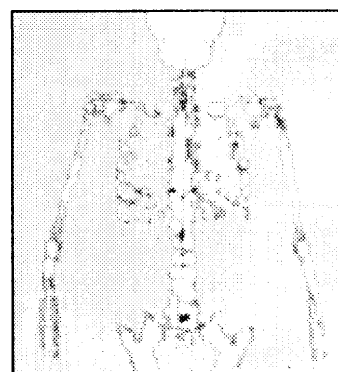


# Public Information About Osteoporosis: What's Available, What's Needed?

## INTRODUCTION AND OVERVIEW

Osteoporosis is a disease characterized by a decreased amount of bone and increased fragility of the remaining bone. Figure 1 illustrates the harmful effects of osteoporosis on bone. Because of their decreased amount of bone—usually referred to as *low bone mass* or *low bone density*<sup>1</sup>—and increased bone fragility, people who have osteoporosis are more likely than other people to experience fractures. The fractures most often attributed to osteoporosis are fractures of the wrist, spinal vertebrae, and hip, but other fractures may also be attributable to osteoporosis.<sup>2</sup>

Many people have or are at risk of osteoporosis. Estimates of the number of people affected vary, depending on several factors, including the level of bone density defined as osteoporosis. In 1993, two international panels of osteoporosis experts defined osteoporosis as bone density more than 2.5 standard deviations below average bone density in healthy young adults. Data collected between 1988 and 1991 as part of the third National Health and Nutrition Examination Survey (NHANES III), a large-scale survey of a nationally representative sample of noninstitutionalized people of all ages, indicate that 17 to 20 percent of American



<sup>1</sup>The term *bone mass* means the amount of bone mineral (primarily calcium) in a particular bone. The term *bone density* means the amount of bone mineral in a unit of bone defined in terms of either area or volume.

<sup>2</sup>The Study of Osteoporotic Fractures, a multicenter study involving more than 9,000 white women age 65 and over, found that fractures of the upper arm, collar bone, hand, rib, pelvis, leg, foot, and toe were statistically more likely to occur in women with low bone density than other women and therefore are attributable, at least in part, to osteoporosis (104).

2 | Public Information About Osteoporosis: What’s Available, What’s Needed?



women age 50 and over—approximately six to seven million women—have osteoporosis, as defined by the expert panels (55). Another 12 to 17 million women age 50 and over have low bone density, defined by the expert panels as bone density between 1 and 2.5 standard deviations below average bone density in healthy young adults (55). The comparable figures for men of all ages and women under age 50 are not yet available.

As interest and concern about osteoporosis have increased in recent years, educational materials and programs have been developed to inform the public about who is at risk of the disease and what can be done to prevent and treat it. Despite these efforts, most people are not knowledgeable about osteoporosis. Some people are simply not aware of the disease. Others are aware but not well-informed about it. Some people who are aware of osteoporosis are not worried about it. Others, who are worried about osteoporosis, are frustrated by what they perceive as a lack of information about the disease.

Each week and especially following any media report about osteoporosis, the National Osteoporosis Foundation, a private, voluntary organization, receives hundreds and sometimes thousands of calls and letters from people seeking information about the disease (95). Box 1 presents excerpts from letters that illustrate some typical questions and concerns of people who contact the National Osteoporosis Foundation for information.

In 1989, several congressional committees and individual senators and representatives requested that the Office of Technology Assessment (OTA) conduct a study of policy issues in the prevention and treatment of osteoporosis.<sup>3</sup> The request letters asked about the appropriate role of public information in the prevention and treatment of osteoporosis, to whom the information should be targeted, and what the message should be. To ad-

dress these questions, OTA identified and analyzed the available public information about osteoporosis. OTA also contracted for a survey of consumer magazines to learn what is being said about osteoporosis in these magazines and to whom the information is targeted (15).

OTA discovered a large quantity of public information about osteoporosis. As attention to women's health issues has grown in the past few years, the amount of public information about osteoporosis has also grown.

The existing print information about osteoporosis consists primarily of newspaper and magazine articles and 2- to 8-page handouts, such as fact sheets, brochures, and booklets. Broadcast information consists of news reports, public service announcements, and health information features on radio and television. The bulk of this public information is produced by the following sources:

- the mass media (i.e., television, radio, newspapers, and magazines) and commercial publishers;
- private organizations (i.e., the National Osteoporosis Foundation, other voluntary associations, health care organizations, dairy industry organizations, and pharmaceutical companies); and
- federal and state government agencies.

This OTA background paper describes the public information about osteoporosis that is available from these sources. Clearly, there is a discrepancy between the large quantity of public information about osteoporosis, on the one hand, and the perceived lack of information and most people's lack of knowledge about osteoporosis, on the other hand. OTA believes that several interrelated problems account for this discrepancy. First, the *existing public information about osteoporosis is not sufficiently disseminated*. As a result, the informa-

<sup>3</sup> OTA's study of policy issues in the prevention and treatment of osteoporosis was requested by the Senate Special Committee on Aging, Senator Charles E. Grassley, Senator John Glenn, the former House Select Committee on Aging, Representative Olympia J. Snowe, Representative Benjamin A. Gilman, and former Representatives Brian J. Donnelly, Thomas J. Downey, and Patricia F. Saiki.

## 4 | Public Information About Osteoporosis: What's Available, What's Needed?

### BOX 1: Excerpts from Letters to the National Osteoporosis Foundation

#### From Iowa

"I would like to have the latest literature you have on osteoporosis—what you can do, take, and eat that will help it from doing any more damage than it's done already for me, "

#### From Nevada

"My wife's illness has been diagnosed as osteoporosis and chronic pain. She has suffered several compression fractures in her spine. The medical center said her bones are paper-thin, and nothing could be done about her condition. If you have any information or suggestions about treatment for osteoporosis that could possibly in any way be of help to my wife or of doctors that really are the best and specialize in this area, I would truly appreciate the information."

#### From Missouri

"Your address was given over TV, 'Good Morning America,' to write to for information on osteoporosis. My bone scan shows osseous atrophy and fx deformations of T8 and T9. Severe pain started about Jan. 29th. Diagnosis—osteoporosis. I am under doctor's care, I thought if you had any information that I might read to help or learn more about osteoporosis I would appreciate this material. I am 77 years old. "

#### From Florida

"So much is written in your bulletin about prevention and almost nothing about what the patient can do herself after she gets it. I have had, for example, 4 compression fractures. Some articles about helpful exercises, activity, as well as recommended calcium and estrogen (how much) would be appreciated. We need help too. "

#### From North Dakota

"Please tell me about osteoporosis prevention. What do you think of boron? Have you heard of Ethical Nutrient Bone Builder? What do you think?"

#### From New York

Please send information for my husband who is suffering from bone deterioration. His mother has severe arthritis and osteoporosis and is now confined to a wheelchair due to her condition. My husband (55) refuses to take calcium since his dentist claims that it can cause kidney stones. Please send research substantiating the need for 1500 mg. calcium (daily) if you think it might prevent further deterioration. Could you recommend an excellent doctor in New York City who could help him?"

SOURCE: Letters provided to the Office of Technology Assessment by the National Osteoporosis Foundation, Washington, DC

(ion may not be available when people need it, and they are unlikely to know where to find it.

Second, *much of the existing public information about osteoporosis is not tailored to the different needs of particular population groups.* Although there are exceptions, most of the existing public information about osteoporosis focuses on prevention of bone loss and targets middle-aged and older white women. The focus on prevention of bone loss is appropriate for some people, but it does not meet the needs of other

people who already have osteoporosis and need to know not only how to avoid further bone loss but also how to prevent falls and fractures and how to cope with the disability and pain that often accompany the disease.

Targeting public information about osteoporosis to middle-aged and older white women is appropriate in a sense since these women are most at risk of osteoporosis. Data from NHANES III show that in each age group, women generally have lower bone density than men, and whites

generally have lower bone density than African Americans and Mexican Americans (54).<sup>4</sup> The interrelationships of age, gender, race, and ethnicity are complex, however, and bone density varies greatly among individuals of the same age, gender, race, and ethnic group. Thus, some young people have very low bone density; some men have lower bone density than some women; and some African Americans and Mexican Americans have lower bone density than some whites. Targeting public information about osteoporosis to middle-aged and older white women does not meet the needs of young people, men, and ethnic minority persons who are also at risk. In fact, this targeting probably fosters the widespread misconception that osteoporosis is a disease of middle-aged and older white women that need not concern these other groups.

Third, and most important, *much of the existing public information about osteoporosis is confusing, contradictory, and incomplete*. To some degree, this problem is inevitable, given the frequent publication of new research findings and the lack of definitive evidence for the efficacy of some proposed methods of prevention and treatment. As is true in many fields of medical research, new findings about osteoporosis raise questions about previously held ideas and make it difficult to determine exactly what constitutes accurate information about the disease at any given time.

The way the mass media present information about osteoporosis adds to the confusion and contradictions that are inevitable in a changing medical field. Research advances in osteoporosis prevention and treatment are frequently presented in brief news reports that do not place the findings in the context of other methods of prevention and treatment or make clear which individuals are most likely to benefit. The contraindications and side effects of new methods of prevention or treatment often are not reported. People who hear these news reports may, in fact, have the latest informa-

tion but still not know whether the information applies to them or how it fits with other information they may have about the disease.

Americans are increasingly urged to become informed about and take responsibility for their own health. Reports in the mass media are one way many people obtain health information. Some, and perhaps many, people use media reports as a basis for decisions about their own health care and health-related behavior. A 1990 article in *Ladies Home Journal* describes the new "Take-Charge Patient" who "does not simply follow doctors' orders" but instead wants to know everything she can about her health, understand the various options for prevention and treatment, and participate fully in decisions about her care (4). Such individuals—women and men—may go to their physician with information they have obtained from media reports and ask for particular medications or other treatments. It has been estimated that one-third of prescriptions for new medications are now written at the request of the patient (16).

The combination of these three factors—1) a changing medical field, 2) brief media reports on new research findings that may not place the findings in context or make clear which individuals are most likely to benefit from particular methods of prevention or treatment, and 3) people who depend on media reports as a primary source of health information—creates public information problems. The problems are not unique to osteoporosis, but they must be addressed by anyone who is interested in increasing public knowledge about the disease.

The growing use of the mass media to promote prescription medications adds to these public information problems. Traditionally, pharmaceutical companies have promoted prescription medications to physicians through direct mailings, personal visits by sales representatives, and advertising in medical journals. In the past dec-

<sup>4</sup> The sample for NHANES III also includes Asian Americans and Hispanic Americans other than Mexican Americans, but the number of individuals in these categories is too small to allow statistically valid estimates of their average bone density (54).

## 6 | Public Information About Osteoporosis: What's Available, What's Needed?

ade, the companies have begun promoting various kinds of prescription medications directly to consumers, usually through the mass media ( 16,45). Sometimes, the companies use print or broadcast advertisements, which have been allowed by the Food and Drug Administration (FDA) since 1985. Often, however, the companies arrange and pay for press conferences or other media events at which research findings or testimonials favorable to their products (or unfavorable to competing products) are presented.

Concerns have been expressed about the latter uses of the mass media to promote prescription medications because the sponsorship of the information often is not clear, and consumers are unlikely to realize that what they see, hear, or read based on these media events is at least in part an advertisement ( 16,45). In the case of osteoporosis, these concerns apply equally to the use of the mass media to promote nonprescription medications—e.g., calcium supplements—and dairy calcium. For these products, as well as prescription medications, the information may be either true or false, but its sponsorship often is not clear, and consumers may not realize that the information comes from an organization whose ultimate objective is to sell a product.

Box 2 describes some of the important research findings that emerged between 1990 and 1993 about etidronate, a medication proposed for the prevention and treatment of osteoporosis. The purpose of the box is not to evaluate the efficacy of etidronate. Rather its purposes are to illustrate the important role of the media in informing the public about medications proposed for osteoporosis and to point out the kinds of problems that may arise because of the way research findings are presented, variation in media coverage of different findings, and widespread dissemination of information about medications that are available on the market but not approved by the FDA for osteoporosis.

Sodium fluoride is another medication for which similar problems have arisen. Sodium fluoride is known to increase bone density and has been prescribed by some physicians for many years for their patients with osteoporosis. Like etidronate, it is available on the market but is not approved by the FDA for the prevention or treatment of osteoporosis. In 1990, the findings of a widely publicized study showed a significant increase in bone density but no reduction in the rate of new spinal fractures and an increase in nonspinal fractures in women who took sodium fluoride compared with women who did not ( 100). These findings led some osteoporosis experts to conclude that sodium fluoride should not be used for osteoporosis except for research purposes (48,53).

During a 1990 osteoporosis conference at which these negative research findings were discussed, one physician asked the speaker what he should say now to the patients for whom he had been prescribing sodium fluoride. The speaker responded that the physician should not have been prescribing an unapproved medication.

In 1994, interim findings were published from a study that is using a lower dose and different form of sodium fluoride. The interim findings show a lower rate of new spinal fractures in 48 women who are receiving sodium fluoride, compared with 51 women who are not (92). These findings were widely covered by the mass media,<sup>5</sup> leading some osteoporosis experts to worry that there will be a surge in the use of sodium fluoride before the interim findings are confirmed in the remaining years of the study or validated by other researchers.

Calcium is a third substance for which public information problems have arisen. Dietary calcium and calcium supplements are widely recommended for the prevention and treatment of osteoporosis, but recently published studies have had contradictory findings about the relationship

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<sup>5</sup>See, for example, Leary, *New York Times*, Apr. 15, 1994 (51) and *Wall Street Journal*, Apr. 15, 1994 (129).

## BOX 2: Public Information About Etidronate, 1990-93

Etidronate is a medication that has been considered for the prevention and treatment of osteoporosis for many years. It is known to reduce bone loss and was approved by the Food and Drug Administration (FDA) for treatment of Paget's disease in 1977 and for two other conditions in 1979 and 1987. Etidronate has not been approved by the FDA for the prevention or treatment of osteoporosis.

On May 3, 1990, the *New England Journal of Medicine* published the results of a three-year, randomized, double-blind, placebo-controlled study conducted in Denmark which found that spinal bone density was significantly increased in 20 postmenopausal women who took etidronate compared with 20 postmenopausal women who did not take etidronate (110). In the last two years of the study, the rate of new spinal fractures was significantly lower for the women who took etidronate, but there was no significant difference in the rate of new spinal fractures in the two groups over the full three-year period of the study. The average age of the women in the study was 68. All the women had low bone density and at least one but not more than four spinal fractures at the start of the study.

On July 12, 1990, the *New England Journal of Medicine* published the results of a second two-year, randomized, double-blind, placebo-controlled study conducted at seven sites in the United States which found that spinal bone density was significantly increased in 195 postmenopausal women who took etidronate compared with 183 postmenopausal women who did not take etidronate (131). In this study, however, the women who took etidronate had half as many new spinal fractures as the women who did not take etidronate (eight versus 17 new spinal fractures in the two groups, respectively). The average age of the women in the study was 65. All the women had low bone density and at least one but not more than four spinal fractures at the start of the study.

On the day the results of the second study were published, at least 400 newspapers nationwide carried stories about the study (25). In the following days and weeks, many magazines, newsletters, and other media carried stories about the efficacy of etidronate in increasing bone density and reducing spinal fractures.

Some women who read or heard these stories went to their doctor, some with a newspaper clipping in hand, to get a prescription for etidronate (62,90). Since etidronate is approved by the FDA for the treatment of other conditions, it is on the market, and prescriptions can be filled even though it is not approved for osteoporosis.

Etidronate causes impaired bone mineralization when taken in high doses or for prolonged periods (24,37). The recommended dose of etidronate for the treatment of Paget's disease and the other conditions for which it is approved by the FDA is higher than the dose used to treat osteoporosis in the two studies described above. Thus, some osteoporosis experts were concerned that etidronate would be prescribed in too high a dose and for too long a period and result in impaired bone mineralization and reduced bone strength (7,90).

On March 8, 1991, in a public meeting of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee, data from the U.S. study were presented, including data which showed that in the third year of the study the women who were taking etidronate had twice as many new spinal fractures as the women who were not taking etidronate (21 versus 10 new spinal fractures in the two groups, respectively) (125). Representatives of the company that produces etidronate and some osteoporosis experts argued that the third-year data should not be regarded as important because the subjects who continued in the third year of the study were self-selected, there were very few fractures overall, and the identification of spinal fractures is problematic. They argued that the increased incidence of fractures in the third year of the study in women who were taking etidronate should be regarded as an instance of spontaneous variation in fracture rates, unrelated to the use of etidronate. Nevertheless, a majority of the advisory committee voted that the data presented to them did not provide substantial evidence for the efficacy of etidronate, and the FDA did not approve the use of etidronate for the prevention or treatment of osteoporosis.

(continued)

## 8 | Public Information About Osteoporosis: What's Available, What's Needed?

### BOX 2 continued: Public Information About Etidronate, 1990–93

To OTA'S knowledge, information about the greater number of new spinal fractures in the third year of the study in women who were taking etidronate was not made known to the public in any way, although a transcript of the advisory committee meeting is available from the FDA. Public information about osteoporosis continues to describe etidronate as an investigational drug, implying that FDA approval has not yet been but probably will be obtained, and fails to note the FDA's 1991 decision not to approve it or the reasons for that decision.

OTA does not know how many women are taking etidronate for osteoporosis. Sales of etidronate increased dramatically after July 1990 (11), and some osteoporosis experts believe that a very large number of women are taking etidronate (33,94). Some osteoporosis experts have told OTA informally that they are concerned about widespread use of etidronate, particularly for middle-aged women who do not have low bone mass or spinal fractures and are taking the drug for preventive purposes. Osteoporosis experts continue to be concerned about whether women who are taking etidronate are taking an appropriate dose, and some osteoporosis experts report seeing women in their clinical practice who have been taking too high a dose of etidronate for prolonged periods (12, 94). Since etidronate is not approved by the FDA for osteoporosis, the company that produces etidronate is prohibited by FDA regulations from disseminating prescribing information for the medication.

In December 1993, the *American Journal of Medicine* published the results of four years of the U.S. study, including the final year when the study was no longer blinded (34). The study data show that the increase in bone density that occurred in the first two years of the study for the women who were taking etidronate was maintained in the third and fourth years. The number of new spinal fractures in the third year of the study is not reported in the journal article but is said by one of the researchers to be 14 new spinal fractures in the women who were taking etidronate and 10 new spinal fractures in the women who were not taking etidronate (130). (OTA does not know why these numbers differ from the numbers presented by the company to the FDA advisory committee in 1991.) The article concludes that there was no significant difference in the rate of new spinal fractures over the three-year blinded portion of the study between the women who took etidronate and the women who did not take etidronate (34). A subgroup of women was identified retrospectively for whom etidronate resulted in a significantly lower rate of new spinal fractures; these were women who had bone density below the mean for all the subjects and at least three spinal fractures at the start of the study.

In comparison with the media coverage of the July 1990 report, there was relatively little coverage of the 1993 report. As a result, the public is probably not aware of the important conclusions of the study: 1) the lack of a significant difference in the rate of new spinal fractures in the study sample as a whole between the women who took etidronate for three years and the women who did not, and 2) the existence of a subgroup of women for whom etidronate did result in a significantly lower rate of new spinal fractures.

SOURCE: Office of Technology Assessment 1994 from sources cited in the text and listed in the references section.

between calcium intake and osteoporosis.<sup>6</sup> Mass media reports of these findings have resulted in confusion about the likely effects on bone density of increased calcium intake. Often, the media re-

ports do not distinguish between different amounts of calcium intake or the effects of calcium intake on bone density in people of different ages and gender.

<sup>6</sup> See, for example, Aloia et al., 1994 (3); Dawson-Hughes et al., 1990 (19); Kanis and Passmore, 1989 (43), and Reid et al., 1993 (98).



In June 1994, the National Institutes of Health sponsored a consensus development conference to develop recommendations on optimal calcium intake for people of different ages and gender. The results of the conference will allow better targeting of public information on this issue. Since scientific research on the relationship between calcium intake and osteoporosis will continue, however, it is likely that public information problems in this area will arise again in the future.

Some of the public information problems that have arisen with respect to these three proposed methods of prevention and treatment—etidronate, sodium fluoride, and calcium—have also arisen for other methods of prevention and treatment, including estrogen and calcitonin, the only two prescription medications that are currently approved by the FDA for osteoporosis.<sup>7</sup> The same kinds of problems can be expected to arise in the future for new methods of prevention and treatment.

The ongoing development and testing of methods of prevention and treatment for osteoporosis is clearly a necessary and positive process, despite the uncertainty it engenders from time to time about the efficacy of particular methods. Likewise, media coverage of new research findings and people's desire to inform themselves about health issues are positive phenomena, despite problems they may cause. Efforts to increase public knowledge about osteoporosis must take place in the context of these phenomena, acknowledging uncertainty and devising ways to respond constructively to media coverage of new research findings and public demand for health information.

When confronted with a lack of public knowledge about a disease or condition and complaints about lack of information about the disease or

condition, public policy analysts often recommend the development of more public information materials and programs. The description in this background paper of the existing public information about osteoporosis is intended to show that a large quantity of public information already exists and to direct the attention of policy makers and others to problems in the dissemination and targeting of the existing information, as well as problems that may arise because of the way research findings are often reported in the mass media, variation in media coverage of different findings, and the widespread dissemination of information about medications that have not been approved by the FDA for osteoporosis.

In 1993, legislation was enacted requiring the director of the National Institutes of Health to provide for the establishment of a resource center on osteoporosis and related bone disorders. The resource center is intended to enhance knowledge about osteoporosis among health care professionals, patients, and the public through the effective dissemination of information (P.L. 103-43). In September 1993, the National Institute of Arthritis and Musculoskeletal and Skin Diseases issued a request for applications from organizations interested in operating the resource center. The Institute received several proposals and expects to award a grant for the resource center by September 1994 (69).

A resource center is likely to improve the dissemination of information about osteoporosis. The organization selected to operate the resource center will have to develop ways of targeting information to different population groups. If the resource center is to be fully effective, the organization that operates it will also have to develop ways of responding constructively to media reports that provide incomplete or contradictory information

<sup>7</sup> Confusion about estrogen has been less about its efficacy in preventing and treating osteoporosis and more about its efficacy in preventing cardiovascular disease and the extent to which it increases an individual's risk of breast cancer and endometrial cancer. These questions are discussed in OTA's forthcoming report on the costs and effectiveness of screening for osteoporosis. As discussed later in this background paper, the FDA's 1991 decision to change the labeling requirements for calcitonin to reflect the lack of evidence for its efficacy in reducing fractures has not been made known to the general public and, to OTA's knowledge, is not noted in current public information about osteoporosis.