs to promote healthy lifestyles and to expand education and outreach programs
- Have public and private payers offer separate coverage for screening and adjust codes so that they are more consistent in their coverage of screening tests
- Increase funding for research to inform innovative programs

Key Lessons and Discussion from Break-out Group Recommendations

Dr. Moritsugu highlighted the key lessons that emerged from the small-group discussions:

- **Teamwork:** Just as each individual is responsible for the product of the group, each stakeholder must play a role as a part of a team that works together to promote bone health.
- **Crosswalk of themes and issues:** Issues such as education, awareness, involvement, research, partnerships, and others cut across all the groups.
- **Richness:** Given how rich the results from the group discussion were in such a short period of time, the opportunity to tackle the issue of osteoporosis by coming together to form an integrated strategy has never been greater.

Following Dr. Moritsugu's remarks, attendees engaged in a general discussion of the break-out group recommendations. The key insights from these discussions follow.

Policy and Coding Issues

Much of the discussion centered on issues related to policy and coding. The NOF has a coding committee that is working with payers on coding issues related to osteoporosis, including bone density screenings. The Centers for Medicare and Medicaid Services (CMS) has also developed a new set of codes that should go a long way toward resolving some of the issues related to osteoporosis; providers need to be made aware of the existence of these new codes. That said, state CMS carriers still maintain control over what coding is acceptable in a local area. Each state has an advisory group to help with this issue. CMS headquarters is unlikely to change their policy of giving deference to these local carriers.

Several attendees warned that the failure to fix coding issues could lead to "unfunded mandates." For example, if the Surgeon General's Report were to recommend bone density screening for all elderly patients hospitalized with a fracture without there also being a change in Medicare DRG coding, hospitals would be under pressure to offer such screenings without payment for them. Other attendees raised policy issues that must be addressed, such as the January 2003 implementation of a \$1,500 cap on rehabilitation services for each Medicare patient. The fear is that full function cannot be restored with this type of reimbursement constraint.

Another policy issue relates to support of basic research. While much is known about bone disease and how to prevent, diagnose, and treat it, further investment in basic research is critical to filling in those many remaining gaps in knowledge and areas of uncertainty.

Partnering with Industry

Several attendees urged the development of closer collaboration with the pharmaceutical, dairy, and other industries that are major stakeholders in bone health. While their primary motive for being involved is to make profits, these industries have financial reserves that dwarf those in the bone health community. These resources can be helpful with many different types of activities, including awareness campaigns, testing of therapies (e.g., combination therapies), and other initiatives. The critical challenge is to find ways to make it in the financial interest of these companies to lend support to efforts to improve bone health. Examples of successful partnerships with private industry do exist. For example, Merck heavily supported

the NORA study. The National Cholesterol Education Campaign successfully partnered with the pharmaceutical and food industries. Formal guidelines can help to set the terms for private sector participation. Negotiations may also be necessary.

Partnering within the Medical Profession

The bone health community should consider joining forces with stakeholders (e.g., professional societies, accrediting bodies) in other areas of the health care field, including other specialties (e.g., dermatology, cardiology, and oncology). These partnerships can be valuable assets in education and training initiatives. For example, the Medical Reserve Corps is a new initiative being developed in local areas. Community volunteers in these areas are addressing a wide variety of public health issues. Information on best practices is being shared via the Internet.

Wrap-up Summary

Dr. Moritsugu closed the meeting by acknowledging the tremendous efforts of the presenters and attendees, thanking them for offering their many different valuable perspectives on the area of bone health. He also reiterated Dr. Carmona's commitment to bring hope to those suffering from bone disease and to invest in a strategy of prevention so that fewer Americans will suffer in the future. The Surgeon General's Report will be the foundation upon which to build the awareness to move all the stakeholders—patients, health providers, policymakers, the research community, and the media—into action. If the energy, knowledge, and commitment of those at the workshop are any indication, the feasibility of concerted action is high.

Dr. Moritsugu highlighted four themes that he heard repeatedly over the two days:

First, the bone health status of the population must be assessed, problem areas identified, and a better understanding developed of why there are disparities between what can be done and what is being done.

Second, the challenge of competing priorities for meeting health care needs can be overcome by developing bone health strategies that are complementary to strategies for the prevention and treatment of other chronic diseases. A good diet, physical activity, and avoiding alcohol and tobacco will help prevent not only bone disease, but also diabetes, cardiovascular disease, cancer, and a host of other illnesses. This issue is a high priority for Dr. Carmona.

Third, bone health messages should be evidence-based and targeted to specific groups of people. Too many patients—including those who shared their personal perspectives at the workshop—simply do not know what they need to about bone health and bone disease. Physicians often lack the necessary knowledge as well. But by developing evidence-based messages and communicating them to those at risk, these patients' children and grandchildren will not suffer the same unfortunate fates. Partnerships between professionals and an active, involved, informed populace are the key to success.

Finally, systems must be developed to enable health care providers to implement appropriate prevention, diagnosis, and treatment of bone diseases. Providers must be trained to use these systems.

As the nation embarks on addressing these challenges, Dr. Moritsugu urged all those involved not to forget the human aspects and the human stories, some of which were heard during the workshop. For example, Jean Mandeville offered a mother's perspective on living with the illness of her son, Jay. While she described the terrible physical complications of Osteogenesis Imperfecta, she also highlighted his deep intelligence, his engaging personality, and the other joy he brings to life. Annie Lorigan described how her osteoporosis prevents her from hugging her grandchildren too tightly or going dancing. Linda Johnson reflected on the loss of independence she has faced because of osteoporosis, while Jewel Lewis chronicled how she lost a full foot in height from Paget's Disease. Katherine Moy Chin shared the very real concerns that Asian women with bone disease face because of language and cultural barriers, while Thomas Carskadon offered a spirited—and at times light-hearted—plea for action to raise awareness among the public and medical community. And finally, the room was dead silent as 10-year-old Julie Gonzalez enthusiastically described learning about bone health with her Girl Scout troop. As Susan Dentzer noted in her remarks, these types of human stories and faces are critical to getting the message out to the public, and they are multiplied by 10 million in this country alone.

Dr. Moritsugu reiterated Dr. Carmona's desire not to write another Federal report that sits on a shelf. As Dr. Slater noted in her remarks, Surgeon General's Reports throughout the years have been catalysts for action to improve the health of Americans. Dr. Carmona is passionate about the need for action, not just talk, and is committed to seeing that the report on bone health has an equal—if not greater—impact on the lives of individuals. For those who care about bone disease, therefore, the development of this report is the beginning of a tremendous opportunity to bring about an improvement in health, an opportunity that

must be seized by everyone, since everyone has an important role to play. The key is to get the message out to providers, to those who suffer bone disease, and to the public at large about the scope of the problem, about the science of prevention, diagnosis, and treatment of bone disease, and (most importantly perhaps) about behavior change. While the media can help with the message, each stakeholder must also carry it within its sphere of influence. In closing, Dr. Moritsugu reminded the audience of Judith Cranford's warning that while "bone disease is often silent, we cannot be silent." He also made a final plea for concerted action by echoing the words of a former Surgeon General who cautioned that the "difference between what we know and what we do can be deadly."