THE EFFECTS OF BONE MINERAL DENSITY TESTING ON HEALTH RELATED BEHAVIOURS IN A RANDOMLY SELECTED POPULATION OF CANADIANS

by

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Abstract

Osteoporosis is a major health problem that can be mitigated by accurate prediction of future risk for bone fractures. Bone mineral density (BMD) testing can be conducted to assess people's risk of fracture, but its value rests on the ability to provide risk information effectively to those individuals who have low BMD; those individuals must then be willing to initiate and maintain recommended lifestyle behaviours and medications.

This study assessed the influence of low BMD results and direct-to-participant feedback of results on awareness of diagnosis, information seeking about osteoporosis, bone-related medication use and health behaviours. Participants included 1,837 women and 869 men aged 40-60 years, from the population-based prospective Canadian Multicentre Osteoporosis Study, who had undergone baseline dual energy X-ray absorptiometry of the hip and spine. Bone-related health behaviour, medication use and risk factors for osteoporosis were measured by questionnaire at baseline and at 3-year follow-up; recall of BMD test results and subsequent information seeking were assessed at Year 3. The diagnosis reported to the participant and/or the family physician, was documented retrospectively by review of the feedback reports.

Correct recall of osteoporosis or osteopenia diagnoses was poor, particularly in men. After adjustment for baseline health behaviour and other important covariates, low BMD results at baseline were associated with subsequent information seeking, and with higher calcium intake, Vitamin D supplement use and osteoporosis-related medication use at follow-up. A report of low BMD had no influence on exercise participation, smoking cessation, high alcohol consumption, or high caffeine intake. Direct-to-participant feedback *v.* feedback only to the physician was associated with increased awareness of diagnosis in those with a borderline or normal diagnosis, greater information seeking, and calcium supplementation in women and men, and increased exercise participation and reduced caffeine consumption in women. Educational strategies that specifically target men and specific interventions to support health behaviour change in those at increased risk of fracture are likely to be necessary if BMD testing in this age-group is to have a significant impact on fracture risk. Direct-to-participant feedback may offer an effective method of increasing awareness of BMD test results and influencing some health behaviours.

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CHAPTER 1: Introduction

1.1 Introduction

Osteoporosis is a major health problem that is expected to contribute an increasing burden on health services as the population grows and ages. The annual cost associated with treatment and care of hip fractures alone in Canada has been estimated to be $650,000,000 (1). Because age is the major risk factor for low bone density and osteoporosis-related fracture (2), the epidemic of fractures attributable to osteoporosis, together with the financial and societal burden that accompanies them, are expected to increase dramatically as life expectancy increases around the globe.

Prevention offers the greatest potential for reducing the impact of osteoporosis on morbidity, mortality, quality of life and economic burden: Once fractures occur, bone loss has reached a stage that is often irreversible. If individuals who are identified as being at higher relative risk for osteoporotic fracture can be encouraged to modify their lifestyles appropriately, or to take effective medications or supplements, then the burden of osteoporosis would be expected to decrease. For such preventive interventions to be effective, however, individuals at risk for fracture must first be reliably identified, individual risk information and recommendations for intervention must effectively reach them, and those at high risk must be prepared to make recommended lifestyle changes and take medications as appropriate, in order to reduce their risk.

The measurement of bone mineral density (BMD) plays a central role in the diagnosis of osteoporosis and in the assessment of fracture risk; the current gold standard method for identifying low bone density in clinical practice and population based settings is dual energy X-ray absorptiometry (DXA). A low test result by DXA should ideally prompt physicians or other health professionals to recommend appropriate interventions and to support women and men with low BMD (and hence an increased risk of fracture) to make lifestyle changes and, if appropriate, to take medications to reduce their risk. The identification of women and men who have low bone density by DXA testing is of potential benefit if the communication of an increased risk of fracture were to encourage those at greater risk to undertake preventive measures.

The potential benefit of DXA testing is offset by its low positive and negative predictive values: many who are identified with a low bone density by DXA are not destined to experience a fracture and similarly, many with normal bone densities will later suffer fractures. A low test

result may lead to increased stress and worry about silent "risk" that may never result in a fracture, or may result in inappropriate precautions (3), and a normal test result may provide false reassurance and complacency. Furthermore, DXA testing is costly. When assessing the value of BMD testing in selected women in the perimenopausal and early menopausal years, the British Columbia Office of Health Technology Assessment cited a lack of data demonstrating that women, or their physicians, acted on BMD results in a way that could affect health outcomes (4). The positive potential of DXA testing can only begin to be realized if it results in positive action, such as appropriate lifestyle change or medication use.

The primary focus of this dissertation was to address whether a sample of mid-aged women and men, from the general Canadian population, who received BMD test results from a DXA test were aware of their test results, and whether low test results prompted information seeking about osteoporosis and the modification of osteoporosis-related health behaviour. Specific health behaviours that were addressed by this research were those that have been demonstrated to be effective, at least to some extent, in reducing the risk of fracture or the loss of BMD or that are recommended preventive or treatment interventions in established osteoporosis practice guidelines: increased calcium intake from diet, use of calcium or vitamin D supplements, participation in exercise, smoking abstinence, moderate alcohol and caffeine intake, and the use of bone-specific medications.

Direct-to-participant feedback of test results may increase the awareness of test results and may further provide the opportunity for individuals to take responsibility for their own health. On the other hand, direct feedback may provide no improvement in understanding and may be less effective than communication through the primary health-care provider. Furthermore, direct feedback may even hinder behaviour change by interfering with the opportunity for physician-initiated discussion of potential lifestyle or therapeutic interventions.

A second focus of this dissertation was to explore the effects on correct recall and awareness of DXA test results (or diagnosis), information seeking and health behaviour change (including the use of bone-specific medications) of direct-to-participant feedback of test results, in comparison with feedback to the FP only.

Although knowledge of an increased risk may be necessary, it may not be sufficient to motivate positive change; the increased risk must also be relevant to the individual and that individual must be prepared to initiate and maintain changes to his or her lifestyle. This suggests that those at greater risk for fracture, such as older women, individuals with a family history of osteoporosis and those with a history of exposure to high-risk medications such as

corticosteroids, would be expected to take more notice of their BMD test results and may be more likely to make appropriate behavioural changes. In other words, different subgroups of the population may respond differently to the equivalent assessment of risk (BMD test results).

A third focus of this dissertation was to assess the potential effects of demographic factors and other risk factors for osteoporosis on correct awareness of BMD test results, information seeking, health behaviour change and osteoporosis-related medical therapy.

This study was made possible by the provision of prospectively collected population-based data from women and men who took part in the Canadian Multicentre Osteoporosis Study (CaMOS) (5). Further data to address the specific questions of this dissertation were collected retrospectively from CaMOS participant files.

1.2 Outline of the Thesis Structure

Chapter 2 follows this introductory chapter and provides an overview of the literature on DXA testing, osteoporosis and its risk factors, and prevention and treatment recommendations. Prior studies that have investigated correct awareness of BMD test results, information seeking and lifestyle change following bone mineral density testing are reviewed in this chapter, as is the small amount of prior research related to direct-to-participant feedback of BMD test results and some theoretical grounding for its consideration as a potentially effective intervention.

The rationale for the study in the context of a summary of the literature discussed in Chapter 2 is presented in Chapter 3, together with the overall and specific objectives of this dissertation research and the conceptual framework that guided the development of the study.

The designs of this study and the Canadian Multicentre Osteoporosis Study (CaMOS), from which this study is derived, are described in Chapter 4. The sample selection, measurement and derivation of the explanatory and response variables, manipulation of the data and analysis methods are described here. Chapter 4 also includes a description of the sampling strategy for the National Population Health Survey (NPHS), from which a selection of variables was obtained and compared with a subset of this study's data to assess the findings' generalizability.

Chapter 5 provides a description of the study sample and a comparison between the sample and the mid-aged CaMOS participants who were excluded due to loss to follow up or lack of a BMD test. The sample is also compared with the equivalent age group from the cross-sectional NPHS (Cycle 2) sample that was completed at the same time as the CaMOS participants were surveyed.

Chapters 6 and 7 present the results of the univariate and multivariable data analyses and Chapter 7 ends with summary tables of the associations that were found between the awareness, information seeking and health behaviour outcomes and all of the explanatory variables that were considered.

Finally, an interpretation of the study findings and their implications, together with a discussion of the limitations of this research are presented in Chapter 8.

CHAPTER 2: Literature Review

2.1 The Burden of Osteoporosis-Related Fractures

Osteoporosis is a chronic disorder in which a complex array of physiological mechanisms brings about a progressive reduction in bone strength and increased risk of bone fracture. The fractures that result are associated with a large burden of morbidity and mortality and a significant cost to the health-care system (1;6-11). Major fragility fractures, particularly of the hip, are associated with excess mortality in both women and men (12;13). Mortality within one year following hip fracture varies considerably by age, but overall, is between 10% and 20% (14-16); between 17-23% of these deaths are believed to be directly due to the hip fracture event. It has been estimated that 1.5% of all deaths in a population aged 50 years and over can be attributed to hip fractures (17). Excess mortality is also associated with clinically diagnosed fractures of the vertebrae[1] (12), although this is possibly due to their relationship with comorbid conditions. Although the incidence of hip fracture is much more frequent in women than in men, mortality has consistently been found to be higher in similarly aged men than women following hip fracture (16-21).

The morbidity associated with osteoporosis-related fractures, particularly of the hip, is substantial. Approximately one half of all hip fracture patients have difficulty walking one year after fracture (14;22); 8% of independently living women who have an osteoporotic fracture of the hip, spine or wrist are expected to require long term care and a further 7% are expected to become dependent for the basic activities of daily living (23). A recent Canadian study found that 41% of community-dwelling women and men aged 50 years and over were no longer living independently one year after a hip fracture (1).

Given the significant associated morbidity, it is not surprising that health-related quality of life (QOL) is significantly affected by osteoporotic fractures (24-27), although the relationship is complex and likely mediated or moderated to some extent by other factors such as comorbidity. Prevalent fractures were associated with poor QOL, as measured by the Health Utilities Index in the Canadian Multicentre Osteoporosis Study (CaMOS) cohort (24), while a prospective study of *predictors* of incident low trauma fractures amongst the menopausal women from the same cohort found that poor QOL, as measured by the SF-36 at baseline, was a risk factor for osteoporotic fractures of the hip, spine and other non-vertebral sites (28). This suggests that other factors that are often associated with QOL such as age, comorbidity and

[1] Approximately two thirds of vertebral fractures remain silent and are not identified clinically.

depression may confound its relationship with fractures. Nevertheless, it is clear that people with osteoporosis-related fractures experience a poorer QOL compared with those without fractures (24-28),

During one year (1990), 740,000 deaths globally were estimated to be attributable to hip fractures and a loss of 1.75 million disability adjusted life-years;[2] equivalent to 0.1% of the global burden of disease world-wide (29). This relative burden is more than 10 times greater (1.4%) if only women in Western countries are considered (29). Evidently, the burden imposed by fractures associated with osteoporosis is significant in terms of both mortality and morbidity, and because a major risk factor for low trauma fracture is advancing age (30;31), the epidemic of fractures has been projected to increase exponentially as life expectancy and median age around the globe increases (32;33). The cost of treatment and care for these cases of osteoporosis is also expected to vastly increase in the absence of effective and acceptable preventive and treatment interventions; the direct and indirect cost associated with hip fracture alone in Canada has been estimated at $650 million, with a projected increase to $2.4 billion by 2041 (1). Fracture treatment is costly and rehabilitation has a low success rate, hence early preventive interventions offer the greatest potential benefit in terms of reducing morbidity, mortality and economic burden.

Age-adjusted incidence rates for osteoporotic fractures in women have decreased since the 1950's in a U.S. cohort (34), while rates stabilized between 1965 and 1983 in a Swedish sample (35), during the 1980's in populations in Canada (36) and Finland (37), and in the early 1990's in a second Swedish population (38). Age-adjusted rates for men, on the other hand, have shown increases over time relative to those seen in women (34;35) leading to a decrease in the male : female ratio of incidence rates in some populations. The increase in incident fractures as the population ages is therefore expected to be greater in men than in women. The age adjusted incidence of fractures in Asia is still increasing (39;40). As fracture rates stabilize or decrease in parts of Europe and North America, the aging populations of Asia, as well as South America, are expected to contribute an increasing relative global burden of fracture cases over the next half century (41;42).

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[2] "Disability Adjusted Life Years" (DALYs) are a combined estimate of the years of life lost due to premature mortality and the number of healthy years of life lost because of disability. These calculations take into account the disability weight associated with hip fracture (0.272 for each year of disability), the age of onset of the disability (because the relative importance of healthy life is adjusted for different ages), the duration of time lost due to death attributable to hip fracture (25% of mortality following hip fracture was assumed to be attributable to the fracture for these estimates) and a time preference, or discounting function, that adjusts for the greater value of health gains now compared to health gains in the future.

The results of two recent studies have provided more evidence that age-adjusted fracture rates are declining in Western countries where greater attention has been paid to the disease. In a retrospective cohort study of Swedish women and men aged 50 years and over, age adjusted hip fracture rates in women decreased between 1982 and 1996, while those in men increased. The authors projected that age-adjusted hip fracture rates would decrease overall by 11% by the year 2010 (compared to 1996). Based on the data for women and men, a decrease in hip fracture rates in women of 19% was projected and an increase of 7% was projected for men. Given these projections, and the expected increased age of the population in 2010, no change in the actual number of hip fractures was projected (43). Jaglal et al. (44) investigated similar trends in both hip and wrist fractures in women and men aged 50 years and over in the population of Ontario, Canada. The age-adjusted incident fracture rates for both hip and wrist fractures in women remained stable between 1992 and 1996, but then declined from 1997 to 2000. Consequently, the authors projected that rates would continue to decline between 2001 and 2005 and that the actual number of hip and wrist fractures would not increase substantially even as the population aged. As observed in the Swedish study, the age-adjusted fracture rates in men did not exhibit the same decline. These results, together with earlier indications of relative increased rates in men, suggest that education and awareness, as well as lifestyle and therapeutic interventions, have made an impact on women's bone health but not on men's, and that there is a need for greater education, awareness, prevention and intervention directed at men.

The Ontario study (44) correlated the decline in fracture rates to concurrent substantial increases in the use of BMD tests in women aged 50 years and over and to increasing prescription claims for bone-specific medications (antiresorptives) between 1996 and 2003 in women aged 65 years and over. While it is possible, as the authors suggest, that increased diagnosis by BMD testing and increased treatment with antiresorptives were responsible for the observed decline in age-adjusted hip and wrist fracture rates in women in Ontario, DXA testing and treatment could not be causally linked to the fracture outcome because interventions and fracture rates were not studied at the individual level. Furthermore, information was not available regarding either DXA test results or adherence to antiresorptive therapy; the authors only had information about the proportion of the population who filled a prescription. Other potential explanations for the decline in fracture rates include increased awareness of the risk factors and consequences of osteoporosis amongst physicians and the lay population, which may have led to initiation, maintenance or improvement in women's exercise participation or healthful diet choices, for example. The use of ovarian hormone therapy (OHT), whether taken

as a preventive intervention for osteoporosis or for other indications, may also have contributed to the change in fracture incidence rates (prescription of OHT was not investigated by the authors). In summary, it is not possible to tell from this study if increased DXA testing, and in particular, the specific results of the tests, influenced fracture rates in Ontario in the late 1990's. Studies of individual level associations between BMD testing, the results of the tests, medication uptake, lifestyle changes and ultimately fracture rates are necessary to clarify the role that DXA testing has played, and may play in the future.

2.2 The Diagnosis of Osteoporosis: BMD and DXA

The term "osteoporosis" is used interchangeably to describe both the process that contributes to fractures, a decreased relative bone mineral density (BMD), and the clinical outcome (fractures). The following operational definitions, based on bone mass measurements in white menopausal women have been developed by the World Health Organization (WHO) (45):

- *Severe osteoporosis*. BMD lower than or equal to 2.5 standard deviations (SD) below the peak adult mean (the mean of a healthy young adult reference population) in the presence of a low trauma fracture.
- *Osteoporosis*. BMD lower than or equal to 2.5 SDs below the peak adult mean without fracture.
- *Osteopenia or low bone mass*. BMD between 1 and 2.5 SDs below the peak adult mean.
- *Normal*. BMD no lower than 1 SD below the peak adult mean.

Measurements of bone density, most often from the proximal femur or lumbar spine, are interpreted by calculating a T-score, which is the number of standard deviations by which a result deviates from the mean bone density in young adults of the same sex. The threshold values, as defined by the WHO, are then used to categorize patients as having normal bone, osteopenia or osteoporosis. Z-scores are also used as an alternative comparison method; the Z-score is the number of standard deviations by which a result deviates from an age- and sex-matched population. As bone density naturally decreases with age, a Z-score for a person past the age of 40 years, when peak bone mass starts to decline, will be higher than the corresponding T-score. Sixteen per cent of young adults within the age range for "peak bone mass" will have a BMD that is 1 SD below peak bone mass (a T-score of -1.0), whereas a person with a Z-score of

-1.0 lies in the lowest 16% of the population of equivalent age. Hence, with a T-score cut-off, the chance of being diagnosed with osteoporosis or osteopenia gradually increases with advancing age.

For Swedish women, for example, the prevalence of a T-score at or below -2.5 (i.e., a diagnosis of osteoporosis), using 20-39 year-old "peak bone mass" in women as the norm (from the National Health and Nutrition Examination Survey, or NHANES), has been estimated to be approximately 3.9% in women at the age of 50 years, increasing to 36.1% at the age of 80 years. For men, using 20-39 year-old men as the reference population, the prevalence of osteoporosis is approximately 1.9% at the age of 50 years and 12.6% at age 80 years (46).

From the CaMOS data, the prevalence rate of osteoporosis of the hip in Canadians aged over 50 years has been estimated at approximately 8% for women and 5% for men (47). Equivalent estimates for U.S. population from the NHANES data, have been similar for men (6%) but higher for women (18%) (48); this difference in prevalence may be explained by an actual difference in the BMD of women aged 50 years and over between the two populations or by somewhat different age distributions amongst women aged 50 to 80 years in Canada compared to the U.S. (47).

Dual energy absorptiometry (DXA), in which the amount of mineralised tissue in a scanned area of bone (g/cm^2) in the hip, spine or total body is measured by passing low-dose X-rays through the bone, is the current gold standard for the clinical measurement of BMD. DXA is relatively more accurate and precise than other currently available technologies for measuring BMD and can be performed quickly with little patient discomfort (49). The accuracy error for DXA (potential error in measurement of the actual BMD of a site) ranges from 5% to 8% (50) and the precision error (the potential error in re-measuring the same sample) is approximately 1% to 2% (49). With a potential error of estimating bone density at 8% above or below an individual's true BMD, there is the potential of a resulting error in the diagnosis and prediction of fracture risk. As was pointed out by the British Columbia Office of Health Technology Assessment (BCOHTA), in their systematic review of the use of selective or population screening in well women, however, the technological performance of DXA is of much less importance than its overall clinical usefulness as a prediction tool for the clinical outcome - fracture (4).

The diagnosis of osteoporosis and the assessment of fracture risk are based on the comparison of a DXA measurement to peak bone mass and are therefore heavily dependent on the population that is used as the reference. Originally, the referent populations for DXA testing

were the DXA manufacturers' samples, which were small samples of relatively healthy young (aged 20 to 29 years) adults. The methods used to obtain these data and descriptions of the populations used for these manufacturers' normal samples were not published. The hip measurements of the reference populations for the two main DXA suppliers (Hologic Inc.™ and Lunar Corp.™) have been found to differ, even when the systematic differences between the values of absolute bone densities between the two systems were corrected (51). The authors of a study that compared the manufacturers' norms to a sample of young British women found large differences in the two sources of norms for both hip and spine values, and concluded that the use of the manufacturer's norms would lead to over diagnosis, excess treatment and unnecessary worry (52). Since 1997, the larger, population-based young adult sample from the third National Health and Nutrition Examination Survey (NHANES III) has been used as the reference population for the hip (53). Because the average BMD values of this large U.S. national representative sample are lower than those of the small samples available in the earlier days of DXA testing, the T-scores from measurements derived by comparison with the NHANES III reference database are higher than those using the older manufacturers' hip norms and there is a reduced probability of diagnosis of osteoporosis or osteopenia (47). Canadian population norms for women and men for both femoral neck and lumbar spine values are now available. Peak bone mass values of young adult women and men in the CaMOS study were found to be very similar to those in the NHANES database, and significantly lower than the manufacturers' norms for both hip and spine measurements (47). Until the publication of the CaMOS data, no reliable population-based values for peak bone mass values at the spine were available.

Measurements for both the lumbar spine (the first four lumbar vertebrae) and the hip are typically generated by the DXA scan, but there have been varying opinions and only limited agreement about which sites should be used to make a diagnosis. Hip measurements are provided for three separate regions of the proximal femur: neck, trochanteric and inter-trochanteric, as well as a total hip measurement which includes all three areas. A measurement for the Ward's triangle, a small area of mostly cancellous bone[3] below the femoral neck, is also provided, but this area is the least reliable of all hip sites and is not recommended for diagnosis (54). The hip region used for clinical and research purposes has varied, both in Canada and internationally, but most of the published research regarding the risk of fracture has used the

[3] Cancellous bone (or trabecular or spongy bone) is osseous tissue with low density and strength and a large surface area; it fills the inner cavities of long bones and protects the bone marrow.

neck of the hip (55;56). Up until 1996,[4] when the Scientific Advisory Board of the Osteoporosis Society of Canada[5] recommended that the neck of the hip be used for clinical diagnostic purposes (57), there were no Canadian guidelines regarding the area of the hip that be used. Very shortly afterwards the International Committee for Standards in Bone Measurement endorsed the use of the total hip measurement as the preferred site (58). A recent position statement by the International Society for Clinical Densitometry (ISCD) which recommended that the lowest of the total hip, trochanter and neck of hip be used (59) is indicative of the confusion and inconsistency that have been associated with the clinical diagnosis of osteoporosis in practice. The ISCD's position has been challenged by the International Osteoporosis Foundation as being without scientific basis (60) and has since been updated by the ISCD to a recommendation of the selection of the lowest of the total hip or femoral neck (61). Values from the femoral neck or the total hip are reportedly the most reliable for diagnostic purposes and, because these measurements are highly correlated, they have similar predictive values for fracture (2;62).

The T-scores that result from measurements taken at the spine and the hip from the same individual can be considerably discrepant; the two sites were discordant for a diagnosis of normal bone density, osteopenia and osteoporosis in 44% of the women in one study (63). The recommended sites for comparison to norms and for diagnostic purposes have changed over time and there is persistent disagreement over which site(s) to use for the prediction of fracture risk (59;60;64). Although there has been a tendency to use the lowest of the measurements at either the spine or the hip to assess fracture risk in patients clinically, and an endorsement of this approach by some groups (59;65), a recent analysis of the BMD values from six population-based cohorts (64) found that selection of the lower of the spine and hip values does not improve the estimate of risk, either for hip fracture, or for any fracture. The hip value alone is reportedly a better predictor of hip fracture risk, whilst the hip value and spine value each predict fractures at other sites equally. A recently published study of a large clinical cohort of women selected from the population-based database of the Manitoba Bone Density Program reported that measurements taken at the hip were superior to those taken at the spine for predicting overall osteoporotic fractures (66). Essentially, the use of the lower of either site increases the proportion of the population that receives a "below normal" diagnosis without improving the

[4] The baseline CaMOS data were collected during 1996 to 1997 and feedback of the DXA results to participants and physicians occurred before, and after, the introduction of the first guidelines on the preferred hip site for clinical diagnosis.

[5] The Osteoporosis Society of Canada is now known as "Osteoporosis Canada".

predictive value of the DXA test. Furthermore, extraneous calcification can erroneously inflate BMD measurements at the spine (67;68), as can vertebral compression fractures. Both calcifications (such as osteophytes) and prevalent vertebral fractures become more common with advancing age, which means that estimates of BMD at the spine can be subject to greater error, particularly in men (67;69) and in people over 65 years (49;70). While the use of the hip value alone for diagnostic, or risk assessment purposes, would appear to avoid the problem of erroneously elevated spinal values, the dialogue about the preferred sites(s) for clinical practice is continuing and there remains uncertainty and inconsistency in the preferred site for the interpretation of bone density tests (71).

2.2.1 Bone Mineral Density and Fracture Risk

Prospective studies have demonstrated that for each standard deviation in BMD value (hip or spine) below the young adult mean the relative risk of any osteoporotic fracture increases by approximately 1.5 times in both women and men (55;72;73). Measurements taken at the hip provide a higher relative risk for fracture at the same site; a hip value that is 1 SD below the peak young adult mean has been shown to have an associated relative risk for hip fracture of 2.5-3.0 (55;56;74).

Analyses provided by Marshall et al. (56), Johnell et al. (55), and Kanis et al. (64) included the combined results of several cohort studies to estimate the relative risk of fracture by BMD.[6] Interestingly, the risk estimates generated from these studies tended to be the same whether populations were drawn from Australia, Sweden, Japan, the U.K., the U.S or Canada. Although a small proportion of the studies had relatively long periods of follow-up, the majority of the subjects were followed for less than five years; the risk estimates generated from the cohorts with longer term follow-ups were comparable to those with shorter follow-up periods (56). Johnell et al. (55) included sufficient subjects followed for 10 years to provide 10-year risk estimates and found that the predictive ability of BMD remained stable as time elapsed after measurement for up to 10 years. Risk estimates of the association between BMD and fracture therefore appear to be stable over time (at least for 10 years), between men and women and across different populations. Although these authors concluded that the relative risk estimate for a fracture 10 years after BMD testing was reliable and stable, there was a trend (not statistically significant) towards a gradual decrease in relative risk as the time between testing and fracture

[6] Note that the latter two studies overlap; a subsample of the data utilised for the study by Johnell et al. (55) was used to answer different questions in the study by Kanis et al. (64).

increased, which suggests that prediction of fracture risk at time periods much longer than 10 years in advance (i.e., for younger men and premenopausal women) may become smaller and less meaningful. The results of longer-term follow up are not yet available from the large population-based studies to determine the risk estimates for fracture at a much later age for young women and men.

Notwithstanding the above mentioned limitations, there is evidence that BMD may be a "purer" indicator of fracture risk in younger people. In their study of the results of 12 large, population-based cohorts (a total of 29,082 women and 9,891 men), Johnell and associates identified a decreasing gradient of hip fracture risk with age; the relative risk for hip fracture for each 1 SD decrease in T-score decreased from 3.68 at age 50 years to 1.93 at age 85 years in women and men combined (55). While the relative risk of a hip fracture associated with a lower BMD may decrease with advancing age, the absolute risk of fracture, however, increases due to the strong association between age and risk of hip (or any osteoporotic) fracture.

Although BMD testing can detect a risk for fracture, it cannot identify which individuals will later fracture. The bone density distribution of women with a hip fracture overlaps significantly with that of women without a hip fracture (75); consequently, the number of false positives or false negatives will vary depending on the position of the "cut-off" value on the normal curve. Use of a cut-off T-score of -1.0 to define those who are at higher risk of fracture, and a relative risk of hip fracture of 2.5 per SD below the mean, for example, results in a relatively high specificity (approximately 85% of women aged 50 years who will be identified as "low risk" will not fracture), but a low sensitivity (only approximately 45% of women aged 50 years who will be identified as "higher risk" will experience hip fracture). This results in a positive predictive value (the probability that a woman aged 50 years who has a T-score of -1.0 will fracture) of only 3.8% (76).[7] This means that, for a 50-year-old woman without any other risk factors, neither a negative nor a positive test result is very informative.

The predictive value of a low BMD test result increases when other risk factors for osteoporotic fracture are taken into account. In one prospective study, Cummings et al. identified several risk factors that, when combined, predicted the incidence of first hip fracture in women more reliably than did low BMD alone (77), and the predictive value increased when BMD was included together with other risk factors. Amongst the risk factors that were

[7] The positive predictive value (PPV) of a test depends both on the relative risk and on the prevalence of the disease in the population. These estimates are based on a 15-year risk of fracture, which has a relatively low prevalence in women aged 50 years. For women aged 65 years, the PPV using the same cut-off for "high risk" is estimated at 20.1% while the sensitivity and specificity rates are similar to those for women aged 50 years.

identified, however, are those that are of little or no value in predicting fracture risk in younger women and men, such as age $\geq$ 80 years, inability to rise from a chair without using one's arms, poor visual contrast sensitivity, and history of a non-hip fracture since the age of 50 years. It could be argued that once a fracture has occurred (even non-hip), or once a woman reaches the age of 80 years and has several other risk factors for fracture (some of which would have been potentially modifiable at a younger age), most available preventive interventions will be limited and any preventive efforts have already proven themselves fruitless. Furthermore, although a woman over the age of 80 years may have a high risk of fracture within 10 years based on a combination of risk factors, her lifetime risk of fracture may be low once the competing risk of death within 10 years is taken into account.

2.2.2 Screening by DXA

The value of DXA testing as a screening tool for the identification of those at increased risk of fracture and the selection of appropriate people for BMD assessment have been extensively reviewed and debated; there has been particular controversy over whether perimenopausal women or younger menopausal women should be screened for low bone density (4;50;78-80).

A WHO study group[8] (50) determined that bone mass measurements meet many of the essential criteria of screening tests as outlined by Cadman (83), and that screening of women at or close to menopause, to help with decisions about uptake of ovarian hormone therapy (OHT), would be appropriate. It has been argued that if women were more likely to adhere to prescribed effective therapy after being identified with low bone mass, then general screening in perimenopausal women may be worthwhile (84). The BC Office of Health Technology concluded, on the other hand, that even selective screening of those menopausal women deemed to be at higher risk for osteoporosis was not warranted (4); a lack of information on the uptake and adherence to therapy and lifestyle change recommendations as well as the low positive predictive value of a BMD test were cited amongst the many reasons why such screening was not recommended. It has since been suggested that, even though screening for osteoporosis may not be justified based on current evidence, developments in therapies and interventions may lead to re-appraisal of the value of screening in the future (78).

[8] Note that the WHO study group's report was released before the results of the Women's Health Initiative (WHI) revealed that the risks of ovarian hormone therapy may outweigh its benefits (81;82)

Most reviewers and experts have concluded that the results of a BMD test alone, in the absence of other risk factors, are not sufficiently predictive of future fracture to justify a population screening approach in women or men under the age of 65 years. Hence, a case-finding strategy is generally recommended whereby those at higher risk of having a low BMD, but also a somewhat higher risk of fracture even when adjusted for BMD, are selected. Variation among different guidelines, however, leads to large differences in the populations that are recommended to undergo BMD assessment.

Table 2.1: Risk Factors that Indicate a Need for Osteoporosis Assessment[a]

Major Risk Factors	Minor Risk Factors
- Age ≥ 65 years	- Rheumatoid arthritis
- Vertebral compression fracture	- Past history of clinical hyperthyroidism
- Fragility fracture after age 40 years	- Chronic anticonvulsant therapy
- Family history of osteoporotic fracture (especially maternal hip fracture)	- Low dietary calcium intake (<1,500 mg per day for menopausal women and men over 50 years)
- Systemic glucocorticoid therapy	- Smoker
- Malabsorption syndrome	- Excessive alcohol intake[b]
- Primary hyperparathyroidism	- Excessive caffeine intake (>4 cups coffee per day)
- Propensity to fall	- Weight < 57 kg
- Osteopenia apparent on X-ray film	- Weight loss > 10% of weight at age 25 years
- Hypogonadism	- Chronic heparin therapy
- Early menopause (before age 45 years)	

[a] From Brown et al. (85).
[b] A definition of "excess" alcohol was not provided by the panel.

The Scientific Advisory Council for Osteoporosis Canada recommends that all women and men over the age of 50 years be assessed for risk factors for osteoporosis and that those with one major or two minor risk factors (see Table 2.1) be assessed for low BMD (85;86). Notably, according to these guidelines, all women and men over age 65 years should receive a DXA test and lifestyle factors such as being a smoker, or having a low calcium intake, or high caffeine or alcohol intake, are considered sufficient as minor risk factors to warrant a BMD test.

The Canadian Task Force on Preventive Health Care recommends screening all women over age 65 years and menopausal women under 65 years in the case of a previous fragility fracture, weight less than 60 kilograms (kg), or certain other risk factors (a white woman aged 50

years who weighs 54 kg would meet the criteria for BMD testing by these recommendations) (87). A low calcium intake is considered sufficient indication by itself for a referral for a BMD test by the WHO Task Force for Osteoporosis, as are other commonly accepted risk factors such as a maternal history of risk fracture or prolonged corticosteroid therapy (88). In the U.S., the National Osteoporosis Foundation endorses a more preventive approach by recommending screening of all menopausal women with at least one major risk factor. Major risk factors include a history of a fragility fracture, a family history of fracture, low body weight, history of use of corticosteroids, and current smoking. Additional risk factors are also listed as potential indications for assessment, including poor health, low calcium intake and low physical activity (89). The European Foundation for Osteoporosis and Bone Disease[9] guidelines for case finding include the requirement of the presence of at least one specific risk factor, such as loss of height, low body mass index and history of corticosteroid therapy, but include the acknowledgement that physicians may need to manage patients who have no known risk factors who would take treatment if their BMD were low (i.e., that BMD testing may be recommended to help women with decisions about taking OHT) (90).

There is evidence that a significant number of women who do not meet the screening guidelines are requesting and attending DXA tests. There are a variety of clinical practice guidelines that address criteria for referral for a DXA test in the U.S, for example, and adherence to these guidelines is reportedly low amongst health-care providers (91). In England, 30% of women who were referred by one clinic did not meet the guidelines for referral in that country (92). The most common reason for a referral for DXA testing amongst a different sample of 3,530 British women was to help in decision making about taking OHT use (93). A qualitative study of general practitioners (GPs) in the U.K. revealed that physicians have difficulty deciding for whom and when to order BMD tests and that factors other than existing guidelines, such as patients' requests and perceived availability of DXA machines, influence these decisions (94). A similar qualitative study of family physicians (FPs) in Ontario, Canada revealed that FPs lack a rationale for ordering BMD tests (95). Flexible referral patterns are likely to be occurring in Canada, where a significant proportion of mid-aged women (under 65 years) are receiving DXA tests (4;44;96). It is believed in fact, that "mass screening" methods have been used to some extent throughout the world (72).

It should be noted that few guidelines exist for BMD assessment in men and premenopausal women. On behalf of the ISCD, Khan et al. (97) recommended that senior men

[9] Now known as the International Osteoporosis Foundation.

should be assessed by BMD measurement and that younger men and premenopausal women should be assessed in the presence of secondary causes of low BMD in conjunction with other risk factors for fracture (i.e., secondary causes of osteoporosis or a fragility fracture must be present).

2.3 Non-Modifiable Risk Factors for Osteoporosis

2.3.1 Age and Gender

There is no disputing that advancing age and female gender are the most significant independent risk factors for osteoporosis (98-101). Compared with women in their 50s, women in their 60s have twice the risk of osteoporosis and women over 70 years have 4 times the risk of osteoporosis (102). Results from longitudinal studies have revealed that men lose approximately 5-10% of their cortical bone mass each decade and that the incidence of hip fractures in men increases exponentially with age just as it does in women (103).

The 10-year probability of hip fracture for a Canadian woman at age 50 years is approximately 0.4%, at age 60 years it is 1.5%, at age 70 years it is 4.7%, and at age 80 years it is 13.7%. For men, the pattern is similar, but with approximately half the risk relative to women of the same age; at age 50 years the risk of hip fracture for a Canadian man is 0.3%, at age 60 years it is 0.9%, at age 70 years it is 2.1%, and at age 80 years it is 6.2% (104). The rates in men are about five years behind those of women, so that a man at age 70 years has the same risk of hip fracture as an average woman at age 65 years (105). Rates for clinically diagnosed vertebral fractures in women and men also increase with age, but more linearly and with a consistent ratio; after the age of 50 there is a 2:1 incidence of fractures in women compared with age-matched men (99;106;107).

Age-adjusted mortality and reduction in life expectancy following fracture are comparable in men and women, although the proportion of years of life lost attributable to hip fracture is even greater in men because of their shorter life expectancy (19). Although age is the strongest determinant of fracture risk, as a non-modifiable risk factor that applies equally to the whole population up until death, it is of limited value for the prediction of an individual's future fracture risk. Age is of much greater value when it can be combined with other factors associated with an increased or decreased risk of fracture.

2.3.2 Attainment and Maintenance of Peak Bone Mass

Osteoporosis is brought about by a gradual loss, or resorption, of bone over time after peak bone mass has been attained. The exact age at which peak bone mass is reached appears to vary by skeletal site, but the results of cross-sectional studies of bone mineral content suggest that bone accrual slows considerably after the age of 15 to 16 years in girls and 18 years in boys (108;109). Bone mass then begins a noticeable natural decline as the rate of bone resorption starts to exceed the rate of bone formation; the age at which this decline first becomes evident varies considerably between sites and has been inconsistent between studies. Cross sectional data from the CaMOS women and men suggest that a decline in femoral neck bone density may be evident as early as the end of the third decade but lumbar spine bone density may remain constant until the end of the fourth decade (47). Regardless of the uncertainty about the age at which peak bone mass starts to decline, it is presumed that the higher the peak bone mass, the longer it will take for this decline to take place with age. Low bone density in mid-aged women and men reflects both the maximum amount of bone mass achieved and the loss of bone after attainment of peak bone mass.

In addition to genetics, there are many factors that are known, or believed, to influence the attainment and maintenance of peak bone mass (or "full genetic potential" for bone strength as defined by Heaney et al. (110)). Many of the factors that play a role in attainment and maintenance of peak bone mass can be categorized as those that influence reproductive and other hormone (such as cortisol) concentrations. Late age at menarche, early age at pregnancy, irregular menstrual cycles and amenorrhea secondary to excessive leanness, intense physical activity, or anorexia nervosa, for example, have all been associated with lower peak bone mass (110;111). Sub clinical ovulatory disturbances as a result of lower progesterone production (i.e., anovulatory cycles or cycles with a short luteal phase) have also been linked to bone loss from the spine in premenopausal women (112;113). Other experiences that are reported to disrupt the hormonal milieu and potentially lead to reduced bone mass include dietary restraint (114-116) and intense exercise (112;117). Low bone density may also result from the use of oral contraceptive agents (OCAs); a recent analysis of the premenopausal women in the CaMOS cohort revealed that those who had ever used OCAs had lower BMD measurements at the spine and trochanter than did women who had never used OCAs (118). The effects of OCAs on premenopausal bone is not conclusive however, as both increases and decreases in BMD have been reported (119). Although there have been reports of an association between a history of

OCA and increased risk of fracture (120;121), these studies have included only limited adjustment for potential confounders.

Apart from hormonal influences, strength, mobility or bone-loading, and alterations in nutrition (particularly sufficient calcium and vitamin D, but also phosphorus, protein and other nutrients) and lifestyle (such as tobacco use and possibly alcohol use) play a role in the attainment and maintenance of peak bone mass (111). Gains and losses in weight (or "weight cycling") also put premenopausal women at risk for reduced BMD (122) and have been associated with increased risk of hip fracture in older women and men (123).

After the achievement of peak bone mass both men and women lose approximately 0.5-1.0% of bone per year, although there is considerable variation between individuals. In addition, there is a phase of more rapid loss during and soon after the menopausal transition (see below) in women. Both men and women may therefore become osteoporotic, with age being a prominent risk factor and women losing bone earlier and more extensively than men. Other risk factors combine with this decline in peak bone mass to bring about a certain level of risk for fractures at an older age. The changes are much more evident in trabecular bone than in cortical bone due to the higher metabolic activity in the former consequently the sites where trabecular bone predominate (the vertebrae and at the ends of long bones) are the most frequently affected by fragility fracture.

By the age of 40 years, women and men have achieved their peak bone mass and, in fact their bone mass is likely to already be on the decline, particularly at vulnerable sites such as the hip. Apart from age and gender, there are several other non-modifiable risk factors for osteoporosis that mid-aged people may possess.

2.3.3 The Menopause and Women's Reproductive Hormones

An accelerated rate of bone loss is associated with changes that occur during the first five to ten years of menopause in women (2;124); this is believed to be associated with low estrogen levels (125). Many studies have demonstrated that this amplified rate of bone loss actually begins before menopause, in the perimenopausal years, as hormone levels begin to fluctuate and ovulatory disturbances become more prevalent, and that bone loss during the perimenopause may even exceed that in the early menopause years (126-130). Menopause, or perimenopause, has also been directly associated with an increased risk of fracture in mid-aged women: In the Kuopio Osteoporosis Risk Factor and Prevention Study, a population-based retrospective cohort study of 14,220 women aged between 47 and 56 years, a comparison was made between the 49%

of women who were menopausal (defined, rather liberally, as at least six months since last menstrual period) by the start of the study period and the remaining women who were grouped together and inconsistently defined as premenopausal or perimenopausal (although this group also included women who were taking hormone therapy). Increased fracture risk in the five year window was associated with being menopausal when adjusted for age, weight, height and other gynaecological factors (131). Due to the young age of this cohort, however, many of these women who were classified as menopausal (i.e., between the ages of 42 and 51 years) would have been very recently perimenopausal and the results seem to implicate perimenopause, rather than menopause, as a risk factor for fracture in the fifth or sixth decade of life.

An increased duration of exposure to gonadal hormones in women tends to provide protection against low BMD and fracture. Exposure is increased by earlier menarche and by later menopause; although the former may have a greater relative influence on risk of fracture in later life (132). Increasing age at menopause has been found to be associated with reduced risk of fracture by some authors (133-135), while others have found that it is not predictive once other important confounders are taken into account (136-140).

Surgical menopause represents a variation on early menopause, but also involves the abrupt cessation of estrogen release from the ovaries, which confers an even greater risk for osteoporosis than the gradual change in hormone levels that accompanies natural menopause (141-145). Hysterectomy (without ovariectomy) has also been tentatively linked to an increased risk of osteoporosis (144;146); it has been suggested that indications for hysterectomy, such as ovulation disturbances and high estrogen levels that in turn are related to menstrual bleeding problems, may be instrumental in an increased risk in hysterectomized women (127). Given that there are serious disparities in the rates of hysterectomy, for various indications, across educational and socioeconomic strata (147;148), hysterectomy may well be linked to an increased osteoporosis risk through both biological and sociocultural pathways.

2.3.4 Race or Ethnicity

There are significant differences in the bone mass and the fracture risk of women and men of different racial or ethnic groups. African American women aged 50 and over, for example, have a lower risk of osteoporosis than non-Hispanic white women (102); African American women appear to attain a higher peak bone mass than white women of an equivalent weight (149;150), and also lose bone less rapidly during early menopause (150). Associated age-adjusted hip fracture rates are approximately 50% lower in African American women than in

white women (151). Similarly, African American men have a lower rate of prevalent vertebral fractures than do white men (152). Overall, white women and men are at the highest risk of osteoporotic fracture (153;154); hip fracture rates are highest in whites living in North America and Europe, intermediate in Asian populations and lowest in black populations. Although hip fracture rates have been found to be somewhat lower in Asian, compared with white, women and men (155;156), bone densities have typically been found to be equivalent in the two populations (102;157), which implicates a role for factors independent of bone density.

2.3.5 Body Mass Index

Even though body mass index (BMI) (or specifically the weight component of BMI) is potentially modifiable, a low BMI is typically treated as a "marker" or a non-modifiable risk factor for osteoporosis in mid-aged or older women and men; a larger body size is believed to have a protective influence. There are well known serious risks[10] of other diseases that are associated with excess weight or obesity and the associations between BMI, loss or gain of weight, weight cycling, and BMD and fracture risk are complex. Thus, it is not surprising that a recommendation for an increase in BMI is not prevalent in clinical practice or in the literature as a potential osteoporosis prevention or treatment intervention for those considered at risk for osteoporosis due to low BMI.

The evidence for the association between low body mass index (BMI), or weight, and increased risk of fracture, independently of age and sex, is consistent (102;154;158-160). De Laet et al. (161) recently analysed the combined international data from 12 prospective population-based cohorts and confirmed that low BMI is a reliable predictor of fracture risk at the hip and other sites in both women and men and that this association is independent of age. Low BMI is also associated with low BMD (162;163) but at low values of BMI (<20 kg/m^2), BMI predicts fracture risk independently of BMD; the association between BMI and fracture risk does not appear to be independent of BMD at greater values of BMI (161).

Although weight gain during adulthood appears to be protective for osteoporosis and fracture (77;158;164), a history of *variability* in weight (or weight cycling), irrespective of BMI, is associated with a low BMD or higher risk of hip fracture (122;123). Weight loss (≥10% of maximum body weight) is associated with an increased likelihood of low BMD and fracture risk (123;165;166).

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[10] Health problems that are associated with excess weight and obesity include hypertension, cardiovascular disease, type 2 diabetes and some cancers.

2.3.6 Family History

The risk of osteoporosis and fracture is greater for people with a family history of osteoporotic fracture. Perimenopausal and menopausal women with a family history of osteoporosis are at increased risk of osteoporosis and fracture (77;102;146;163) and premenopausal women with a family history of osteoporosis have been found to have lower BMD and may experience a greater loss of bone density over time (162;167;168). Men with a maternal history of fracture also have lower BMD (154;169). A meta-analysis of seven international prospective cohort studies confirmed that family history of fracture, particularly hip fracture, is associated with increased risk of osteoporotic fracture in both women and men and that the associated risk is independent of BMD (170).

2.3.7 Chronic Illness

A history of certain chronic illnesses, including rheumatoid arthritis, anorexia nervosa or eating disorders, malabsorption syndromes (such as inflammatory bowel disease, Crohn's disease, chronic liver disease), renal disease, hyperparathyroidism, hyperthyroidism and Cushing's syndrome has been included in some position papers, consensus statements and guidelines as a potential risk factor for fracture or low bone density (85;87;89;171;172).

Based on a systematic review of the available literature up to 1997, Espallargues et al. identified anorexia, type 1 diabetes, primary hyperparathyroidism and pernicious anaemia as "high" risk factors for osteoporosis, and hyperthyroidism, type 2 diabetes and rheumatoid arthritis as "moderate" risk factors (160). There is reasonable evidence of an increased risk of fracture in both women and men with a history of rheumatoid arthritis; this association persists even when prior corticosteroid use is taken into account (173;174). A history of anorexia nervosa is a well established risk factor for decreased bone density and fracture (175-177). While the evidence for a relationship between bulimia and low bone density has been suggested (178) it seems likely that associations observed in early studies can be explained by comorbidity with anorexia (177;179).

Osteoporosis guidelines have not generally included diabetes as a risk factor, although type 1 diabetes has been identified as a risk factor for decreased BMD and associated fracture and for low BMD (180-182). An increased BMD in women and men with type 2 diabetes was identified, while controlling for BMI, in a cross-sectional analysis of the CaMOS cohort (183). An association between increased BMD and type 2 diabetes has been similarly reported, while

taking BMI or weight into account, by others (184-186) although type 2 diabetes has also been found to be associated with increased risk of fracture (185). A prospective cohort study of risk factors for incident low trauma fracture in middle age (44 to 50 years) identified diabetes (type not specified) as a major risk factor for fractures of the hip, vertebrae, and forearm in men and women; the other chronic conditions that were considered by these authors, and not found to be associated with increased risk, were angina, cancer and hypertension (187;188). Even though risk ratios varied somewhat, the overall risk factors for men and women were found to be very similar (187;188).

The greatest bulk of the evidence for the role of a history of chronic conditions has been derived from studies of women and there is relatively little information on the association between a history of chronic conditions and fracture in men. Still, risk factors for osteoporosis in men are often assumed to be the same as those in women for practical purposes (86;189) and there is no reason to expect the impact of chronic illnesses, or medications, on bone to be qualitatively or quantitatively different in men compared with women (103).

2.3.8 Exposure to Medications

Certain medications, particularly anticonvulsants and oral or inhaled corticosteroids, have been associated with increased risk of osteoporosis and fractures. Oral corticosteroids are considered to be an established risk factor for osteoporosis and fracture (85;190); this robust association is independent of age, gender and underlying disease (174;191). Use of inhaled corticosteroids has also been associated with decreased bone mineral density (192;193), although the association between inhaled corticosteroids and risk of fracture is less consistent (192;194). Anticonvulsant use has been associated with an increased risk of fracture in women and men (77;195;196); this association may be partly explained by seizures (197) but there is also reasonable evidence of a direct, deleterious effect of these medications on bone density (198-202). In their systematic review of studies of risk factors for fracture, Espallargues et al. classified the history of use of corticosteroids as a "high" risk factor (i.e., previous studies had found an associated relative risk or odds ratio of 2 or more); a history of use of anticonvulsants carried a similarly high risk for fracture (160).

Evidence for the effects of other medications on fracture risk, including diuretics, thyroid hormone therapy, and anti-ulcer agents has been less consistent (160).

2.3.9 General Health and Socioeconomic Status

Although general health, education and socioeconomic status are not typically considered to be risk factors for osteoporosis or fracture, these factors have been observed to be associated with this risk, just as they are with other chronic conditions, and can therefore serve as indicators of those at greater risk. Poor self-rated general health is associated with low BMD (203;204) and is predictive of future fracture in both men and women (28;77;187;188). A case-control study of menopausal women in Sweden revealed that, even when other relevant risk factors were taken into account, women who had experienced a hip fracture were more likely to have a lower household income, to have lived in more crowded housing or to have lived without a partner in the three decades preceding the fracture; education level, on the other hand, was not associated with hip fracture risk (in unadjusted or adjusted analyses) (205). In contrast, an earlier case-control study of menopausal women with hip fracture in Southern Europe found a protective effect of more education (206).

Two separate population-based studies in the U.S. that relied on estimated neighbourhood incomes (generated from postal codes) as a proxy for individual socioeconomic status identified a link between higher rates of hip fracture in women and men and lower neighbourhood socioeconomic status (207;208). Further, these disparities in risk were apparent even when other potential confounders such as self-reported race or ethnicity and estimated fluency in English were taken into account (208).

2.3.10 Previous Fracture

A history of a low trauma fracture is associated with an increased risk of another fracture (146;209;210). A review of studies of the risk associated with previous fracture (211) and a recent international meta-analysis of 11 cohorts that included the data from 15,259 men and 44,902 women (212) both reported that the risk of fracture is consistently about twice as high in people with a prior fracture compared with those with no prior fracture. Furthermore, this association is evident in both women and men, it is independent of BMD (211;212) and the risk of subsequent fracture increases with the number of prior fractures (i.e., the relationship is dose dependent) (211).

2.4 Modifiable Risk Factors and Medical Therapy

Certain risk factors for osteoporosis, including older age, female gender and "white" race are not modifiable. Several modifiable or lifestyle factors are, however, believed to play a role

in bone loss after peak bone mass has been achieved. Information about the role of these risk factors in minimizing the rate of bone loss is typically given by family physicians or other specialized sources, such as Osteoporosis Canada, to individuals who are considered to be at risk for fracture or who have been diagnosed with osteoporosis. A sufficient intake of calcium and vitamin D, by diet or by supplements is advised as well as regular participation in weight bearing exercise (such as walking, running, aerobics), abstinence from tobacco smoking and a restriction of alcohol consumption to a maximum of two drinks a day. Some sources also suggest restricting caffeine intake to less than four cups of coffee per day. Variations in lifestyle appear to be associated with significant differences in risk for fracture and may account for a large component of the risk (132), which suggests that successful modification of unhealthful behaviours would contribute to a reduction in fracture risk. Modifiable risk factors, or health behaviours, may be particularly targeted amongst those who receive low BMD test results and have a greater relative risk of fracture.

Ovarian hormone therapy (OHT) acts by both slowing bone resorption and stimulating new bone formation and has been recommended, and has been offered in the past, to menopausal women as a common method of preventing and treating osteoporosis (213). OHT is no longer endorsed as a preventive option however (85;214) since the results of the Women's Health Initiative (WHI) revealed that the risks of OHT may outweigh the benefits (81;82). Currently available treatments for osteoporosis include bisphosphonates, raloxifene, calcitonin and teriperatide. Three bisphosphonates are approved for the treatment or prevention of osteoporosis in Canada; etidronate, alendronate and risedronate. These medications act by binding to the surface of bone and slowing the activity of the (bone resorbing) osteoclasts. Bisphosphonates are indicated for the prevention and treatment of osteoporosis in men, menopausal women and individuals who are taking steroid medications. Calcitonin, a thyroid hormone, is indicated for the treatment (but not prevention) of osteoporosis and also acts by slowing down osteoclast activity. Raloxifene's effects on bone are similar to those of estrogen and it is indicated for the prevention and the treatment of osteoporosis in menopausal women. Teriperatide, a parathyroid hormone analog, activates the (bone building) osteoblasts and is approved for treatment of menopausal women and men with severe osteoporosis who do not respond to or cannot tolerate other osteoporosis therapies.

2.4.1 Calcium

There is a vast literature on the role of calcium on bone health and osteoporosis, and there is substantial evidence that sufficient dietary calcium is necessary to maintain bone mass and to protect against osteoporosis. The benefits of increased dietary calcium or the addition of calcium supplements to fracture risk in mid aged women or men are less certain however.

A meta-analysis of controlled trials published in 1990 by Cumming showed that the rate of bone loss was reduced by about 50% in menopausal women taking calcium supplements and that calcium supplementation appears to be most effective when there are low baseline intakes of calcium (i.e., there is a threshold effect), at an older age and when BMD is lower or there is clinical evidence of osteoporosis (215). In a more recent summary of randomised controlled trials (RCTs) and observational studies of children, adolescents, adult women and a few studies that included men, Heaney concluded that increased calcium intake was clearly effective at improving bone health. More than 90% of the RCTs reviewed and three quarters of the observational studies reported reduced or arrested bone loss at some skeletal site or decreased fracture risk (216). Studies of women in the early menopausal years generally found smaller effects on bone mass than those of premenopausal or later menopausal women (216). Even though it is unlikely that a woman in her perimenopausal or early menopausal years can take enough calcium (either through diet or supplements) to restore the accelerated bone loss that occurs during this time, the goal is to achieve sufficient calcium intake that bone loss is minimized and to ensure that insufficient calcium is not one of the factors that contributes to a decline in BMD.

Although the relationship between calcium intake and fracture risk has been elusive in many observational studies (217-219), randomized clinical trial data have tended to demonstrate an association between increased calcium intake and decreased risk of fracture in menopausal women. A Cochrane review of clinical trials in menopausal women, published up to 2001, concluded that calcium supplementation had a clear positive effect on bone density, and there was a trend towards a reduction in risk for vertebral fractures, while the effect on non-vertebral fractures was uncertain (220).

Results from the WHI randomized double blind placebo controlled trial of calcium and vitamin D on fracture risk in menopausal women were recently reported (221). Whereas BMD was significantly higher in the treated group, there were no significant differences in hip or non-hip fracture rates in the intention to treat analysis. Comparison between only those who adhered to therapy did, however, reveal a significant protective effect of supplementation on hip fracture.

As seen in other studies, effects were greater in older women, in those who were not taking additional calcium supplements and in those who had low baseline intakes of calcium (<800 mg/day) from all sources. Very few of the women in this study had a low intake of calcium and further supplementation was allowed in both arms of the study; the average intake of calcium at baseline was over 1,000 mg per day, which means that women in the treatment group were taking over 2,000 mg per day on average. An increased risk of kidney stones was observed in the calcium and vitamin D treated group, which also reflects the particularly high calcium intake levels. Thus, while these results indicate that calcium supplementation has no impact on fractures in healthy women who already have adequate intakes of calcium, the study results also demonstrate that there are potential benefits for women with low dietary calcium intake (221).

A low dietary calcium intake has been documented as a significant risk factor for low BMD in observational studies of middle-aged men (222;223), but there is a distinct lack of clinical trials that have assessed the impact of calcium supplementation on men. The results from one prospective study of men aged 30 to 87 years indicated that calcium supplementation for three years in those with a high baseline calcium intake (mean = 1,159 mg/day) has no effect on BMD change (224) and a randomized controlled trial that included just over 800 elderly men with previous fractures who were followed for up to five years found that calcium (combined with vitamin D) was not effective at preventing a further fracture (225). The potential long-term effects of calcium supplementation in mid-aged men on fracture risk are unknown.

There is evidence that calcium supplementation may interact with other interventions such as OHT and other medications (226;227), even during the period of rapid bone loss in women. A retrospective cohort study of early menopausal women taking OHT, for example, found that those who took calcium supplements in addition to OHT lost less bone mass over the two year study period than women on OHT alone (226). A review of clinical trials of OHT that compared studies that had administered OHT plus calcium supplements or diet modification to those that administered OHT only concluded that significantly greater increases in bone mass were seen in menopausal women with higher calcium intakes. There was also some evidence of a similar potentiation by calcium of the effect of calcitonin (227).

Despite the variable evidence of its influence in some subgroups, calcium is recommended as a necessary adjunct to therapy for osteoporosis in both women and men, and essential levels of calcium intake are advised for the prevention of osteoporosis in pre-, peri- and menopausal women, and in men (85;228). A statement prepared at the 1993 Consensus Conference of the Osteoporosis Society of Canada concluded that dietary calcium was

unambiguously important for bone health and recommended an optimum minimum intake as a preventive measure against osteoporosis of 1,000 mg/day of calcium for women and men aged 19 to 49 years, and between 1,000–1,500 mg/day for women and men aged 50 years and over (229). Clinical practice guidelines available in Canada in 1996 (at the time of the CaMOS baseline) recommended that adults obtain between 1,000 and 1,500 mg of calcium per day for "optimal bone health" (230). Osteoporosis Canada recommendations for daily intake of calcium for the prevention of osteoporosis are now 1,000 mg/day for premenopausal women and for men between the ages of 18 and 50 years, and 1,500 mg/day for menopausal women and men over 50 years (228). Health Canada and the Institute of Medicine recommend 1,000 mg/day for those aged between 19 and 50 years and 1,200 mg/day for those aged over 50 years (231).

2.4.2 Vitamin D

A deficiency of vitamin D is known to lead to below optimal calcium absorption and to increased parathyroid hormone excretion, which in turn stimulates osteoclast activity and increased bone loss (232); adequate amounts of vitamin D are necessary for bone health. Synthesis in the skin by UV light is a major source of vitamin D, but a significant portion of vitamin D is derived from diet, particularly during the winter or in parts of the world where sun exposure is more limited (233). Other factors that are associated with decreased synthesis of vitamin D in the skin are use of sunscreen, greater melatonin pigmentation and advancing age (234;235). It is believed that suboptimal dietary intake of vitamin D contributes to accelerated loss of bone mass and may also be associated with increased fracture risk (49;234). Vitamin D inadequacy (or low levels of vitamin D intake) have been linked to increased fracture risk in cross-sectional (236) and prospective (237) studies of menopausal women. Studies in Europe and North America, including Canada, have demonstrated that vitamin D insufficiency is prevalent in the middle-aged and in the elderly (233-235;238;239), which suggests that supplementation of vitamin D may be required for optimal bone health for many people, even in middle age.

Results from intervention studies have indicated a reasonably clear benefit of vitamin D supplementation on bone mass and fracture risk in older menopausal women, but the evidence for an effect in perimenopausal or early menopausal women, or in younger men is less consistent.

In a placebo controlled study of healthy menopausal women (mean age 62 years), treatment with 400 IU/day of vitamin D_3[11] slowed the normal seasonal bone loss and increased bone remodelling that occurs in the winter months (242). A later study by the same authors compared vitamin D_3 supplements of 100 IU per day to 700 IU per day and found a dose response effect; the higher dose was more effective at slowing bone loss in menopausal women (243). A trial that compared three groups of women and men randomized to either vitamin D_3 supplements, calcium supplements or placebo reported that bone loss at the hip in the vitamin D_3 treated group over four years was half way between the calcium and placebo treated groups (244), but not significantly different from either. The baseline level of vitamin D in these women and men (who were all aged 60 years or over) was relatively high, which suggests that supplementation in people with higher levels of vitamin D may have less potential benefit.

Fracture risk appears to be reduced with vitamin D supplementation in older women and possibly in men, although many of the trials of vitamin D supplementation have included calcium supplementation so that the effects of each cannot be separated. Trials in non-institutionalized women and men aged 65 years and over (245) and in healthy ambulatory elderly women (246;247), for example, have shown that supplementation of vitamin D_3 together with calcium supplementation reduces the incidence of hip (246;247) or other non-vertebral fractures (245;246). On the other hand, vitamin D_3 supplements, alone or combined with calcium, were of no measurable benefit in preventing further fracture in a large trial of vitamin D_3 supplementation for elderly women and men with a previous fracture (225). Overall, the balance of the evidence suggests that vitamin D supplementation is beneficial for older women and men: A recent meta-analysis of vitamin D_3 supplementation in ambulatory or institutionalized people aged 60 years or over concluded that supplements of 700 to 800 IU per day were effective at reducing hip and non-vertebral fracture risk in this population, but 400 IU per day was not effective (248). An earlier review and meta-analysis of placebo controlled trials of various forms of vitamin D_3 therapy in menopausal women concluded that vitamin D supplementation is effective at reducing the risk of vertebral fracture (249). It is plausible that supplementation is of more benefit when baseline intake of vitamin D is low or suboptimal. As pointed out by the authors of one meta-analysis (249), very few authors have documented baseline levels of vitamin D intake which limits the assessment of this potential explanation.

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[11] Vitamin D supplements are available in two separate forms, as Vitamin D_2 (ergocalciferol) and as Vitamin D_3 (cholecalciferol). Vitamin D_3 is now known to be a more potent and effective form of Vitamin D in the human body (240;241). The majority of intervention trials of the effects of Vitamin D on bone have used Vitamin D_3, even though Vitamin D_2 has been the more readily available form in prescriptions in North America.

Intervention studies of vitamin D therapy on BMD in early menopausal women and younger men have not shown significant effects. Loss of BMD at the lumbar spine or femoral neck was no different over five years in early menopausal non-osteoporotic women treated with low dose vitamin D_3 compared with placebo (250), although the dose of vitamin D_3 was likely insufficient to confer a benefit and it is not known whether selection of high risk women would have shown different results. Likewise, a twin study of young menopausal women (with a mean age of 59 years) to determine the effects of larger supplements of vitamin D_3 (800 IU per day) found no effect on BMD after two years of treatment (251). A randomized controlled trial of vitamin D_3 supplementation combined with calcium in normal healthy men aged 30 to 87 years also found no impact of the combined therapy compared with placebo after three years (224). The effects of vitamin D supplements on subgroups of younger women or men with either low baseline BMD or low baseline vitamin D levels are unknown.

Although there is only limited evidence that vitamin D supplementation alone is sufficient as a therapy for osteoporosis or to prevent fracture, adequate vitamin D is still recommended as an essential adjunct to preventive therapy and treatment for osteoporosis (85;228), and a dietary intake of between 400 and 800 IU of vitamin D per day was recommended for people with osteoporosis by guidelines and statements published by the Scientific Advisory Board of the Osteoporosis Society of Canada during the time that the CaMOS study began (229;230). Dietary sources of vitamin D are considered necessary in Canada because sun exposure is not sufficient to provide the full vitamin D requirements. Osteoporosis Canada's recommended intake level for vitamin D (from diet and supplements combined) for all men and women under 50 years of age is now 400 IU per day; this recommended requirement increases to 800 IU per day for men and women over 50 years of age (85;228). Joint guidelines provided for the Canadian and U.S. public from the Institute of Medicine and Health Canada (231) list somewhat lower dietary reference intake values for Vitamin D; 200 IU per day for men and women aged 19 to 50 and 400 IU per day for those aged 51 to 70 years.[12]

2.4.3 Exercise

Exercise plays a role in reducing bone loss or enhancing bone gain and, in people who have been diagnosed with osteoporosis, the benefits of exercise are believed to include an

[12] Health Canada's website now notes that these 1997 values may underestimate Vitamin D requirements and recommends that all women and men aged 50 years and over should take a daily Vitamin D supplement of 400 IU per day in addition to following Canada's Food Guide (252)

indirect protection against fractures by improving mobility and muscle strength and by reducing the risk of falls (253). A statement paper prepared at the 1995 consensus conference of the Osteoporosis Society of Canada concluded from a review of the available evidence that regular, moderate physical activity as a therapy for people with osteoporosis was warranted (254). In the same year that CaMOS began, Canadian guidelines for the management of osteoporosis from the Scientific Advisory Board of the Osteoporosis Society of Canada were published that included the recommendation of regular participation in an exercise program as part of a treatment regimen for osteoporosis (230).

The weight of evidence from cross-sectional and prospective non-randomised studies indicates that current or recent exercise has a protective effect on bone mass as well as on fracture risk in women and men (102;107;154;159;255-258). Even though this protective effect has not been consistently found, either for BMD (162;259) or for fracture risk (139;260), physical inactivity is clearly considered a "high" risk factor for osteoporotic fracture (160).

A Cochrane review of randomized controlled trials to assess the effects of exercise in preventing and treating osteoporosis in menopausal women was published in 2002 (261). This review included 18 studies (only one of which included fractures as an outcome) with a total of 1,423 participants. The authors concluded that aerobic exercise, resistance exercises and walking were all more effective than no prescribed program of exercise for reducing loss of BMD at the spine, while walking was effective at the hip. A similar meta-analysis that was published two years earlier and included all but two of the studies in the Cochrane review, as well as an additional eight RCT studies in premenopausal women, reached a similar conclusion about the effects of exercise in premenopausal women; the relative effectiveness of exercise on spinal BMD was comparable in premenopausal and menopausal women (262).

The potential impact of exercise therapy on fracture risk is less definitive. A recent review of trials that included exercise therapy as an intervention and fracture as an outcome identified only a handful of trials that met the eligibility criteria: subjects who would typically be considered at high risk for fractures (including all elderly people and menopausal women), fracture as an outcome and follow-up longer than eight weeks. Three trials of exercise in mid-aged populations were identified; all three included menopausal women. A meta-analysis of these three trials, which incorporated only 322 women when combined, showed a non-significant reduction in spinal fractures with the intervention (RR = 0.52, 95% CI = 0.17–1.60). The authors concluded that it is still unclear whether exercise interventions reduce the risk of fracture and that more RCTs are required to evaluate their effectiveness (263). RCTs of exercise

interventions have tended to be small, of short duration and are challenged by high rates of non-compliance or drop-out.

Despite the dearth of evidence from prospective studies for the effectiveness of exercise interventions on fracture risk, there is no doubt that the potential physical and mental health benefits of regular exercise in mid-age reach well beyond osteoporosis and fracture prevention. Current Canadian guidelines recommend that women and men should be encouraged to participate in exercise as a preventive measure against osteoporosis (85;87).

2.4.4 Smoking

The majority of studies that have investigated the effects of smoking on bone have found a positive association between smoking and reduced BMD (154;158;258;264) as well as increased fracture risk (107;159;219;255); but other studies have found no association between smoking and fracture risk (139;265). The effects of smoking on bone may be modified by other factors; there is evidence that smoking has a greater effect on BMD or fracture risk in those with a lower BMI (266), advancing age (267) and male gender (158) and that there is an interaction between smoking and OHT use in menopausal women (264;268). A recent meta-analysis of smoking and risk of fracture in men and women from 10 prospective cohorts, including CaMOS, showed that current smokers were at greater risk of low trauma fracture compared with non-smokers and that this association was partly independent of BMD and BMI. Further, the relative risk of smoking was greater in men than in women for osteoporotic fracture at sites other than the hip, but the relative risk for hip fracture was comparable between men and women (269). An earlier meta-analysis of 19 cohort and case control studies and 29 cross-sectional studies reached a similar conclusion; smoking was associated with lower BMD and with fracture in menopausal women and this association was independent of low BMI and less exercise participation (267). These authors estimated that 13% of hip fractures in women are attributable to smoking and that the relative risk of hip fracture in smokers compared with non-smokers increases with advancing age. Similar patterns were observed in men, although the data were limited (267).

The effects of smoking on BMD and on fracture risk are greater in current smokers than past smokers (264;267;269;270), which suggests that smoking cessation has the potential to improve risk status. Smoking is included as a risk factor for osteoporosis by guidelines in Canada and the U.S. (85;89); European guidelines have included discussion of the potential positive influences of smoking cessation on bone health but have not gone as far as to list smoking as a risk factor (90;172).

2.4.5 Alcohol

Although moderate alcohol intake may have a protective effect and has been observed to be associated with increased BMD in women and men (144;162;271), excessive alcohol intakes have consistently been found to be predictive of low BMD (272;273), loss of BMD over time (158) and fracture risk (136;274-276). A heavier intake of alcohol (more than two drinks per day) has been implicated as a risk factor for osteoporosis and fracture in both women and men. A recent international analysis of 5,939 men and 11,032 women from three cohorts, including CaMOS, determined that alcohol intake had a nonlinear effect on the risk of fracture; an increased risk of hip or any low trauma fracture was evident in women and men who consumed more than two alcoholic drinks per day. This increased risk appears to be at least partly independent of BMD and smoking (277). Excessive alcohol use is currently listed as a risk factor for osteoporosis by Osteoporosis Canada (86).

2.4.6 Caffeine

Excessive caffeine intake is believed to increase the risk of osteoporosis; the effect may be mediated by its interference with calcium retention and its association with low calcium intake. There is evidence from retrospective and prospective cohort studies for a moderate association between a high caffeine intake and fracture risk or low BMD (77;184;275;278-280), although the vast majority of the subjects studied have been women. Other prospective studies have found no association between caffeine intake and either bone loss (158) or fracture risk (219). It has further been suggested that the effects of high caffeine intake are only evident in those with low calcium intakes (278;279;281). High caffeine intake ($\geq$ 4 cups of coffee a day) is regarded as a minor risk factor for osteoporosis (85;282) or as a lifestyle factor that should be modified in preventive interventions (87) in some published guidelines. Other guidelines do not mention caffeine at all (88-90;172).

2.4.7 Medical Therapy

OHT (estrogen with or without progesterone) was the recommended first choice of treatment or prevention of osteoporosis in menopausal women during the time of the CaMOS baseline and Year 3 follow-up data collection (230). OHT has consistently been found to be effective in the prevention or slowing of bone loss and in the reduction of the risk of osteoporotic fracture (107;163;184;213;283). The Women's Health Initiative (WHI) randomised controlled primary

prevention trial of estrogen plus progestin *vs.* placebo was stopped in 2002 when an increased risk for invasive breast cancer in the treatment arm was detected. Other significant risks of OHT that were identified by this trial were increased risks of coronary heart disease, stroke and pulmonary embolism. On the other hand, the risk of hip fracture, as well as colorectal cancer, was significantly reduced in those treated with combined OHT (81). It is now generally agreed that the risks of OHT are likely to outweigh its benefits and it is no longer recommended as the first choice of therapy for osteoporosis (85;214).

Two bisphosphonates, alendronate and etidronate, were approved in Canada for the prevention or treatment of osteoporosis when the CaMOS baseline was conducted. The selective estrogen receptor modulator (SERM), raloxifene was approved for the prevention and treatment of postmenopausal osteoporosis, in 1998, before the three-year follow up of the CaMOS cohort began. Calcitonin was also available and reportedly being used as an alternative treatment, although it was not specifically approved as a medical intervention and therapy for osteoporosis (230). Bisphosphonates, raloxifene and calcitonin have been found to effectively increase and prevent loss of spinal bone density and fracture risk in menopausal women (284-293). There is evidence that alendronate is effective in increasing BMD and reducing vertebral fracture risk in men (294;295), while cyclical etidronate has been found to prevent bone loss in men with corticosteroid induced osteoporosis (296;297). There is limited information about the effects of calcitonin on men (297). Other agents have been approved for the treatment or prevention of osteoporosis since the completion of the three-year follow-up, such as risedronate and parathyroid hormone. Androgen therapy has been found to improve BMD in men with osteoporosis that is secondary to hypogonadism (low levels of testosterone); however, the majority of men with osteoporosis have normal gonadal function (297). None of these medications is without potential drawbacks; all have associated side effects that contribute to low rates of adherence.

2.4.8 Summary of Prevention and Treatment Recommendations

Appropriate lifestyle choices, such as adequate calcium intake and exercise, and smoking cessation are indicated for everyone as a means of maintaining or achieving optimal health, including bone health; in theory, these lifestyle decisions should not be influenced by measurements of bone density (57;85;87;89;172). Guidelines from Osteoporosis Canada (86) emphasize adequate calcium and exercise as preventive interventions and list excessive caffeine and alcohol consumption and smoking amongst the risk factors for osteoporosis. The Canadian

Task Force on Preventive Health Care (87) recommends that menopausal women, irrespective of their diagnosis from a BMD test, should have their lifestyle assessed. Physicians and other health professionals in Canada should be expected to stress the importance of these health behaviours to women and men with low BMD test results in particular, either as the only intervention or as an adjunct to pharmacological therapy. In turn, receipt of a low bone density measurement may be expected to motivate people to change their lifestyle in order to reduce their fracture risk. In addition to its general preventive role, calcium is specifically recommended in many countries as a treatment (together with other interventions) for osteoporosis (90), and both calcium and vitamin D are recommended as an adjunct to treatment for osteoporosis in Canada (85;228).

The Canadian Task Force on Preventive Health Care recommended in 2004 that menopausal women who are found to have osteoporosis should be treated with a bisphosphonate or raloxifene; if these cannot be tolerated then OHT or calcitonin should be considered. Treatment, other than lifestyle evaluation and modification if indicated, is not recommended for women with osteopenia if they are under age 65. The lifestyle recommendations include adequate calcium intake (1,000-1,500 mg/d), adequate vitamin D intake (400-800 IU/d), sufficient exercise (three times per week for at least 20-30 minutes each time), moderate caffeine intake (fewer than four cups of coffee per day) and smoking abstinence (87). Bisphosphonates are recommended as the first-line treatment for men with osteoporosis (or low bone mass) (85;297), but are not recommended for treatment of premenopausal women except in the presence of identified secondary causes of osteoporosis (85).

At the time of the CaMOS baseline between 1996 and 1997, there were limited recommendations and guidelines for the management of women with osteoporosis, and osteoporosis in men was barely addressed. The Osteoporosis Society of Canada recommended in 1996 that sufficient intake of calcium and vitamin D should be attained and that people should be counselled to exercise. In addition, high alcohol intake and smoking were recognized as high-risk behaviours for osteoporosis. OHT was recommended as both the preventive and treatment therapy of choice for menopausal women and bisphosphonates (alendronate and etidronate were approved at the time) were cited as a reasonable alternative for women with established osteoporosis, and for men. Other agents that have been used to prevent or treat osteoporosis, such as raloxifene, calcitonin, sodium fluoride, calcitriol and cyclical clodronate were not specifically approved for these purposes at the time of the CaMOS baseline but were available by prescription (230).

2.5 Awareness of Test Results Following BMD Testing

It is generally accepted that patients who are informed and knowledgeable about their health and about specific diseases that may affect them are more likely to be proactive in seeking information, to make positive changes to their lifestyles, to initiate medications when appropriate, and to adhere to physicians' recommendations or prescriptions. Hence we would expect individuals who are aware that they are at greater risk for fracture and those who are more knowledgeable about osteoporosis in general to be more likely to make positive changes than those who are less knowledgeable or are uncertain about their risk.

Although an increase in knowledge (or awareness) does not always lead to a change in behaviour, it is likely that some kind of knowledge is necessary before a conscious decision to make a change in health behaviour will be made. Knowledge is therefore typically considered to be a necessary, but not a sufficient factor for health behaviour change and many intervening factors are presumed to be involved in the process of behavioural change as explained in the following summary by Green and Kreuter:

> "Behaviour may not change immediately in response to new awareness or knowledge, but the cumulative effects of heightened awareness, increased understanding, and a greater command (recognition and recall) of facts seeps into the system of beliefs, values, attitudes, intentions and self-efficacy, and eventually into behaviour." [13]

There is a vast body of literature concerned with the role of factors such as beliefs, values, attitudes, intentions and self-efficacy in the complex pathway between knowledge and health behaviour. The scope of the following review is limited to studies that have focused on the specific assessment of correct knowledge of BMD test results and its association with information seeking and health behaviour or uptake of, and adherence to, medical therapy.

Estimates of correct knowledge or awareness of results (or diagnosis) after bone density testing have mostly been derived from retrospective studies of women referred for testing by their physicians (3;299;300). A limitation of such retrospective studies is that the women who took more notice of their results, and were therefore more likely to be correct, may also have been more likely to respond to the invitation to take part in the study, which would tend to give an inflated estimate of correct awareness. Furthermore, the definition of "correct" awareness of

[13] From Green, L.W. and Kreuter, M.W. (1991) Health Promotion Planning. An Educational Approach. 2nd Edition.. p. 156. (298)

test results has varied and this has a potentially large influence on the apparent awareness that screened women have of their test results.

In Rubin and Cummings' widely cited retrospective study of 327 women (aged between 23 and 96 years) who had been referred for a BMD test seven months previously, 85% of the participants who reported that they had received a "low" test result (defined as a BMD value that fell below the age-, sex- and race-adjusted mean) were correct (3). The proportions of women that incorrectly reported that their test result was "normal" or that reported that they did not know their results were not documented; the assessment of correct awareness of test results was therefore incomplete. The women in the study were predominantly white and menopausal with a high level of education and high prevalence of risk factors for osteoporosis, which limited the generalizability of the results; these characteristics of the sample may explain the reported high rate of correct awareness of test results.

A more recent study reported that one third of 956 women aged 46 - 90 years who had received a diagnosis of osteopenia or osteoporosis after referral for BMD testing and then had initiated OHT, raloxifene or a bisphosphonate, were unclear about their test results (whether they had osteopenia or osteoporosis) between four and twelve months after the initiation of therapy (299). Correct awareness was low, even though this sample would be expected to be biased towards women who were more likely to be correct about their test results due to the selection of only those who had initiated therapy, and therefore must have discussed their results with a physician. Medication adherence was found to be associated with self report of a diagnosis of osteoporosis; those who were uncertain about their diagnosis, or who believed that it was not osteoporosis were 1.6 times more likely to discontinue their medication. This latter subgroup, however, included the women who were correct about a diagnosis of osteopenia, who may have appropriately had less reason to adhere to therapy. Despite limits to the interpretation of the results due to the grouping together of those women who were correct about their osteopenia results with women who were incorrect about their osteoporosis results, the findings demonstrate that perceived osteoporosis disease status is a factor in the discontinuation of therapy, which implies that a correct awareness of test results could also be a factor in the initiation and maintenance of bone-specific health behaviour change.

In another study, only 48% of 977 women and 37 men (aged 34 – 93 years) were able to provide their correct diagnosis 18 months after they had been referred for DXA testing (300). Responses in this case were counted as correct if: (a) the participants who were informed of a diagnosis of either osteopenia or osteoporosis reported a low test result and (b) the participants

recalled a normal test result as such. This estimate of correct awareness in the referred population is likely to be more representative than those derived by the two studies above (3;299) because of its more complete definition of correct reporting as well as inclusion of referred patients with both normal and low test results. Just less than 50% correct awareness of test results is a disappointing rate for a referred sample. Furthermore, the authors did not include the 20% of participants who returned a questionnaire but declined to answer this question. If these selective non-responders are assumed to have been unaware or unsure of their test results, correct awareness of test results in the sample drops to as low as 38%. As has been observed in other studies (299;301), the participants who received low BMD test results were less likely to be correct than those with normal results; in particular those with a diagnosis of "osteopenia" were the least likely of all to be correct about their diagnosis (31% were correct or 26% if the non-responders are included). Despite the low rate of correct responses, 80% of the participants in this study reported that their physician had passed on the results from the test. This suggests that either the communication between the physician and patient (or the "patient education") was at fault or that the participants were not sufficiently interested to take notice of their results or to retain the information. Thus, although it is assumed that test results must first be communicated to patients before they can be aware of their risk, even when results are communicated, patients may not always understand or commit them to memory. The participants who were correct about their low test results, compared with those who were incorrect about low test results, were more likely to have been prescribed and to have adhered to medication. This analysis was not stratified by diagnosis, however, so there is potential confounding by a diagnosis of osteopenia, which was associated with more incorrect responses and also carries a lower indication for therapy and arguably greater justification for non-adherence. Although this study is unique in that the sample included men, no information specific to the men was provided; the results were not stratified by sex (presumably because of the small number of men in the study) (300).

A Canadian study has similarly reported that women are less likely to be correct about low BMD test results than about normal results; "osteopenia" was the least frequently correctly reported diagnosis reported by a prospective cohort of Canadian women aged over 50 years who had been referred for BMD testing (301). Fifty one percent of the women with an osteopenia diagnosis thought that their results were normal when interviewed by telephone three months after testing and a further 25% were unclear about their results. In contrast, only 6.4% of women with a diagnosis of osteoporosis thought that their results were normal, while 50% were unclear. Women who had a normal result were the most likely to be correct; none of them reported a low

test result and 30% were unclear of their result. Women who were correct about their osteoporosis diagnosis were more likely to have initiated OHT or bisphosphonates than those who were incorrect. The authors interpreted their results as indicating that communication between the physician and patient is crucial to therapeutic decision-making (301). It is not, however, possible to determine the cause: Patients may have taken prescribed medications because they had a better understanding of their low test results and associated risk for fracture or they may have paid more attention to their results because their physicians recommended therapy.

Pickney and Arnason (300) commented that older age of the patient, specialty of the physician and time since the DXA were not associated with correctly reporting test results in unadjusted analyses. Except for the diagnosis from BMD testing and whether the results were discussed with a physician, other potential predictors or confounders of correct awareness of test results (such as education level and risk factors for osteoporosis) have not been addressed by previous researchers (3;299-301).

The results from these observational studies of referred samples (299-301) suggest that the perception of low test results in women is associated with uptake or adherence to therapy, and that improvement in communication between physicians and patients or patient education may lead to improved appropriate medication uptake. Such results further imply that improved communication of BMD test results or diagnosis could be associated with positive lifestyle changes.

The only previous study of correct awareness of BMD test results in a non-referred sample included 515 mid-aged women (aged 45-54 years) who were randomly selected from a population health register in Aberdeen, Scotland to participate in a randomized controlled trial to assess the effect of direct-to-participant feedback on knowledge of test results (302). The cut-off for a report of a low bone density for this study was the lowest quartile of the sample; these women were informed that their BMD was below average (in the lowest 25%)[14] and that they may be at risk of osteoporosis in later life. Two years after testing only 43% of the women were able to correctly recall whether they were at increased risk; this is comparable to the rates of correct awareness reported in referred samples (300;301). Also in line with previous studies, the

[14] The study by Campbell et al. was conducted before the release of the WHO diagnostic guidelines for osteoporosis (50). Other investigations of the effects of BMD feedback in premenopausal women, conducted since the release of the WHO diagnostic criteria, have also utilized alternative, less stringent, methods of defining higher risk for fracture in their feedback (303-306). Few premenopausal women meet the WHO criteria for high risk ("osteoporosis"), furthermore, the criteria were derived for use with menopausal women, although they are now often applied to premenopausal women and men in clinical practice or research.

25% who were told that they were at greater risk were less likely to be correct; only 26% of the women in the lowest quartile were able to recall their low result.

2.6 Information seeking and Knowledge about Osteoporosis

Seeking out or accessing information would be expected to lead to an increased level of knowledge about osteoporosis, particularly if the baseline level of knowledge in the population is low. In general, studies that have assessed knowledge about osteoporosis have demonstrated only poor to moderate levels of knowledge about the consequences of osteoporosis, its risk factors and preventive interventions (307). Women (308-310), people with a higher education (308;311-313), and those with a family history of osteoporosis (314;315) are the most likely to be knowledgeable about the disease. People who have previously received information about osteoporosis are also more knowledgeable (312;316), which indicates that information seeking about osteoporosis is likely to improve knowledge about osteoporosis.

A recent presentation at the 2006 American Society for Bone and Mineral Research Conference reported that men aged 40 to 79 years who had been referred for DXA evaluation and diagnosed with osteoporosis or osteopenia were no more knowledgeable about the risk factors for osteoporosis than were matched controls who had not received a DXA test or an equivalent diagnosis. Knowledge about risk factors was low overall in these men who were from predominantly rural communities, but was particularly poor regarding the role of smoking and excessive alcohol consumption. Diagnosis was not associated with knowledge, even though men who had been diagnosed with osteoporosis or osteopenia were less likely to report a low calcium intake or excessive alcohol use. Although no causal relationships between diagnosis and changes in knowledge and health behaviour can be inferred from this case-control study, because baseline levels of these variables were unavailable, it is the only available report of levels of knowledge about risk factors in a population of men who have been deemed to be at high risk (317).

As pointed out by Werner (307) in her review of studies of people's knowledge of osteoporosis, the assessment of knowledge is based on the assumption that increased knowledge will be associated with increased participation in preventive behaviours. A logical extension of this assumption is that information seeking about osteoporosis will lead to increased knowledge and may have an indirect impact on preventive behaviours. It has been proposed that health information seeking behaviour could be regarded as a process that may lead to specific health behaviours, or that it may define people who are considering health behaviour change (318).

Efforts to obtain information about health in general have been found to be associated with positive health behaviours and fewer risky behaviours (318;319). Both gender (being female) (318;319) and older age (319) are predictive of more information seeking about health.

People who participate in (or who are seriously considering participating in) osteoporosis-related health behaviours such as increased calcium intake or calcium supplement use (316;320-324), regular physical activity (320;323-325), and use of OHT (316;320), as well as those who demonstrate a greater likelihood of stopping steroid use (316), have been shown to have increased knowledge about osteoporosis in cross-sectional and intervention studies. It is evident however that knowledge alone does not necessarily influence health behaviour (326). Thus, the association between increased osteoporosis knowledge and positive health behaviours, or even the intention to change behaviour, has not been consistently identified. In one well-designed intervention study involving a large sample of randomly selected premenopausal women from the Tasmanian population, a group education intervention led to increased knowledge about osteoporosis, but this greater knowledge was not associated with increased self-efficacy regarding calcium intake and physical activity either six months, or two years, after BMD testing and education (303). A low BMD test result (defined as a mean T-score < 0) was similarly not associated with increased self-efficacy (303). Interestingly, women in the low BMD group showed a gradually increasing level of knowledge between six months and two years after testing compared with the normal group, which suggests that they may well have sought information over time as a result of their BMD test results (303).

No association was found between knowledge and dietary calcium intake or weight bearing exercise participation in two other studies involving young college aged women (327;328) and in a small intervention study of three distinct groups of women (31 young college students, a community sample of 35 women aged 22 to 83 years, and a group of 18 mid-aged nurses) in which each group received a different intervention (329). It is notable that studies that have found no association between increased knowledge and health behaviour change have most often involved younger women. A possible explanation for this discrepancy with studies of older women is that younger women may be less motivated to make behavioural changes, even when they are aware of the risks, because the threat of osteoporosis is more distant and may seem less relevant to them (330).

Other authors have examined the association between whether subjects have discussed their BMD test results with a physician and their behaviour change or medication uptake and adherence. Discussion of BMD test results with a physician may represent a form of information

seeking (if consultation were initiated by patients or if patients sought information during the consultation). It is also possible that a physician would have initiated the consultation and that the transfer of information was also initiated by the physician. The latter scenario may be more likely in cases where the subjects had originally been referred for a BMD test by the physician as opposed to self-referred.

A large proportion of women who have been referred for BMD testing report that they have discussed their test results with their physician. Ninety-five percent of women aged between 23 and 96 years in a retrospective sample that was randomly selected from those referred for BMD testing in the San Francisco area recalled that they had discussed their results with a physician or health-care provider (3), similarly 80% of retrospectively sampled women and men who had been referred for BMD testing at a Wisconsin health centre reported having received their test results from their physician (300). Likewise, a prospective study of women referred for DXA testing near Boston found that 79% of the participants had discussed their results with a physician (331). Because these were referred populations, the rates of a low diagnosis (either osteopenia or osteoporosis) were relatively high; ranging from 53% to 83% of the sample (3;300;331), suggesting that other risk factors may have been present and which may have influenced these women's sense of susceptibility.

Non-referred subjects who have been invited to attend BMD testing as part of a study would be expected to have lower rates of low test results and hence potentially lower reported rates of discussion of test results with a physician. Only 33% of a convenience sample of premenopausal women who underwent testing said that they had discussed their test results with a physician. Twenty percent of the sample had been informed that they had low test results (Z-score < -1.0), however, and 76% of this subgroup had discussed their results with a physician, which indicates that, appropriately, diagnosis is a major factor (306). Although no association was reportedly found between discussion of the results with a physician and positive lifestyle change, it is not clear how the authors defined a change in health behaviour, and the number of women who changed their behaviour was not reported.

Discussion of BMD test results with a physician or other health-care provider has been shown to be associated with the initiation of therapy (OHT or bisphosphonates) in prospective studies of Canadian women aged 50 years and over who had been referred for testing (301), and mid-aged women (aged 54 to 65 years) who volunteered to participate in a study on osteoporosis prevention (332). These findings suggest that those who discuss their results with a physician are more likely to start medication, although cause and effect cannot be established. It is not

possible to determine if the consultation influenced the participant's decision to start medication, or whether the physician initiated the consultation because of low test results and indication for therapy, or indeed if the participant initiated the consultation because of an interest in initiating therapy or lifestyle change. Furthermore, these studies (301;332) did not address whether the initiation of medication was appropriate; consultation or discussion with a physician is only potentially valuable if it leads to *appropriate* treatment or behavioural change.

Appropriate treatment following BMD testing was taken into account by Solomon et al. (331) in their study of a referred sample of mostly menopausal women. Bisphosphonates or calcitonin were much more likely to be taken by the women who received a diagnosis of osteoporosis and somewhat more likely to be taken by the women with a diagnosis of osteopenia. No women in the normal BMD group initiated bisphosphonate or calcitonin therapy, which was considered appropriate. In this homogeneous group of white women, many of whom had other risk factors for osteoporosis, OHT use did not appear to be influenced by the BMD test results; the women who had received a normal result were just as likely to be taking OHT as were the women who received a diagnosis of osteoporosis.[15] Consultation with a physician was not associated with initiation of appropriate therapy. The women who reported that they understood their test results, however, were more likely to have initiated appropriate therapy than were the women who stated that they did not understand their results (331). This suggests that simply consulting with a physician is not sufficient; the quality of the discussion or consultation is likely to play a role in patient understanding, initiation of health behaviours and medication uptake.

The sources of osteoporosis information that have been accessed by particular populations have been described by three previous studies. The findings have indicated that information sources that men and women use to learn about osteoporosis are not limited to the doctor's office. In fact, other sources of information about osteoporosis have been cited at least as frequently as have health professionals by Canadian seniors (310) and more frequently than health professionals by young college women (328) and women who were referred for (but not yet attended) DXA testing (333).

Television, newspapers, books, friends, and family physicians were each cited by approximately 30% of seniors as common sources of osteoporosis information in a community-based convenience sample of women and men (310). Other sources, such as family members

[15] This study was completed before the results of the Women's Health Initiative were available, when OHT was amongst the first line of therapy for the prevention of osteoporosis and heart disease, and for the relief of menopausal symptoms.

and the internet, were much less frequently mentioned. Women in this sample had a significantly higher awareness and knowledge about osteoporosis than had the men, even though the same number of women and men cited each of these top five sources. The likelihood of having accessed information from *any* source (or the number of people who had not sought information at all) was not presented (310).

A study of college women with a mean age of 19 years reported media as the main source of information about osteoporosis. Seventy-nine percent of these young women who had received information about osteoporosis reported that it had been acquired from television programs, 68% had gained information from magazines and 43% reported receiving information from a doctor or other health-care provider (328). Fifty-seven percent of the women who had been referred for DXA testing at two Canadian centres had initially "heard about osteoporosis" through newspapers and magazines, but only 11% had acquired such initial information from a health-care practitioner (333). The descriptive results from these three very different populations suggest that media sources such as television, newspapers and magazines are heavily relied upon as sources of information about osteoporosis and are more likely to be used as sources than are family physicians.

The potential impact of BMD testing on information seeking about osteoporosis was assessed in a study of a convenience sample of women who were recruited through advertisements (334). This descriptive study found that, of the women whose test results fell in the lower third for their age, 72% sought information from either a health-care provider or another source while only 42% of those whose results fell in the upper third for their age sought information. Although this sample is likely to represent more highly motivated women than the general population, the results suggest that the reports received following BMD tests can play a role in prompting information seeking (334).

In summary, the bulk of previous studies have indicated that increased knowledge about osteoporosis, or receipt of information about osteoporosis, is associated with an increased likelihood of positive health behaviour or medication uptake. So far, there has been no information about what predicts information seeking following BMD testing, or the preferred sources of sought information, in a population-based sample of women or men. People who receive low BMD test results and understand that they are at increased risk for fracture may be expected to seek information about osteoporosis as a means of learning about lifestyle modification options and the availability of medications that may decrease their risk; furthermore, such information seeking behaviour is likely to be a step in the process towards a

change in health behaviour. On the other hand, it is plausible that receipt of a low test result can lead to avoidance of more information when it causes anxiety or mental discomfort. Such avoidance of information has been documented, particularly with regard to genetic testing for cancer risk (335). In the case of osteoporosis, a lack of information seeking behaviour may indicate either avoidance of information, disinterest or lack of need (i.e., the level of knowledge is already high).

2.7 Behavioural Change Following BMD Testing

The majority of studies that have attempted to determine whether bone-specific changes in behaviour follow the receipt of low BMD test results have included women who have been referred by their physicians for BMD testing. Many have used convenience samples, often recruited retrospectively, which limits the generalizability of the findings to these specific populations.

Table 2.2 summarizes the published research that has specifically investigated the impact of low BMD test results (or awareness of low test results) on bone-specific health behaviour. The publications in Table 2.2 are limited to those that have specifically examined BMD test results as a predictor and health-behaviour change as an outcome. Studies of the effects of other interventions, such as educational materials on lifestyle changes, have not been included unless BMD test results were also considered as an explanatory variable in the study. Studies that have measured change after receipt of low BMD results, without comparison with changes made following normal or higher test results (i.e., no comparison group) have not been included.

Table 2.2: Previous Studies of the Effects of Low BMD Test Results on Bone-Specific Health Behaviour

Authors / Sample Size at Follow-up	**Study Population / Age**	**Baseline Measures / Adjustment for Confounders / Analysis**	**Definition of Low Test Results in Feedback / Independent Variable (IV)**	**Time: BMD Test to Follow-up**	**Outcomes**	**Findings: Association between Low Test Results and Health Behaviour**
Cook et al., 1991 (336) n = 380	- Women - Prospective - Volunteer sample from 4 medical practices Age 30+ years	No behavioural baseline measures. Other predictors considered: Age, Income, Education. Bivariate (Chi-squared). (No adjusted analyses)	Above average, average or below average for age. IV: Feedback of average, above average or below average results.	1 year	Self reported change: - Diet - Exercise - Alcohol - Smoking - Other habits	+ve association (below average v. average/above average): - Change in diet - Change in exercise No association with: - Smoking - Alcohol consumption - Other habits
Rubin and Cummings, 1992 (3) n = 261	- Women - Retrospective - Randomly sampled from all those referred for BMD test during 14 mth period. - Age 23-96 years (mean age = 59)	No behavioural baseline measures. Covariates: Education; Family History; Previous fracture; comorbidity; perception of risk. Bivariate (Chi-squared) and some multivariable regression	Above ("normal") or below ("low") mean for age. IV: Self report of normal or low test results	4-24 months (mean = 7 mths).	Self reported change: - Ca+ supplements - Vitamin D supplements - Milk/Ca+ rich foods - Exercise - Coffee, tea or cola - Alcohol - Smoking - Estrogen therapy - Other therapy (sodium fluoride or calcitonin) - Worry or fear of falling	+ve association (low v. normal): - Started Ca+ supplements - Started Vit. D supplements - Increased milk/Ca+ rich foods - Started or increased exercise - Reduced coffee, tea or cola - Started estrogen therapy - Started other therapy - Increased worry about osteoporosis - Increased fear of falling No association with: - Decreased alcohol intake - Smoking cessation

Authors / Sample Size at Follow-up	Study Population / Age	Baseline Measures / Adjustment for Confounders / Analysis	Definition of Low Test Results in Feedback / Independent Variable (IV)	Time: BMD Test to Follow-up	Outcomes	Findings: Association between Low Test Results and Health Behaviour
Holt et al., 1997 (337) n = 312	- Women - Retrospective - Convenience sample from those referred for BMD testing - Aged 39 – 88 (mean age = 62)	No baseline measures No adjustment for confounders Bivariate tests of association	Feedback not described IV: Self report of normal or low test results	Up to 6 months	Self reported change: - Calcium - Exercise - Diet - Estrogen - Bisphosphonates - Calcitonin	<u>+ve association (low v. normal):</u> - Increased calcium intake - Increased exercise - Changes in diet - Started medications (estrogen, bisphosphonates or calcitonin).
Jones and Scott, 1999 (305) n = 271	- Premenopausal women - Prospective - Convenience sample from another study (young mothers, more likely to be smokers, less likely to have breastfed) - Mean age = 33	Baseline data not comparable to follow-up (collected during pregnancy and 6 years before DXA) Bivariate tests	Normal (T-score ≥ -1.0) or Low (T-score < -1.0) BMD. IV: Feedback of low or normal results	1 year	Self reported change: - Use of Ca+ supplements - Calcium intake - Physical activity - Smoking Continuous measures at follow-up (unadjusted for baseline): - Calcium intake by food frequency questionnaire - Exercise questionnaire	<u>+ve association (low v. normal):</u> - Increased Ca+ supplement use - Increased Ca+ intake - Increased physical activity - Higher calcium intake by food frequency questionnaire - Lower overall sports participation by questionnaire <u>No association with:</u> - Smoking cessation

Authors / Sample Size at Follow-up	Study Population / Age	Baseline Measures / Adjustment for Confounders / Analysis	Definition of Low Test Results in Feedback / Independent Variable (IV)	Time: BMD Test to Follow-up	Outcomes	Findings: Association between Low Test Results and Health Behaviour
Jamal et al., 1999 (306) n = 669	- Premenopausal women - Prospective - Convenience sample recruited via adverts (79% university or college educated, 41% had FH of osteoporosis) - Age 18–35 years (mean age = 28)	Baseline measures taken, using different methods to follow-up. Covariates: Age, weight, FH, education Unadjusted regression (presented) and adjusted regression (data not presented)	Normal (Z-Score > -1.0) or Low (Z-Score ≤ -1.0) BMD. IV: Feedback of low or normal results	1 year	Change in behaviour relative to baseline (derivation of outcomes used for the analysis of association with diagnosis was not defined by authors). - Use of Ca+ supplements - Use of Vit. D supplements - ≥ 3 km walking / week - ≥ 1 cup milk / day - Smoking - ≥ 1 alcoholic drink / day - ≥ 3 cups caffeinated drinks / day	<u>+ve association (low v. normal):</u> - Use of calcium supplements - Use of Vit. D supplements <u>No association with:</u> - ≥ 3 km walking / week - ≥ 1 cup milk / day - Smoking - ≥ 1 alcoholic drink / day - ≥ 3 cups caffeinated drinks / day
Rimes et al., 1999 (334) n = 298	- Women -Prospective - Convenience sample recruited via adverts - Age 32-73 years (mean age = 54)	Baseline measures taken into account. No adjustment for covariates. Descriptive analyses, Chi-squared, t-test and ANOVA	"Below fracture threshold" or not. Cut-off for feedback not described IV: Lowest $^1/_3$ compared with highest $^1/_3$ based on Z score (analysis limited to n = 180)	1 week and 3 months	Behaviours undertaken "to prevent or slow down bone loss" (open ended question). Change determined by comparison with baseline: - Calcium supplements - Other mineral or vitamin supplements - Diet - Exercise - Drug prescribed by doctor - Other Changes in: Worry, anxiety, perceived susceptibility	<u>+ve association (low v. high):</u> - Greater number of preventive behaviours - At least one preventive behaviour - Uptake of calcium supplements - Increased anxiety - Increased perception of risk <u>No association with:</u> - Exercise - Other mineral or vitamin supplements - OHT uptake

Authors / Sample Size at Follow-up	Study Population / Age	Baseline Measures / Adjustment for Confounders / Analysis	Definition of Low Test Results in Feedback / Independent Variable (IV)	Time: BMD Test to Follow-up	Outcomes	Findings: Association between Low Test Results and Health Behaviour
Marci et al., 2000 (338) n = 701	- Menopausal women - Retrospective - Convenience sample of those referred to an osteoporosis clinic - Age 50+ years	Baseline measures available; not taken into account in defining change. Covariates: Ed, age, history of OP, previous fracture, comorbidity, FH of OP, worry about OP. Multivariable logistic regression to adjust for confounders	Normal (T-Score ≥ -2.0), moderate low bone mass (T-Score < -2.0 and ≥ -3.0), severe low bone mass (T-Score < -3.0). IV: Feedback of normal or below normal BMD	15-55 months. (Mean = 2.9 years)	Self report of changes to prevent osteoporosis: - Calcium supplements - Dietary consumption of milk / calcium-rich foods - Exercise habits - Smoking habits - Caffeine intake - OHT - Limited activities to avoid falling - Safety precautions	<u>+ve association (low v. normal):</u> - Started Ca+ supplement use - Increased dietary calcium - Started exercise - Smoking cessation - Decreased caffeine - Initiated OHT - Initiated precautions to prevent falls - Increased worry about OP
Rolnick et al., 2001 (332) n = 508	- Menopausal Women - Prospective - Convenience sample invited from a care organization - Menopausal - Age 54-65 years	Baseline measured but not taken into account in definition of change. Covariates were not taken into account in analyses of associations between behaviour change and BMD test results. Bivariate analysis (Chi-squared)	WHO definitions of normal, osteopenia and osteoporosis. IV: Feedback of normal, osteopenia and osteoporosis	6 months	Self report of changes initiated in last 6 months since DXA test. - Calcium intake - Vitamin D intake - Diet or eating patterns - Exercise Prescription data and self report: - Started OHT - Started other medications	<u>+ve association (low v. normal):</u> - Increased vitamin D intake - Started OHT - Started other bone-specific medication <u>No association with:</u> - Increased calcium intake - Modification of diet - Increased exercise

Authors / Sample Size at Follow-up	Study Population / Age	Baseline Measures / Adjustment for Confounders / Analysis	Definition of Low Test Results in Feedback / Independent Variable (IV)	Time: BMD Test to Follow-up	Outcomes	Findings: Association between Low Test Results and Health Behaviour
Wallace et al., 2002 (339) n = 129	- Perimenopausal and menopausal women - Retrospective - Convenience sample recruited from women referred for DXA testing. - Aged up to 65 years (mean age = 54)	Baseline measures of all behaviours Covariates: Age, osteoporosis knowledge, health beliefs. Multivariable linear and logistic regression, adjusted for baseline behaviours and confounders	WHO definitions of normal, osteopenia and osteoporosis. IV: Feedback of normal, osteopenia and osteoporosis	4 months	- FFQ for total calcium - Ca+ intake meets recommended daily intake; (Ca+ intake derived from FFQ dichotomised to more or less than 1,500 mg/day). - Exercise scale; dichotomised to more or less than 60 minutes/ week.	<u>+ve association (low v. normal):</u> - Intake of total calcium <u>No association:</u> - Intake $\geq$ 1,500 mg Ca+ - $\geq$ 60 minutes exercise / week
Patel et al., 2003 (340) n = 102	- Men - Prospective - Convenience sample of patients with prostate cancer recruited from urology practice ($^2/_3$) and healthy men recruited from adverts - Age 48-84 years	Baseline not taken into account in definition of change Bivariate analyses only (no adjustment for covariates)	WHO definitions of normal, osteopenia and osteoporosis. IV: Feedback of normal or osteopenia *v.* feedback of osteoporosis	Mean = 1 year	Self report of changes in: - Calcium supplements - Vitamin D supplements - Diet - Exercise - Smoking - Caffeine intake - Use of bisphosphonates - Fall prevention habits - Fear of falling	<u>+ve association (low v. normal):</u> - Started calcium supplements - Started vitamin D supplements - Started bisphosphonates - Increased fear of falling <u>No association with:</u> - Change in dietary calcium - Change in exercise patterns - Change in alcohol intake - Change in smoking - Change in caffeine intake - Limiting of activities related to falling

Authors / Sample Size at Follow-up	Study Population / Age	Baseline Measures / Adjustment for Confounders / Analysis	Definition of Low Test Results in Feedback / Independent Variable (IV)	Time: BMD Test to Follow-up	Outcomes	Findings: Association between Low Test Results and Health Behaviour
Hamel et al., 2005 (333) n = 1057	- Women - Prospective - Convenience sample recruited from women referred for DXA testing. - Mean age = 58 years	Baseline measures of behaviours: Baseline calcium intake was taken into account in estimation of change in calcium in diet. No other adjustments for baseline measures. Other covariates: History of previous fracture, age ≥ 45. Logistic regression	WHO definitions of normal, osteopenia and osteoporosis. IV: Feedback of normal v. feedback of osteopenia or osteoporosis	3 months	Self report of changes in: - Calcium intake - Exercise -Dietary calcium intake estimated from FFQ of calcium rich foods Self report of current use of: - calcium supplements - Vitamin D supplements - Bisphosphonates - Estrogen - Natural remedies	<u>+ve association (osteoporosis v. normal or osteopenia v. normal):</u> - Self report increased calcium - Use of Ca supplements - Use of Vit.D supplements - Use of natural remedies - Use of bisphosphonates - *Non-use* of estrogen <u>No association with:</u> - Change in dietary calcium - Self report of increased exercise
Winzenberg et al., 2006 (304) n = 415	- Premenopausal women - Prospective - Randomly selected population-based sample (64% response rate and 88% retention to follow-up) - Premenopausal - Age 24 – 44 years (mean age = 38)	Baseline measures of all behaviours and covariates; not clearly taken into account in analysis of association between diagnosis and behavioural change Bivariate analyses	Normal (T-Score ≥ 0) or Low (T-Score < 0) BMD. IV: Feedback of low or normal results.	2 years	Self report of changes in: - Use of calcium supplements - Dietary Calcium intake - Physical activity - Smoking cessation Calcium intake and use of calcium supplements also derived from FFQ; physical activity also derived from questionnaires. Muscle strength and endurance fitness (objective measures)	<u>+ve association (low v. normal):</u> - Started calcium supplements - Increased physical activity <u>No association with:</u> - Dietary calcium intake - Smoking cessation - Strenuous activity - Change in leg strength - Change in work capacity

As can be seen from Table 2.2, the majority of previous investigations of the effects of BMD test results on health behaviour have assessed women; the single report that measured behavioural change in men recruited two thirds of its sample from men who had a history of prostate cancer (and two thirds of these men were hypogonadal and thus at high risk for osteoporosis) and the remaining third (men in the community) were recruited through advertisements (340). Virtually all of the studies either recruited women from a referred population or they used a convenience sample. Some of the referred samples were recruited retrospectively, after their test results were known (3;337;338), which may limit the generalizability of the results to more motivated individuals, who were more likely to have made changes because of their test results. There are no population-based studies of the association between BMD test results and bone-specific health behaviour change in perimenopausal or menopausal women, or in men. The association between BMD test results and behavioural change was investigated in a randomly selected population-based sample of premenopausal women in Southern Tasmania (304). Follow-up has been short term for the most part; only two studies included a mean follow-up period of more than one year after BMD testing (304;338).

Although some of the authors listed in Table 2.2 reportedly measured pre-test levels of behaviour (such as the amount of calcium intake, exercise frequency, use of supplements, alcohol or caffeine intake) only three of these studies clearly documented that these values were taken into account when assessing at least some of the changes following BMD testing (333;334;339). Most often, the participants were simply asked to report if they had changed these behaviours at the follow-up, whether or not the baseline behaviours had been measured (3;305;332;336-338;340). Holt et al. (337), for example, asked specifically, "What did you do differently because of your DXA test results?" This latter approach to questioning is subject to potential bias, not only because women with low test results may be more likely to report relatively more changes than women with normal results, just because they believe that the behavioural change is expected of them (recall bias), but also because behavioural changes that were not perceived by the women as due to BMD test results would not be documented (observation bias).

In the large Canadian study reported by Hamel et al., a combination of approaches was used to assess behavioural change (333). A change in calcium intake was derived from the difference between the self report of current intake of calcium-rich foods at follow-up and the current intake reported at baseline, supplement and medication use were represented by reported use at follow-up with no adjustment for baseline, and subjects were asked simply if they had

changed their calcium intake and exercise. Interestingly, diagnosis of osteoporosis was found to be associated with a self reported change in calcium intake in this sample, but not with the difference in calcium intake based on the food frequency questionnaire (FFQ). The assessment of change in calcium intake with the FFQ may be a more objective and less potentially biased method in this situation. On the other hand, the measurement of calcium intake based on a few select foods may have been too crude a measure to accurately reflect a change, as the authors suggested (333). Estrogen use was found to be significantly more frequent in the women who had been diagnosed with a normal BMD compared with those who had osteoporosis (333); the authors did not adjust their analysis for baseline differences and it is apparent that this difference is explained by more frequent use of estrogen in the "normal" diagnostic group, even before the DXA test.

The much smaller study by Wallace et al. (339) included adjustment for baseline levels of health behaviours (calcium and exercise) in the analyses and found that neither dietary calcium intake nor exercise behaviour were associated with a low BMD test result: The only predictors of post scan calcium and exercise were pre scan calcium and exercise. It is feasible that these more objective measures of behaviour change, taking baseline levels into account provide a more accurate reflection of true behavioural change. There are other explanations for the observed lack of impact of BMD test results in this study, however, because the time between DXA testing and follow up was very short (only up to three months) and possibly too soon for behavioural changes to have taken place, and there was a particularly high attrition rate (50%), which limits the interpretation of the results. Rimes et al. (334) compared follow-up measures of specific behaviours that were reported in response to the question, "Do you do or take anything to try to prevent or slow down bone loss?" with responses to the same question at baseline to identify behavioural changes. Due to the wording of the question, information about participation in any of the behaviours for other (health or non-health) reasons was not available.

Because subjects cannot be randomized to receive low or normal test results, baseline health behaviours would not be expected to be randomly distributed between BMD diagnostic groups and should be taken into account in any analysis of the association between test results and behavioural change. If women with low BMD results already participated in little exercise, or had a low baseline calcium intake, for example (as may be predicted given that lack of exercise and low calcium are risk factors for low bone density), they also have greater potential to make positive changes. Women who are already exercising several times a week on the other hand, have less room for improvement and ceiling effects may be observed.

Winzenberg et al. (304) comprehensively measured baseline behaviours and determined change in calcium intake and exercise both objectively, by comparing follow up behaviours to baseline, as well as by self reported change. These randomly selected premenopausal women were more likely to begin taking calcium supplements (as measured by the FFQ) and to increase their physical activity (by self report) if they received a report of a low BMD test result, which suggests that young, low risk women would be prepared to make adjustments to their lifestyle in response to low BMD results. Furthermore, the authors found that after two years, bone mineral density had increased in the women who had commenced calcium supplements and in the women who reported persistent increases in physical activity relative to the women who did not report such lifestyle change. In contrast to the impact of a low BMD test result, an education intervention (small group education *v.* leaflets) did not have any effect on health behaviour or change in BMD.

All of the studies listed in Table 2.2 that investigated change in the use of calcium or vitamin D supplements found that those who had been told, or believed, that they had low bone mineral density were more likely to start taking such supplements after they received low test results (3;304-306;333;334;337;338;340). On the other hand, changes to dietary calcium intake were observed to occur following low BMD test results in some studies (3;305;337;338), but not in others (304;306;332;333;339;340). Changes in exercise behaviour and decreased caffeine intake in response to low test results were inconsistently reported. The methods for defining the diagnosis, length of follow-up and definition of "change" likely influenced these outcomes to some extent. Two of the publications that found positive change in many of the behaviours, for example, used women's self reported diagnosis, rather than the actual diagnosis received, as the predictor variable (3;337). The women who perceived that they were at greater risk for osteoporosis were more likely to participate in bone-specific health behaviours (341) or adhere to bone-specific medications (299) than were the women who perceived themselves at lower risk or as "normal", irrespective of their actual BMD test results.

Marci et al. (338) reported that women with a low BMD were more likely to stop smoking than were women with normal results. These findings, while encouraging, are surprising because smoking behaviour is notoriously difficult to modify. It is not clear, however, whether women who were diagnosed with a normal BMD were just as likely to quit smoking: The women were asked specifically if they had stopped smoking "to prevent osteoporosis as a result of having their first bone density test". These women may have stopped smoking for several reasons (in keeping with the secular trend), but those with a diagnosis of osteoporosis

were more likely to cite the diagnosis as the reason for quitting and therefore more likely to respond positively to this question. No other studies that have assessed smoking behaviour have identified any impact of low BMD test results (3;304-306;336;340), and alcohol intake has been similarly resistant to change (3;306;336;340).

Factors that are associated with a low BMD test result, such as age, a family history of osteoporosis or a history of corticosteroid use may also be expected to be associated with behavioural change. People with other risk factors may have greater motivation to make changes in an attempt to lower their own risk of fragility fractures once they learn that they have a low BMD. On the other hand, those with other risk factors may have already modified their behaviours and would then be less likely to respond to a low BMD test result with a lifestyle change. In either case, such other risk factors for osteoporosis could confound the relationship between a report of a low BMD and health behaviour change. Marci et al. specifically reported the effects of factors other than diagnosis on behavioural change in multivariable adjusted models (338). They found that, in addition to a low BMD test result, a higher education level was associated with decreased caffeine intake, increased exercise and smoking cessation after testing and a history of a previous fracture was associated with decreased caffeine and increased dietary calcium intake (338). Pre-test knowledge and health beliefs about osteoporosis and age were considered as potential confounders by Wallace et al. (339), but none of these variables was found to be associated with behaviour change after BMD testing. A history of a previous fracture was considered as the other explanatory variable of interest (together with diagnosis by DXA) by Hamel et al. (333); previous fracture was not associated with any lifestyle change, but may have influenced uptake of etidronate following DXA testing in women with low BMD test results. Subgroup analysis of only those women aged 45 years and over was carried out, but no further covariates were considered. Other authors who have reportedly adjusted their analyses for other risk factors have not reported the effects of these covariates (3;306).

The role of the presence of other risk factors in the response to low BMD test results requires further investigation; there is limited information about whether lifestyle changes are more or less likely to occur in high-risk subgroups, such as those with a history of corticosteroid or anticonvulsant use, low body mass index or smoking.

2.8 Medical Therapy Following BMD Assessment

Although receipt of low BMD test results has consistently been found to be associated with greater uptake of bone-specific medications, such as bisphosphonates

(3;332;333;337;340;342) and OHT (3;332;338;343-345) , several authors have observed that uptake of medication has been lower than would be expected: It is not uncommon for individuals who have been diagnosed with osteoporosis, even if they have been referred by their physician for BMD testing, to fail to initiate medical therapy. Only 58% of women aged 45 years and over who had been referred for testing to one of two Canadian centres and then received a diagnosis of osteoporosis were taking a bisphosphonate or OHT six months after DXA testing (333). A survey of physicians who had referred women for BMD testing to a community hospital in Boston revealed that, although physicians had recommended calcium or vitamin D to a large proportion of the women whose results indicated osteopenia or osteoporosis, only 54% were prescribed medication (38% OHT and 16% bisphosphonates) (346). A similar proportion of women in California who were diagnosed with osteoporosis filled a prescription for OHT or a bone-specific medication; 50% of the women who had been referred by a physician and found to have osteoporosis apparently did not receive medical therapy (342). Given that adherence to both OHT (347-350) and bisphosphonates (347;351) has been shown to be poor, far fewer of these women would be expected to remain on these therapies. Other risk factors may play a role in decisions about therapy; women with a history of corticosteroid use or a previous fracture for example, were more likely to initiate therapy even when diagnosis was taken into account (342).

Only 41% of a sample of men (67% of whom had prostate cancer with the majority being hypogonadal and on androgen deprivation therapy) who received a diagnosis of osteoporosis had initiated bisphosphonate therapy within a year of receiving BMD test results; although the prevalence of other medical conditions in this atypical sample may have influenced the rate of treatment with medication (340).

Even lower rates of medication uptake may be expected in people who have not been referred by their physicians for BMD testing. Indeed, an observational study of the effects of DXA testing on hip fracture reported that a sub-sample of the population-based cohort of community-dwelling women and men aged 65 years and older who participated in the Community Heart Health Study and were invited for DXA screening showed only minimal uptake of medications within a year of BMD testing after being informed that their results were below average for their age (352). Only 1% of the women and men with below average results started taking bisphosphonates, only 7% took up calcium supplements and, amongst the women, there was no difference in estrogen use between those who received average and those who received below average results (352). Likewise, in another study, only 18% of women (mean

age 59 years) and men (mean age 63 years) who were reported to have T-scores < -2.0 after being invited for a heel ultrasound, while attending a health fair, had initiated treatment of estrogens, bisphosphonates or calcitonin six months later, even though the test results had been reported directly to their physicians (353). This latter study compared therapy following low BMD test results in women and men; no difference was evident between the number of men and women who initiated therapy following a low BMD test result, although generalizability is limited because of the sampling method (353).

Differences have been observed in the treatment of men and women following moderate or low trauma fractures; men are less likely than women to undergo appropriate further investigation (such as a DXA test) or to be treated for osteoporosis following such a fracture (354-357). The proportion of women and men who have received medical therapy for osteoporosis, or even been referred for BMD testing, after experiencing a low trauma fracture in middle age or later has consistently been found to be well below expectations (163;355-357). Clinical guidelines emphasize that low trauma fracture is a major risk marker for further fracture in women and one that requires appropriate evaluation for osteoporosis and treatment (85;89;230); but the association between previous fracture and osteoporosis risk in men, as well as guidelines for assessment of risk in men are less well established (97).

2.9 Direct-to-Participant Feedback of Test Results

It is feasible that directly informing women, as well as men, of their test results may prompt changes in bone-specific lifestyle behaviours. Individuals who have already received information about their test results and their personal risk estimate prior to a consultation with their physician would be expected to have an increased level of awareness that could lead to active enquiry and exploration about the risks of osteoporosis and the options for prevention, possibly due to an increased level of engagement. When patients have more active participation in their interactions with physicians (i.e., as "activated" patients) their clinical outcomes, as well as their satisfaction with the interaction with the medical system, are generally more positive (358).

As discussed by Roter (359), increased patient participation in their health care serves to facilitate dialogue and ultimately the full involvement of patients in the negotiation and evaluation of health services that apply to them. A recent discussion of potential system changes to improve health related behaviour in patients accessing the health-care system has suggested that "pre-activation" would serve to assist patients to make more enquiries and to take more

action in their own care (360). Pre-activated patients have also been found to have better health outcomes, possibly because of closer adherence to clinical recommendations (361). Pre-activation can be accomplished by the provision of written materials, as well as face-to-face discussions or computer interactions, prior to a medical consultation: Patients who have received adequate information about their condition and have participated in decision making are more satisfied, have greater self-efficacy and healthier behaviour overall (360).

Although the activated patient concept goes beyond simply providing patients with test results, informing people directly about their relative risk of fracture based on their BMD test results may facilitate patient empowerment and participation in decisions about their treatment or health promotion interventions. Receipt of test results directly may provide both the opportunity and the incentive for women and men to initiate a consultation with their physician and to seek further information about osteoporosis from health providers and from other sources. Ultimately, direct-to-participant feedback allows people to maintain control of their own test results as well as their bone health, which may in turn lead to increased motivation to make positive lifestyle changes.

Direct-to-participant feedback of test results may also serve to prime participants by giving them a chance to formulate questions and to approach a physician consultation prepared to seek the information that they require to make decisions about lifestyle change or therapy. Physician-patient interviews that involve more information-giving compared with question-asking by the physician are associated with adherence to recommended therapies (362;363).

On the other hand, direct-to-participant feedback may provide more immediate and more accessible information about test results to those who either would not choose to follow-up with their physicians to learn about their results, or whose physicians may not initiate a consultation; the latter situation may be more likely to arise in the case of "normal" test results. Wallace et al. (339) found that four months after testing, referred women with normal test results who were randomized to receive their results from a consultant directly after their scan reported lower susceptibility to osteoporosis than did women whose normal results were sent to their physician. There were no differences in perceived susceptibility by women with low test results, or in changes in dietary calcium or exercise behaviour between the two interventions. Although the authors concluded that direct feedback to the patient by the consultant did not add anything for those women with low test results, the enhanced perception of susceptibility in the women with a normal test result whose feedback went directly to their physician supports the value of ensuring that feedback reaches *all* participants or patients. Direct feedback presumably provided

reassurance and had no apparent negative impact on the health behaviour of the women with normal test results.

Campbell et al. evaluated the impact of direct-to participant feedback on correct awareness of DXA test results in a randomly selected population-based sample of mid-aged women (302). The women who were randomized to receive their feedback directly (in addition to their physician) were significantly more likely to be correct about their results compared with those whose results were sent only to their physician (58% *v.* 36%). The authors did not find, however, that direct-to-participant feedback had a significant effect on exercise level, smoking status or uptake of OHT in these predominantly perimenopausal women. The results suggest that while direct-to-participant feedback may offer an improved means of communicating BMD test results as an alternative to the traditional method of sending DXA test results to the physician, it may not be sufficient to facilitate behavioural change.

Interpretation of the study by Campbell et al. (302) is limited, however, because the follow-up questionnaires were mailed to the participants, which provided women with the opportunity to look up their reports at home: Women who had received their results directly therefore had a potential advantage because their results would be expected to be more easily accessible. In addition, the WHO diagnostic guidelines were not used to assess risk of fracture in this group; women in the lowest quartile were informed that their BMD was below average (in the lowest 25%) and that they may be at risk of osteoporosis in later life, which limits generalizability to the current standard practice that uses the WHO criteria to determine risk of fracture (50).

Further clarification of the effectiveness of direct-to-participant feedback on correct awareness of BMD test results and behaviour change is required: The method for assessment of correct awareness should provide no advantage to the group that receives feedback directly and, as is now common in clinical practice, the standard WHO criteria for diagnosis (50) should be used to define risk. Furthermore, the potential impact of direct-to-participant feedback on awareness and behavioural change in men must be evaluated.

2.10 Summary

This literature review began with an overview of the burden of osteoporosis and the role of DXA testing in identifying those at increased risk of fracture. A background was provided regarding the role of non-modifiable risk factors relevant to women and men in middle age, and the potential contributions of modifiable lifestyle factors and medical therapy to the risk of

osteoporosis and fracture were discussed in the context of the published literature. A selection of studies that have explored relationships between knowledge, awareness, information seeking and osteoporosis related health behaviour was briefly discussed and the literature specific to the impact of BMD test results on awareness of risk, information seeking and health behaviour change was reviewed in greater detail. The review included the only study that investigated the effects of direct-to-participant feedback on correct awareness of test results.

This review has indicated that information regarding awareness of BMD test results and the impact of BMD test results on information seeking and health behaviour modification in mid-aged women (particularly women who are perimenopausal) is limited and there is a paucity of information regarding the impact of BMD testing in men. The potential impact of direct-to-participant feedback of DXA test results has not been sufficiently explored. If findings about these potential effects of DXA testing are to be generalized to the more broadly screened population, these questions must be investigated in a large randomly selected sample of both women and men, followed prospectively, for a long enough period to allow new behaviours and treatment interventions to become established. A relatively large study with longer follow-up, in a general population that includes men, has so far been lacking.

CHAPTER 3: Rationale and Objectives

3.1 Rationale

The burden of morbidity and mortality arising from osteoporosis is substantial and is increasing with the advancing age of the population, and these increases are expected to become more evident in men relative to women. Because the treatment and rehabilitation of osteoporosis and its consequences, namely bone fractures, are costly and often not successful, preventive interventions offer the greatest potential in alleviating some of the burden. Although there is evidence of decreasing trends in age-adjusted fracture rates amongst women in Canada and other developed countries, the role that DXA testing may have played in this downturn is unknown.

Several non-modifiable risk factors for osteoporosis have been recorded in the literature, and these can and have been used to identify mid-aged women and men who are at increased risk of fracture. Modifiable behavioural risk factors, such as low calcium intake, low vitamin D intake, low exercise participation, high alcohol use, smoking, and high caffeine intake can be targeted and potentially modified in people who are at relatively increased risk of fracture as a preventive intervention, or as an adjunct to medical therapy for the treatment of osteoporosis. Reliable medical therapies are available for the treatment of people who are identified as having a low BMD by DXA testing.

Although DXA testing has a low positive predictive value for fracture, it still offers the most reliable means of predicting whether a woman or man of a specific age has a relative increased risk of osteoporotic fracture. DXA testing is only recommended for men and for women under 65 years of age if other risk factors are present: There is evidence in the literature, however, that these guidelines are not always followed, or well understood, and that perimenopausal and early menopausal women receive a significant proportion, if not the majority, of DXA tests. Furthermore, it has been suggested that a more generalized approach to screening may be warranted in the event that more reliable treatments and interventions become available or if adherence rates are to be improved. Given that BMD testing is likely utilised for more than diagnostic purposes, and that a more general population-screening approach remains open to debate, a better understanding of the potential effectiveness of this intervention in terms of awareness of risk, health behaviour change and medication uptake or adherence in a randomly selected population is required.

BMD testing can only be expected to have an impact on the morbidity and mortality associated with osteoporosis if the provision of test results has an influence on the health

behaviours that affect osteoporosis risk and on effective medical interventions. Previous authors have cited a lack of information about such potential benefits of BMD testing on preventive interventions (4;56). As pointed out by one author in the field: "Bone densitometry, like any other diagnostic test, has no role whatever if it is not to influence either physician or patient in their management or behaviour" (364).

In order for BMD testing to have an impact, risk information and recommendations for interventions must effectively reach individuals who have been identified as being at greater risk for fracture by DXA, and who will implement the recommended or warranted changes to their lifestyles and medical therapy. An understanding of the test results, and an increased risk status, is likely to be a necessary step in bringing about change in behaviour or uptake of therapy. Not surprisingly, previous studies of the effects of DXA testing have demonstrated a link between correct awareness of low test results and uptake of therapy. The majority of the literature reporting on awareness and understanding of BMD test results, however, has involved volunteer or convenience samples of women who have been referred for DXA testing by their physician. In addition, other potential predictors or confounders of correct awareness of BMD results, such as risk factors other than BMD, have not been adequately addressed. Correct awareness of test results in men has not been described at all.

BMD testing may be expected to prompt information seeking about osteoporosis, and those with low test results may be the most likely to seek further information. Information seeking may be a process that is indicative of a readiness to make a behavioural change, even if a change is not evident or measurable. An association between information seeking about osteoporosis and health behaviour change has been reported by some authors, but not others. The impact of DXA testing on information seeking about osteoporosis and the sources of information that are used after DXA testing have not been examined in a population-based sample of women, and have not been addressed at all in men.

As with the literature about correct awareness of test results, most previous studies of lifestyle modification following BMD testing have utilised volunteer or convenience samples of women who have been referred for testing, and the studies have tended to have short follow-up periods. Very few previous studies have taken into account baseline levels of the behaviours of interest in their analyses of behavioural change and in the interpretation of their results. Furthermore, the investigation of the potential role of other subject-related factors, such as age or other risk factors for osteoporosis, has been limited to the assessment of a select few, if any, of these factors. There is, therefore, virtually no information about whether lifestyle changes are

more or less likely after DXA testing in high-risk subgroups, such as those with a family history of osteoporosis, low body mass index or a history of corticosteroid or anticonvulsant use.

It is assumed that in order for DXA test results to motivate lifestyle change or uptake of medication in those at higher risk for fracture, the increased risk must first be conveyed to the individual, whether directly or through a physician, and the individual must take notice of their "diagnosis" or risk status. An awareness of increased fracture risk is likely to be a prerequisite for lifestyle modification; an efficacious method of communicating BMD results and risk information would therefore be expected to be critical to the effective management of osteoporosis and fracture risk.

Direct-to-participant feedback of test results may provide a relatively effective means of conveying risk about osteoporosis. The literature suggests that patients who receive adequate information and have had more active participation in their interactions with physicians (activated patients) demonstrate greater self-efficacy and healthier behaviour. Direct feedback to participants may also serve to relay test results in the most effective way, particularly for people whose results do not indicate an increased risk of fracture. One previous study investigated the effects of direct-to-participant feedback on test result awareness and health behaviour in mid-aged women (302). This research was conducted in Scotland, before the availability of the WHO diagnostic criteria; the impact of direct-to-participant feedback of DXA test results has not been studied with women in Canada, using the WHO diagnostic criteria for feedback, or not in men at all.

3.2 Objectives of the Study

The overall aim of this study was to examine the potential effects of bone mineral density testing in a population-based sample of mid-aged Canadian women and men by describing its association with correct awareness of bone density test results, information seeking about osteoporosis, and osteoporosis related health behaviour change.

The specific objectives were:

(1) To describe the relationships between correct knowledge of test results three years following testing and both a diagnosis of osteoporosis or osteopenia by bone density measurement and the method of test result feedback.

(2) To describe the information sources accessed by women and by men following DXA testing.

(3) To examine the associations between self reported information seeking about osteoporosis during the three years following testing and both bone density test results and the method of test result feedback.

(4) To explore the associations between changes in osteoporosis related health behaviour three years after DXA testing and both bone density test results and the method of test result feedback.

(5) To assess the influence of other known risk factors on test result awareness, information seeking and health behaviour change while taking diagnosis by bone density measurement into account.

3.3 Overview of the Study Design

This research was designed to assess the impact of an "at risk" diagnosis of osteopenia or osteoporosis, compared with a normal test result or "no increased risk" as a result of BMD testing on awareness of test results, information seeking about osteoporosis, osteoporosis related health behaviour change and the use of medical therapy three years after DXA. In addition, the effectiveness of a simple intervention in the form of direct-to-participant feedback of test results was explored.

These objectives were addressed using prospectively collected baseline (1996-1997) and three-year follow-up (1999-2000) data and retrospective data collected from participants' files, and by means of a natural experiment (or quasi-experiment) that occurred within the ongoing Canadian Multicentre Osteoporosis Study (CaMOS). A proportion of the data utilised for this study was collected as part of CaMOS; a prospective cohort study designed to estimate the incidence and prevalence of osteoporosis and fractures, as well as the effect of potential risk factors, in a random sample of women and men from nine centres across Canada (5;365). Further data were collected from the CaMOS participant files, with the specific purpose of addressing the unique objectives of this dissertation.

It would be neither ethical nor practical to compare the effects of feedback of low BMD results with feedback of normal BMD results to study participants by randomised intervention. For this study, the potential effects of a low BMD test result compared with a normal test result were examined by the observational method, with consideration for the potential effects and influences of a broad range of uncontrolled factors. The selection of these latter variables was informed by the review of the published literature, but also determined by the availability of the

relevant information from data collected during the CaMOS baseline interview or retrospectively from the participant files at the CaMOS centres.

All participants were invited to attend a DXA test at baseline as part of the CaMOS study protocol. Because the method for interpretation and feedback of these test results to the study participants was not part of the CaMOS protocol, each participating centre adopted its own method of relaying test results. The results of the DXA test were relayed to the study participant, to the physician, or to both by the CaMOS centres using standard reports that resembled those that were typically generated following BMD tests of clinically referred patients by the testing centres involved. The method of feedback of test results varied between centres, and also within some centres. There were no further study interventions; all health behaviour interventions and actions were left to the physicians, the existing structure and the community programs that were available. The study is presumed to provide information about the effectiveness of a report of low BMD test results in the context of the programs, facilities and resources that were available at the time of testing. Hence the current study examined outcomes following a "real world" scenario of feedback of normal or "at risk" test results, by a quasi-experimental study of direct-to-participant feedback of simple test results in a standard format.

The study population was composed of a randomly selected sample of Canadian women and men aged between 40 and 60 years. Study participants were not selected for their risk status, although they naturally included a proportion of women and men who would meet the criteria for selection for DXA testing (85;87;228). In this respect, the study population is considered to model a community screening program for mid-aged women and men across Canada.

The results of this dissertation research provide insight into test result awareness, information seeking, behavioural change and use of bone-specific medications in women and men who are selectively screened for osteoporosis, as well as the impact that BMD testing may have if general DXA screening were provided to the mid-aged population. The findings also provide information about those subgroups of the population that are relatively resistant to health behaviour change specific to osteoporosis so that these groups may be targeted by osteoporosis prevention and treatment programs. Finally, this study provides an indication of whether direct-to-participant feedback of test results leads to improved correct awareness of test results, or increased information seeking about osteoporosis, lifestyle change or bone-specific medication use three years after DXA testing compared with feedback only to the physician.

3.4 Conceptual Framework

The conceptual framework for this thesis research is outlined in Figure 3.1. An organizational structure for the characterization of the factors that may be expected to influence the effects of DXA test results on awareness of results, information seeking and health behaviour change has been borrowed from parts of the PRECEDE model of health promotion (366). The variables that have been measured and taken into account are emphasised in the outlined model in bold, and are described in greater detail in the following chapter.

The PRECEDE model, which was originally designed to guide the systematic development and evaluation of health education programs, groups the various influences of health behaviour into three categories: predisposing, enabling and reinforcing factors (366). Predisposing factors provide the rationale and motivation for change and are typically, although not always, psychological in nature. Specific psychological predisposing factors, such as beliefs or attitudes have not been measured as part of this study. Factors that have been measured, however, include those that may be expected to influence such psychological predisposing factors (or "motivation for change"). These include the presence of risk factors for osteoporosis that study participants and their physicians may have been aware of, such as a family history of osteoporosis or a history of corticosteroid use, as well as demographic characteristics (many of which are also related to an increased or decreased risk of osteoporosis) such as age, sex and level of education.

Enabling factors are antecedents that enable motivation for behaviour change to be realized. Typically these factors are related to systemic conditions such as programs and resources that are available in the community. Within the context of this study, enabling factors may have been influenced by, or have been associated with, the nine CaMOS study centres; services and resources such as osteoporosis and health promotion programs may have been available to a varying extent in the different communities.[16] In addition, inclusion in the participants' or physicians' feedback of a recommendation for further action (such as the

[16] Environmental, system and cultural variables that may be associated with the location of the testing centres have not been measured for this research. However, the potential influence of the "Centre" level variable on the outcomes is considered in the analyses and interpretation. The CaMOS centres are highly correlated to the method of feedback of the test results, which presents limitations to the interpretation of the influence of these two enabling factors. This is discussed in more detail in Chapter 4.

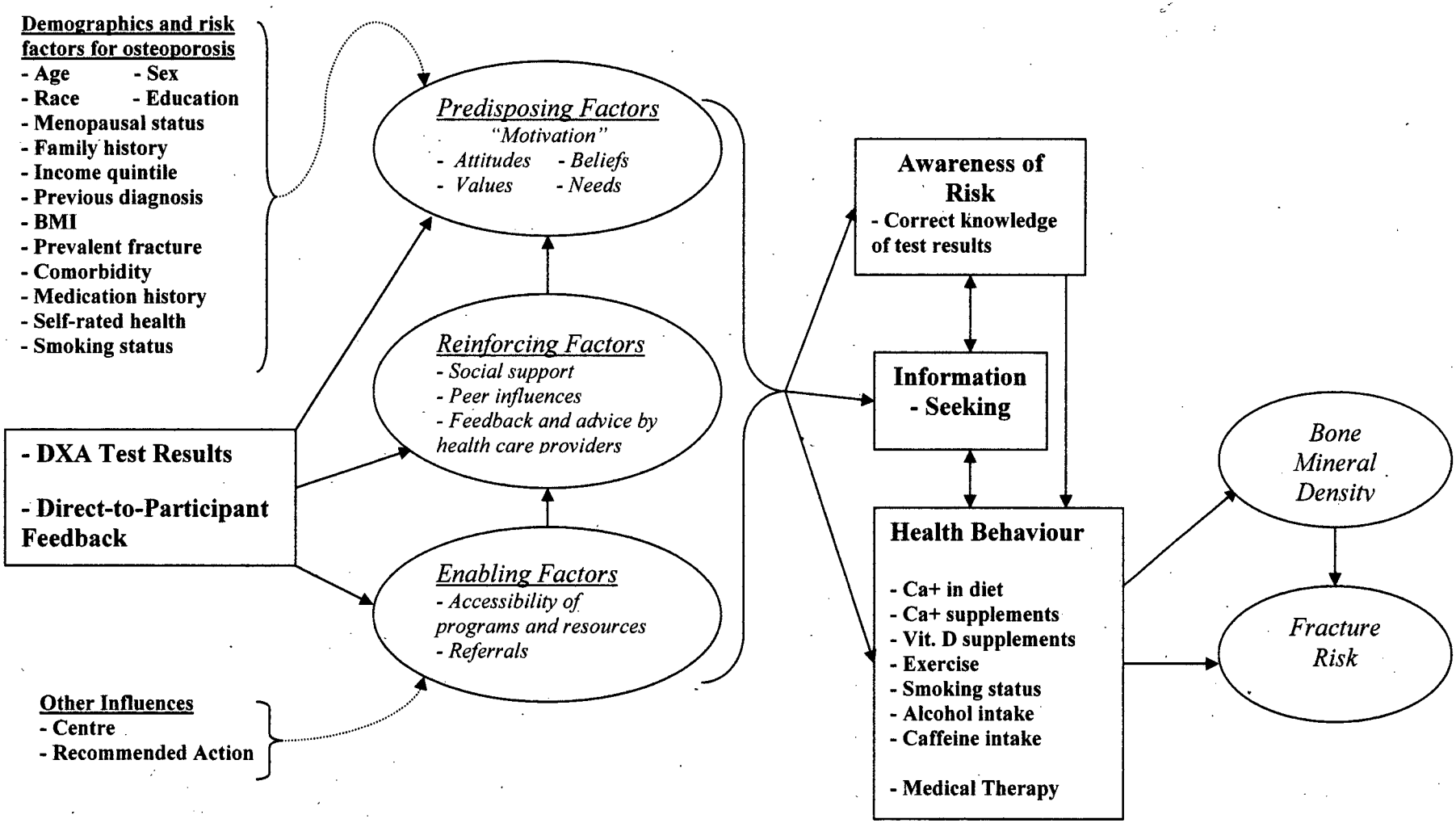
suggestion that the participant be referred to a specialty clinic) may also be expected to influence enabling factors.

Reinforcing factors provide reinforcement, or incentives, for the health behaviour to persist once it has been initiated and include the effects of support from significant others, health-care providers and peers as well as vicarious reinforcement. Reinforcing factors, although important, have not been addressed in this study.

The framework acknowledges that both correct awareness of test results and information seeking about osteoporosis are likely to be important process variables that precede a positive change in health behaviour. These outcomes, however, were all measured at the same time (at the Year 3 follow-up); the assessment of potential causal relationships between these outcomes is not addressed. Instead, each of these outcomes is considered as a desirable endpoint of an effective screening procedure. Osteoporosis specific health behaviour change is the most desirable of these outcomes in people who are identified at higher risk for fracture by DXA testing, and where a health behaviour change is warranted, because correct awareness of test results and information seeking do not have direct effects on BMD or fracture risk. Correct awareness of risk status (or test results) and information seeking about osteoporosis do indicate, however, that people have received and understood their test results, and that they are in a position to make an informed decision about their own health behaviour.

The conceptual framework presented in Figure 3.1, was derived with the aid of borrowed concepts from the PRECEDE model in order to guide the selection of important variables, as well as to inform the design of the study. No behavioural model was included in the conceptual design of the original CaMOS study; the CaMOS study was not designed to assess behavioural outcomes. The research for this dissertation was designed as an observational study to determine the effectiveness of DXA test results and direct-to-participant feedback. While the important role of intervening psychological and cognitive processes as well as environmental factors between these interventions and the behavioural outcomes is acknowledged, these intervening variables were not measured or addressed by this research. Thus, this study was not designed to test any particular model of health behaviour, health promotion or health-care utilisation; the conceptual model outlined in Figure 3.1 has been generated only as a guide for study design.

Figure 3.1: A Conceptual Framework of Factors Contributing to the Impact of DXA Test Results on Information Seeking and Osteoporosis Specific Health Behaviour



CHAPTER 4: Methods

This was a retrospective analysis of a sub-sample of the prospective Canadian Multicentre Osteoporosis Study (CaMOS) (365). Women and men aged 40 to 60 years at baseline who completed the full CaMOS interview, had participated in bone density testing at baseline, and then took part in a CaMOS follow-up interview three years later were eligible for this study. A full description of the participants is included in Chapter 5.

4.1 The CaMOS Study

The larger CaMOS cohort is an age-, sex-, and region-stratified random sample of community-dwelling women and men aged 25 years and over from nine study centres across Canada (Vancouver, Calgary, Saskatoon, Hamilton, Toronto, Kingston, Quebec City, Halifax, and St. John's). At baseline, all of the participants resided within 50 kilometres of one of the study centres. Individuals were eligible for participation if they matched the age- and sex-stratification criteria and if they spoke and understood English (all centres), French (Quebec City) or Cantonese or Mandarin (Vancouver and Toronto).

Households were originally selected *via* a random sample of listed residential telephone numbers. These randomly selected households were first contacted by mail and the eligible residents were invited to participate. The households were then contacted by telephone and one individual was randomly selected from those household members that satisfied the stratification and selection criteria. Complete details of the recruitment methods and criteria are available (5;365). To account for the greater risk of fracture with age and in women, the CaMOS strata increased in size with age and twice as many women as men were selected within each age group.

The population-based random sample is believed to represent approximately 40% of the population of Canada, but it does not include nor represent either institutionalized Canadians or the Aboriginal populations of northern Canada (5;365). In addition, the sample represents English-speaking Canadians, as well as a proportion of the population who speak French, Cantonese or Mandarin.

CaMOS, which is now in its 12th year of follow-up, involves researchers affiliated with universities across Canada.[17] The main objectives of the CaMOS study are to

[17] Dr Nancy Krieger and Dr David Goltzman are the national principal investigators for CaMOS; the founding national principal investigator was Dr Alan Tenenhouse. Centre directors for CaMOS are Dr.

determine the incidence and prevalence of osteoporosis in the Canadian population by region, to describe and determine the influence of certain risk factors on bone density and fracture risk, to assess the impact of osteoporosis on health status and to estimate the cost of osteoporosis and associated fractures in Canada (5;365).

Baseline data collection for CaMOS involved bone mineral density (BMD) measurements by dual energy X-ray absorptiometry (DXA) of the lumbar vertebrae (L1 to L4) and three sites at the hip (neck, trochanter and Ward's area), and height and weight measurements. An extensive questionnaire regarding demographics, illnesses and medications, family history, diet, exercise, reproductive history, smoking, alcohol consumption and health status was administered, one on one, by trained interviewers. In addition, all participants aged 50 years and older were asked to undergo lateral X-rays of the lumbar and thoracic spine for the diagnosis of prevalent vertebral fractures. The recruitment and baseline data collection phases of the CaMOS study took place during 1996 and 1997 (5;365).

Following baseline data collection, an interpretation of the results of the DXA tests and spinal X-rays was sent to every participant and/or his or her family physician (FP). The procedure for interpretation and feedback of these test results was left to the discretion of the CaMOS centre directors; each CaMOS centre therefore adopted its own method for interpretation and feedback of results.

All CaMOS participants aged 40 to 60 years at baseline were eligible for follow up at Year 3, at which time the BMD, height and weight measurements were repeated and information was collected by individual interview regarding current diet and other lifestyle variables as well as changes in reproductive status, family history, medications, illnesses and health status. The participants also were queried about their knowledge of their baseline BMD and whether they had sought information about osteoporosis.

The CaMOS mid-aged sub-sample (i.e., those aged 40 to 60 years at baseline) of "full" participants included 3,139 men and women with a mean age at baseline of 52 years, 89% of whom were followed-up at Year 3 (889 men and 1,904 women). Although they were considered "full" participants by the CaMOS study (they completed the full

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Jerilynn Prior (Vancouver), Dr. David Hanley (Calgary), Dr. Wojciech Olszynski and Dr. K. Shawn Davison (Saskatoon), Dr. Rick Adachi and Dr. Alexandra Papaioannou (Hamilton), Dr. Robert Josse and Dr. Sophie Jamal (Toronto), Dr. Tassos Anastassiades and Dr. Tanveer Towhead (Kingston), Dr. Jacques Brown and Dr. Louis Bessette (Quebec City), Dr. Susan Kirkland and Dr. Stephanie Kaiser (Halifax) and Dr. Carol Joyce and Dr Christopher Kovacs (St John's). National co-ordination of the study, since its inception, is provided by Ms. Suzette Poliquin.

questionnaire), a small number of these participants did not take part in the baseline DXA test (see below).

As part of the CaMOS protocol, participants were invited to complete a short "refusal" questionnaire at baseline if they declined to participate in the full study. Thirty percent of the women and 33% of the men aged 25 to 80+ years who were contacted completed this short questionnaire, which included questions related to major risk factors for osteoporosis including, sex, race, family history of osteoporosis and current cigarette smoking status. A comparison of the CaMOS participants who completed the full questionnaire and those who completed the refusal questionnaire indicated that full responders were more likely to have risk factors for osteoporosis (a family history of osteoporosis or a history of a previous fracture) and were less likely to be current smokers (367). The CaMOS sample, in general, may be over representative of those at higher risk of developing osteoporosis. No information was available, however, on risk factors for 25% of the women and 30% of the men who were contacted for the study; these participants did not agree to complete the full questionnaire or the refusal questionnaire. Participation rates within subgroups of the men and women who were invited to take part in CaMOS have shown that, although the full participation rate for the CaMOS sample (all ages) was only 43%, the participation rate was higher in the sample aged 40 to 59 years (this age range includes most of the participants who were eligible for the present study). The full participation rate for this mid-aged group was 67% for women and 50% for men. The highest baseline response rate by gender, and of any age group in CaMOS, was that of the 40- to 49-year-old women (68% of women in this age group who were invited to participate agreed to full participation) (367).

Further generalizability of the sample selected for this study to the Canadian population was assessed and is presented in the following chapter (Chapter 5) by comparison of the study sample with cross sectional data from the 1996 Canadian National Population Health Survey (described below).

4.2 Sample Selection for this Study

All 3,139 mid-aged (40 to 60 years old at baseline) CaMOS participants were initially eligible for the study. Because the study objectives were focused on the effects of reported baseline BMD test results, those subjects who did not complete a baseline BMD test were excluded (n =117). The outcome variables for this study were derived from

responses to questions on the Year 3 questionnaire; subjects who were lost to follow up at Year 3 were therefore excluded from the study sample (n = 316 of those who had completed BMD testing at baseline).

Information regarding baseline diagnosis and feedback destination (for those who completed a BMD test), as well as demographic, medical and health behaviour information from the baseline questionnaire, was collected for all 3,139 CaMOS mid-aged participants. The information collected from those who did not undergo a BMD test or were not followed up at Year 3 was used for comparison with the study sample (i.e., the included participants).

4.3 The NPHS Sample

Responses to selected demographic and health measurements that were equivalent and available on both the CaMOS questionnaire and the household component of the 1996-97 National Population Health Survey (NPHS) questionnaire (368) were compared in an attempt to evaluate how the participants from the current CaMOS sub-sample compared with a much larger randomly selected survey population that is considered to be representative of a significant proportion of the Canadian population.

The NPHS (cycle 2) was conducted by Statistics Canada during the same time period that the CaMOS baseline sample was collected, between 1996 and 1997. The purpose of the NPHS was to collect and measure information related to health and the health status of Canadians. Although a substantial proportion of the respondents to the NPHS were part of a longitudinal component that has been surveyed every two years, the data used for the current comparison are cross-sectional. The household component population of the NPHS was made up of household residents of both rural and urban areas in all Canadian provinces (the Yukon, Northwest Territories and Nunavut were excluded). Certain populations were not part of the sample: people living on native reserves, on Canadian Forces bases, and in institutions such as hospitals, residential care facilities and correctional centres. In addition, some remote areas of Quebec and Ontario were not covered by the survey.

The NPHS sample was created using a two-stage stratified sampling design (dwellings were selected from within clusters). In all provinces except Quebec, the Labour Force Survey design was used to select the sample. In Quebec, the Enquête sociale et de santé conducted by Santé Quebec in 1992-1993, with a two-stage design similar to the

Labour Force Survey design, was used. After an initial random selection of households, one member of the household was chosen to be the respondent. Methods were incorporated to eliminate potential bias of over-sampling occupants of smaller households. The complex sampling scheme was a carefully designed process aimed at minimizing sampling bias. Interviewers were well trained and supervised. Quality assurance measures were implemented at all steps of data collection and processing in an attempt to minimize non-sampling error. The overall response rate for the NPHS survey was approximately 79%[18] (368). Sampling weights to adjust for differing opportunity to respond and for non-response were included in the dataset provided by Statistics Canada and were employed in the current generation of frequencies from the NPHS sample. Comparisons were made between the study sample from CaMOS and the equivalent age-[19] and gender-matched sub-sample of the NPHS.

4.4 Collection and Derivation of Variables

4.4.1 Collection of the Feedback Data

Two of the main exposures of interest for this study were the diagnosis that the participant received (based on the lower of the spine or hip DXA measurements and labelled here as "Normal", "Osteopenia" or "Osteoporosis") and the destination of the feedback ("to the FP", "to the participant" or "to both the FP and the participant").

Early investigation of selected feedback letters from the nine study centres revealed that the diagnostic criteria for osteoporosis or osteopenia, as well as the recommendations accompanying the diagnostic information (such as whether treatment or referral to an osteoporosis clinic should be initiated), were not consistent between centres and within some centres. The form and destination of the feedback were not part of the original CaMOS study protocol and each of the nine study centres developed its own feedback content and method of delivery. The recipients of the feedback (the participant and/or the FP) were therefore determined within each centre.

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[18] The NPHS household response rate was 82.6% and the response rate of selected persons within the households was 95.6%.

[19] The NPHS public use data files provide "age" only as a grouped variable, in 5-year intervals (i.e., ages 40-44, 45-49, 50-54, 55-59 and 60-64 years). The NPHS sample aged 40 to 64 years was selected for comparison with the CaMOS sample aged 40 to 60 years. The NPHS sample included approximately equal distributions of participants in each age range, whereas the CaMOS sample included a greater number of participants in each increasing age range because of sampling design. Because the age distributions within each of the 2 populations were not directly comparable, any differences that were found between the 2 populations were investigated further by analyses stratified by 5-year age group.

To ensure that the diagnosis received by each participant was accurately coded, copies of standard "form" letters as well as random samples of feedback letters pertaining to BMD results and spinal X-ray results (stratified by date, BMD measurements, and gender) were requested from each centre. These letters were carefully reviewed for consistency. It was determined that to accurately code the information that was sent to the participant and/or his or her physician, and to determine the destination of the feedback in each case, all available individual feedback letters should be reviewed. It was also determined that the consistency of the feedback protocol and diagnostic criteria at each centre would best be determined by a review of the files and other information on site at each centre. Consequently, the data related to feedback diagnosis (and criteria for the diagnosis), any recommendation included in the feedback to the participant or FP, the destination of the feedback and reasons for declined BMD tests were collected from the original participant files *on site* at each of the nine study centres (Vancouver, Calgary, Saskatoon, Hamilton, Toronto, Kingston, Quebec City, Halifax and St. John's) by the author.

The data were collected retrospectively after the Year 3 follow up of the CaMOS participants had been completed. For each of the 3,022 mid-aged baseline CaMOS participants who completed the BMD test, copies of the baseline DXA reports, all available copies of feedback letters addressed to the participants and/or their family physicians, radiology reports and letters regarding the X-ray and all notes, log books and other documentation dating to the time of the original feedback were reviewed, in every case, to determine where the results were sent and the exact content of the feedback. The files of the 117 CaMOS mid-aged participants who did not have a baseline BMD test were reviewed for information regarding reasons for declining the BMD test.

In addition to an examination of all available information in the individual files, the study coordinator was interviewed at every centre to determine the general protocol followed at baseline and whether there were any deviations from or flexibility in the planned feedback protocol. In centres where other individuals played a significant role in the feedback process, those individuals were interviewed: a technician (Saskatoon), interviewers (Saint John's) and a secretary (Kingston). In three centres (Saskatoon, Quebec City and Halifax), there was a change in study coordinator between the beginning of the CaMOS study and baseline feedback, and the time of this data collection. The original study coordinator was contacted by telephone and interviewed in each of these

three centres in addition to the current coordinator. The directors of the centres were also consulted directly regarding the feedback rationale and protocol in seven of the nine centres (the director was unavailable at two centres).

The data collected at the centres were used to generate the "Feedback Destination", "Diagnosis by Feedback", "Report of a Significant Vertebral Fracture" (from X-ray) and "Recommendation for Further Action" explanatory variables. Information regarding reasons for no BMD test, together with information regarding the adopted criteria for diagnosis of osteopenia or osteoporosis was summarized descriptively.

The Vancouver data were collected from the participant files twice; once at the beginning of the data collection period and again at the end, after all other centres had been visited. This step was performed as a check to ensure that the coding criteria had remained unchanged over the course of data collection. It was not feasible to re-visit the other eight centres. It was found, however, that the criteria for the feedback variables were reliable; when the Vancouver data were entered a second time the coding had not changed.

All information regarding feedback was entered and coded directly into an Excel database by the researcher.

4.4.2 Derivation of Variables from the CaMOS Questionnaire

The remaining variables, including all outcome variables, were derived directly from responses to one or more questions on the CaMOS questionnaires at baseline and Year 3. Table 4.1 summarizes the sources of each of the explanatory and response variables and summarizes how each variable was derived and classified. Further description of the derivation of some of the more complicated variables follows in the text below.

Copies of the relevant questions from the CaMOS questionnaires at baseline and Year 3 are listed in Appendices A and B, respectively. All questions included in the CaMOS questionnaire that were used for this study were developed or selected by individuals in the original CaMOS research group (5;365). In some cases, the questions were modified from existing questionnaires, but the modified versions did not undergo reliability or validity testing. In other cases, the questions were written by members of the CaMOS research group without reference to existing questionnaires. The exceptions amongst the questions used for this study were the question regarding race or ethnicity and the general health question from the SF-36 (see Appendix A). The former was taken directly from the questionnaire used by Statistics Canada for the National Population

Health Survey (368). The reliability and validity of the SF-36 (369) has been tested extensively on diverse populations.

Table 4.1: Source and Derivation of all Explanatory and Outcome Variables

Variable	Source	Notes/Comments
Main Explanatory Variables		
Feedback Diagnosis	Copies of feedback letters, logbooks and interviews with CaMOS personnel	Potential Explanatory Variable and used to derive "Correct" outcome (see below). 3 Categories based on lowest of hip and spine values: - Normal, Osteopenia or Osteoporosis
Recalled Diagnosis	Year 3 questionnaire: Question 1.5	Used to derive "Correct" outcome variables (see below) and as an alternative potential explanatory variable for the health behaviour outcomes. - "Normal / High", "Osteopenia / Borderline / Low without Osteoporosis", "Osteoporosis / Low" and "Don't Know"
WHO Diagnosis	Raw BMD test data from feedback reports and CaMOS database	Alternative explanatory variable to feedback diagnosis, used to derive "Correct by WHO" alternative outcome variable. Categories based on raw (unstandardised) BMD results and WHO guidelines: - Normal (T-scores > -1.0) - Osteopenia (T-scores $\leq$ -1.0 and > -2.5) - Osteoporosis (T-scores $\leq$ -2.5)
Destination of Feedback	Copies of feedback letters, logbooks and interviews with CaMOS study personnel	Potential Explanatory Variable in 3 Categories: - To family physician only - To participant only - To family physician and participant
Potential Effect Modifiers or Confounders		
Recommendation for Action	Copies of feedback letters	Dichotomous Variable (Yes/No): - Recommendation for treatment or for referral to an osteoporosis clinic in the feedback

Variable	Source	Notes/Comments
Report of a Significant Fracture[c]	Copies of Radiology reports and feedback letters	Only applicable to those aged 50 to 60 years who attended the X-ray examination. Dichotomous Variable: - A noted significant prevalent fracture in the spinal X-ray report to the FP and/or participant - No significant prevalent fracture reported to the FP and/or participant
Age Group	Baseline questionnaire: Age in years at baseline	2 categories derived from continuous data: Aged 40-49 or 50-60 years.
Body Mass Index (BMI)	Baseline measurements of height and weight taken at DXA appointment or during interview	Divided into quartiles of BMI within each gender - Lowest quartile - Second lowest quartile - Second highest quartile - Highest quartile $BMI = \frac{\text{Weight (kg)}}{\text{Height (metres)}^2}$ Continuous variable for comparisons among excluded/included/NPHS participants
Race/Ethnicity[d]	Baseline questionnaire: Question 1.7.	Dichotomous: "White" or "Non-white" [e]
Reproductive Status (Women only)	Baseline questionnaire: Questions 5.2, 5.3, 5.4.	4 categories: - Premenopausal - Naturally Menopausal - Surgically Menopausal - Premenopausal Hysterectomy
Education	Baseline questionnaire: Question 1.8	4 categories - Incomplete High School (HS): ≤ Grade 12 (≤ Grade 13 for those who attended HS in Ontario) with no high school certificate or diploma. - Complete HS: Graduated HS with certificate or diploma. - Postsecondary Ed.: Trade/professional certificate or some university without certificate or diploma - University degree.
Estimated Neighbourhood Income Quintile	Baseline questionnaire: First 3 digits of the postal code. Income levels were generated using the PCCF+ Version 3G program from Statistics Canada.	Quintiles of estimated income level: - Lowest quintile - Second lowest - Middle - Second highest - Highest quintile

Variable	Source	Notes/Comments
Centre	Baseline questionnaire: Centre (location) at baseline	9 Centres: Vancouver, Calgary, Saskatoon, Hamilton, Toronto, Quebec City, Kingston, Halifax or Saint John's; all participants lived within 50 km of the centre at baseline.
Awareness of a Family History of Osteoporosis	Baseline questionnaire: Question 7.2	Dichotomous: - Awareness of at least one family member with a diagnosis of osteoporosis ("yes") - No awareness of a family member with a diagnosis of osteoporosis ("no", "don't know" or "not applicable" to each type of family member)
Awareness of a Previous Diagnosis of Osteoporosis	Baseline questionnaire: Question 2.1 (Osteoporosis)	Dichotomous: - Awareness of a previous diagnosis ("yes") - No awareness of a previous diagnosis ("no" or "don't know")
History of Comorbidity	Baseline questionnaire: Question 2.1 (Rheumatoid Arthritis, Eating Disorder)	Dichotomous: - Awareness of a previous diagnosis of Rheumatoid Arthritis and/or an Eating Disorder ("yes") - No awareness of a previous diagnosis of either disorder ("no" or "don't know")
History of "High Risk" Medication Exposure	Baseline questionnaire: Question 3.1 (anticonvulsants and/or corticosteroids))	Dichotomous: - Awareness of ever having taken cortisone (oral, inhaled or injection) and/or anticonvulsants (phenytoin, phenobarbital, seizure pills); "yes" - No awareness of ever having taken these medication; "no" or "don't know"
Self-Reported Health Status[f]	Baseline questionnaire: Question 14.1	Collapsed to Dichotomous Variable: - "Excellent" or "Very Good" - "Good", "Fair" or "Poor"
"Correct" Awareness: Outcome Variables		
Correct	Year 3 questionnaire: Question 1.5 and Feedback Diagnosis	Dichotomous. - "Correct"; exact match between recalled diagnosis and feedback diagnosis - "Not Correct" (includes incorrect responses and "don't know")

Variable	Source	Notes/Comments
Closely Correct	Year 3 questionnaire: Question 1.5 and Feedback Diagnosis	Alternative Outcome. Dichotomous. - "Closely Correct": Correct recall of a normal diagnosis or recall of "osteopenia" or "osteoporosis" if the feedback diagnosis was *either* osteoporosis or osteopenia - "Not Closely Correct": Incorrect by above definition or "don't know"
Correct by WHO	Year 3 questionnaire: Question 1.5 and WHO Diagnosis (see above)	Alternative Outcome Variable. Dichotomous: - Exact match between recalled diagnosis and WHO diagnosis. - Incorrect report of WHO diagnosis, or "don't know"
Health Behaviour: Potential Effect Modifiers (baseline) and Outcome Variables (Year 3).		
Information seeking	Year 3 questionnaire: Question 1.6	Dichotomous (Yes/No): - Information sought about osteoporosis from at least one source.
Current Cigarette Smoker	Baseline questionnaire: Question 9.1 and 9.2 Year 3 questionnaire: Question 9.1 and 9.3	Dichotomous (yes/no) - Has ever smoked cigarettes daily for at least 6 months and is currently smoking cigarettes.
Calcium (diet alone); mg/day Calcium (supplements and diet); mg/day	Baseline and Year 3 questionnaires: Q. 3.2 and 10.1.	Continuous Variables: - Estimated elemental calcium from dietary sources derived by CaMOS from report of average portion size and frequency of eating calcium-rich foods over previous 12 months. - Estimated total elemental calcium derived by combining dietary calcium and amount of calcium intake from supplements (derived by CaMOS, from dose and frequency of use of any reported current supplements taken on a regular basis).
Current Calcium Supplements	Baseline and Year 3 questionnaires: Q. 3.2	Dichotomous (yes/no): - Calcium supplements currently taken regularly
Current Vitamin D Supplements	Baseline and Year 3 questionnaires : Q. 3.2	Dichotomous (yes/no): - Vitamin D supplements currently taken regularly
Current Regular Exercise	Baseline and Year 3 questionnaires: Q. 11.3	Dichotomous (yes/no): - Currently participates in any regular activity or program for exercise

Variable	Source	Notes/Comments
Current Specific Osteoporosis Medication Use	Baseline and Year 3 questionnaires: Q. 3.2	Dichotomous (yes/no) - Currently taking any medication commonly or occasionally used to treat or prevent osteoporosis (other than hormones): bisphosphonates, raloxifene[g], calcitonin or fluoride
Current Ovarian Hormone Therapy (OHT) Use (Women only)	Baseline Questionnaire: Q. 5.5, 5.6 Year 3 questionnaire: Q. 5.10, 5.11 and 5.12	Dichotomous (yes/no): - Currently taking estrogen and/or progestin/progesterone.
Current Osteoporosis Related Medication Use	Baseline Questionnaire: Q. 3.2, 5.5, 5.6 Year 3 questionnaire: Q. 3.2, 5.10., 5.11, 5.12.	Dichotomous (yes/no): -Current use of OHT and/or any specific osteoporosis medication Derived from a combination of above 2 variables
High Alcohol Intake	Baseline and Year 3 questionnaires: Q. 10.2	Dichotomous: - Less than 2 alcoholic drinks per day - 2 or more alcoholic drinks per day. Derived from reported frequency of servings of alcoholic drinks on average over past 12 months
High Coffee Intake	Baseline and Year 3 questionnaires: Q. 10.2	Dichotomous: - Less than 4 cups of coffee per day - 4 or more cups of coffee per day. Derived from reported frequency of servings of caffeinated coffee on average over past 12 months
Total Caffeine	Baseline and Year 3 questionnaires: Q. 10.2	Continuous variables: Total caffeine derived by CaMOS from report of the average frequency of servings of caffeinated and decaffeinated coffee, tea and colas over the past 12 months.

[c] Prevalent fractures were diagnosed by radiologists at each of the 9 CaMOS centres. Reports of fractures were considered to be "significant" if there was a report of a fracture in the feedback and no indication that it was "minor" or "insignificant". Compression fractures that specifically stated that there was no more than 20% compression on any vertebra were considered to be not significant.

[d] The term "race" is used here as a descriptor of participants' self identified race or ethnicity when asked to describe their race or colour and is assumed to reflect participants' perception of their personal ethnic or cultural background.

[e] The "Non-white" group includes all participants who indicated a race other than "White", even if they also described themselves as "White"; participants were not limited to one response to this question.

[f] From the SF-36 (369), a widely used generic measure of health status. The complete SF-36 was administered as part of the CaMOS protocol; only the response to the first question (the "in general..." health question) was used for this study.

[g] Raloxifene was not approved by Health Canada for the prevention of osteoporosis in women until after completion of the baseline data collections, but was available at Year 3.

4.4.3 Potential Effect Modifiers

Factors that may be associated with correct awareness of test results or osteoporosis-related behavioural change, and that may also be associated with the potential explanatory variables were considered as potential confounders and as potential effect modifiers, where appropriate. Categories of certain variables (race, education and self-rated health status) that were derived directly from the CaMOS questionnaire(s) were combined (see Table 4.1) because of sparse numbers in some categories, to distribute the sample more evenly across subgroups and to facilitate the interpretation of results.

Two continuous variables, age and body mass index, were converted into categorical variables. Age was dichotomized into a 40 to 49 year group and a 50 to 60 year group. Both women and men over the age of 50 may be considered at more serious risk for osteoporosis and may be more likely to be treated, or advised differently than are younger women and men: Previous guidelines concerned with the screening and treatment of osteoporosis have been restricted to those aged 50 years and over (72;85), in whom the potential benefits of assessment and intervention are considered to be greater. There is relatively little known about the potential benefits of any form of intervention (lifestyle or medication) on the long term bone density or fracture risk of women or men under the age of 50 years. The age of 50 years, which is close to the average age of menopause in women, is the cut-off age for increases in the recommended daily intakes of calcium and Vitamin D. Intakes recommended by Osteoporosis Canada increase from 1,000 mg/day of calcium and 400 IU/day of Vitamin D for women and men aged 31 to 50 years, to 1,500 mg/day of calcium and 800 IU/day of vitamin D for those aged 51 to 70 years (85). Furthermore, personal communications with physicians who managed patients with osteoporosis led to the conclusion that there is a "cut-off" at age 50 years whereby patients are treated differently and test results may be taken more seriously. Finally, participants in the CaMOS study were only eligible for an X-ray test if they were 50 years of age or over. Subgroup analysis within this age group allowed for the inclusion of a report of a significant prevalent fracture as a potential explanatory variable.

The participants' body mass index (BMI) distribution was divided into quartiles within each gender to facilitate interpretation. A difference of one "unit" of BMI was not considered to be a meaningful measure for comparing behavioural outcomes; it is, however, common to describe individuals as "larger" or "smaller". The division of the sample into four equal groups created a "large" and a "small" group, with the two middle groups representing an average size. Significant associations could then be interpreted more meaningfully with reference to the

relatively "larger" or "smaller" group. In addition, preliminary analysis suggested that there were non-linear associations between the continuous form of BMI and some of the other variables, and that the distributions of BMI were skewed to the right (particularly for women); a categorical form of BMI was considered to be more appropriate. For comparison between the CaMOS participants that were included in this study and those that were excluded, and with the NPHS sample, however, the continuous measure of BMI was used.

Since 1998, standardised categories of BMI have been available and widely used in clinical practice and in research to classify individuals as underweight (BMI < 18.5), normal (BMI of 18.5 – 24.9), overweight (BMI of 25 – 29.9), or obese (BMI of 30 or more) (370;371). Canadian guidelines for defining "health risk" categories of BMI (with different cut-off values to those that are now commonly used) were available before 1998 (372), but the use of these categories was much less prevalent in practice in 1996/1997 (at the time of the CaMOS data collection and feedback of BMD test results) than they are now. Canadian osteoporosis guidelines that were available at the time of the CaMOS baseline data collection simply stated that "low body weight" was an important predictor of osteoporosis (230). The BMI variable for this dissertation was therefore divided into quartiles to reflect the participants' and their physicians' expected general perception of their body size and potential risk for osteoporosis at the time.

Derivation of the variables for Reproductive Status in women and for the Estimated Neighbourhood Income Quintile involved relatively more complex derivations. The methods for obtaining these particular variables are explained below.

Reproductive Status: Women were not specifically asked to report their current reproductive status on the baseline questionnaire, although they *were* asked if their periods had stopped for at least 12 months. To derive the closest measure possible of the women's perceived reproductive status at baseline, the answers to several baseline reproductive questions were used: Whether periods had stopped for at least 12 months; the age at which periods had stopped; whether there was a history of ovariectomy; the number of ovaries removed and the age at which they were removed; whether there was a history of hysterectomy and the age at the time of hysterectomy.

Four categories of baseline reproductive status were created from the responses:

- Premenopausal. Women who had not had a double ovariectomy and whose periods had not stopped for more than 12 months. Women with ovariectomy more than 12 months previously who were unaware of the number of ovaries removed, but whose periods had

not yet stopped for more than 12 months were included. Four women who had a hysterectomy (without a double ovariectomy) within the last year while still premenopausal were included.

- Naturally Menopausal. Women whose periods had stopped for more than 12 months. Women who had an ovariectomy and/or hysterectomy after their periods had already stopped were included.
- Surgically Menopausal. Women who had a double ovariectomy before their periods stopped naturally. Women with ovariectomy (without hysterectomy) who were unaware of the number of ovaries removed but whose periods stopped at the time of ovariectomy were included.
- Premenopausal hysterectomy. Women who had a hysterectomy (without double ovariectomy) before their periods had stopped and their "menopausal" status cannot therefore be determined based on whether their periods had stopped. Three women who had a premenopausal hysterectomy with ovariectomy but were unsure how many ovaries were removed were included.

Neighbourhood Income Quintile: The first three digits, or forward sortation area (FSA), of each participant's postal code were used to generate an estimate of their neighbourhood income quintile using the SAS program, PCCF+ Version 3G (373). This program automatically assigns an estimated income quintile to each valid postal code by matching it to a series of files derived from the Postal Code Conversion Files that have been prepared by Statistics Canada using summary statistics of the 1996 Canadian census. Although there are more recent postal code conversion files available, the 1996 census version was used to give the closest possible approximation to neighbourhood income quintiles at the time of the CaMOS baseline data collection.

It should be noted that the size of FSAs vary considerably across Canada, and the precision of this estimate of neighbourhood income would therefore be expected to vary widely as well. In 1996, the population of Canada was 28,846,761 and there were 1,696 FSAs. Consequently, although the average population in each FSA would have approximated 17,000, the size of the FSAs included in the Canadian census ranges from populations as small as 45 (located in metropolitan Toronto) to populations as large as 129,420 (in rural Quebec) (374).

4.4.4 "Correct" Knowledge of BMD Test Results: Outcome Variables

The outcome variable of interest for the analysis of correct awareness of test results was whether, when asked at Year 3, participants were able to correctly state their baseline diagnosis from their initial BMD feedback. Derivation of the exactly "correct" outcome variable is summarized in Table 4.1 and demonstrated in Chapter 6.

Although the above definition of "correct" was used for the main analysis, other variations of the "correct" variable were derived for comparison because there were alternative ways of defining whether a participant was correct in his or her self-diagnosis. Because the diagnoses of "osteoporosis" and "osteopenia" could both be considered an "abnormal" diagnosis (or an increased risk of fracture) by participants, the categories for osteoporosis and osteopenia were collapsed to derive a "Closely Correct" variable that coded participants as correct based on a dichotomous division between normal and abnormal results. Coding of the "closely correct" variable is demonstrated in Chapter 6. This variable was used as an alternative outcome variable in the analysis of correct knowledge of test results for sensitivity analysis.

The criteria used within the centres for a diagnosis of osteoporosis or of osteopenia varied. Although there were guidelines available at the time from the World Health Organization (WHO) regarding definitions of osteoporosis (particularly for menopausal women), as defined by T-scores (50), these guidelines were not always followed in the participant feedback for various reasons (see Chapter 5). In some centres, the WHO guidelines were followed strictly for the diagnosis of osteoporosis or osteopenia. Because the actual T-scores from the BMD test were sometimes sent to participants or to their family physicians, there is a possibility that participants or their physicians may have revised their diagnosis to the equivalent "WHO" diagnosis: In cases where the WHO diagnosis and the diagnosis received in the feedback were incongruent, a family physician may have re-interpreted the BMD scores to a participant and provided the WHO diagnosis, or a participant may have revised it themselves by discovering the WHO criteria on the Web, for example. This scenario presents a possibility that, for some cases, participants would have had a greater chance of being "incorrect" because the participants, either alone or through their physicians, may have modified their diagnoses to the WHO equivalent. For those cases where the diagnosis received in the feedback and the WHO diagnosis were incongruent, the participants may have been correct based on the WHO criteria, but not correct based on the diagnosis provided in their feedback. A version of the correct knowledge of test results was therefore derived whereby participants were correct if they correctly provided their "WHO diagnosis". In addition, there was a definition of correct

whereby the participants were considered correct if they provided *either* the correct feedback diagnosis *or* the correct WHO diagnosis (Either Correct). The WHO diagnosis[20] was determined from the raw T-scores generated by the DXA machines at each centre; this was the measurement that was provided to participants or family physicians with the feedback information. The coding of this variable is identical to that for the "Correct" variable, except that the WHO criteria for osteoporosis and osteopenia were used to derive the diagnosis from the reported T-scores (see Table 4.1). These variables were used as alternatives to the exactly correct variables in sensitivity analyses.

In summary, the main outcome variable, "Correct" and three variations of this variable were designed to derive binary outcomes of correct or incorrect responses at Year 3 regarding the BMD diagnosis at baseline.

Main outcome variable

- Exactly correct ("Correct") based on the diagnosis received in the feedback.

Alternative Outcome Variables for sensitivity analyses:

- Closely correct regarding a normal v. abnormal (or higher risk) result as reported in the feedback ("Closely Correct").
- Exactly correct based on the diagnosis derived using the WHO criteria ("Correct by WHO").
- Exactly correct based on the diagnosis derived from WHO criteria or the feedback diagnosis ("Either Correct").

4.4.5 Health Behaviour: Baseline Measures and Outcome Variables

The osteoporosis related health-behaviour outcomes were all derived from answers to questions on the CaMOS questionnaire at Year 3 (see Table 4.1); participants were asked about their current behaviour or their behaviour, on average, over the preceding 12 months. The same behavioural measures, covering comparable time frames were recorded at baseline for all of the behaviours (except for information seeking).

The average mg per day of dietary calcium intake was derived by CaMOS from the responses to the food intake questions at baseline and Year 3 (see Appendices A and B).

[20] As per WHO guidelines, T-scores > -1.0 were coded as normal bone density measurements, T-scores $\leq$ -1.0 and > -2.5 were coded as osteopenia and scores $\leq$ -2.5 were coded as osteoporosis.

Participants were asked to estimate their average intake of specific calcium-rich foods over the past 12-month period. These questions were formulated by the CaMOS research group and were not tested for validity or reliability. The calcium content of each of the foods in the questionnaire was estimated by CaMOS with reference to the Canadian Nutrient File (375); the amounts used by CaMOS to calculate calcium intakes are listed in Appendix C. The measurement of calcium in the diet is limited somewhat by shortcomings of the dietary calcium portion of the CaMOS questionnaire. During the period between baseline and the Year 3 follow up, Health Canada approved calcium fortification of orange juice and soy beverage products and these fortified beverages became widely available in Canada.[21] These sources of dietary calcium were not, however, included with the questions regarding calcium-rich foods on the Year 3 questionnaire. The baseline measure of calcium in the diet may therefore be a relatively more accurate measure of calcium intake and the estimated intake of dietary calcium at Year 3 may be an underestimate because it does not take into account the potential contribution of fortified beverages.[22]

The amount of elemental calcium acquired from supplements was derived by CaMOS from a database of supplements and multivitamins established for the specific purpose of estimating the amounts of calcium in various multivitamin and mineral supplement products. In contrast to the dietary questions that were referenced to the last 12 months, the questions about use of calcium supplements (as well as Vitamin D supplements, OHT and osteoporosis-specific medications) referred specifically to *current* use at the time of the interview. Total caffeine intake[23] was calculated by CaMOS using the values listed in Appendix D.

The sources, derivation, and classification of all of the behavioural variables are listed in the last section of Table 4.1.

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[21] Calcium-fortified soy and other plant-based products first became available on the Canadian market when Health Canada issued an Interim Marketing Authorization to allow their sale on November 11, 1997 (376) . Fortified orange and tangerine juices became available to Canadians when the first of a series of Temporary Marketing Authorizations to permit the sale of fortified juice was issued on August 1, 1999 (Source: Dr. J. Johnson, Health Canada Food Director, Nutrition Evaluation Division, Health Products and Food Branch, Health Canada; Personal Communication, 2006). An Interim Marketing Authorization was recently issued, in April 2006, for the sale of fortified orange and tangerine juices (377).

[22] Results from unpublished marketing data (A.C. Nielson; by personal communication to Dr. Susan Barr, 2007) show that sales of fortified soy and rice beverages made up less than 1% of the total fluid dairy sales in Canada during 2003-2005, which suggests that the exclusion of these beverages from the questionnaire may not have had a substantial impact on dietary calcium intake estimates during 1999-2000.

[23] The caffeine content of beverages was estimated by CaMOS with the aid of various sources including the Web and popular literature. The amounts used by CaMOS are comparable, however, to estimates from the Canadian Nutrient File (375).

4.5 Data Management and Analyses

The data management, manipulations, statistical analyses and modelling were performed using SPSS, version 13.0 (SPSS Inc., Chicago IL.) and SAS, version 8.0 (SAS Institute Inc., Cary, NC.)

4.5.1 Data Management

Where responses were missing to questions on the CaMOS questionnaires the data were coded as missing. Extensive efforts were made to minimize missing data from the information that was collected at the centres regarding content and destination of the feedback; if essential[24] original copies of letters were missing from the files every attempt was made to obtain alternative copies through the hospital information systems or from the central CaMOS data storage facility in Quebec. If the feedback information was still not retrievable, the information was coded as missing.

Data obtained for every variable was checked for unusual or out of range values by means of histograms, bar charts or descriptive statistics. If unusual values were identified, they were verified by referral to the original questionnaires (CaMOS personnel at the data centre in Montreal, Quebec were contacted for this purpose), and corrected if necessary.

4.5.2 Data Analyses

All descriptive statistics and association and regression modelling procedures were stratified by gender. Comparisons between the eligible mid-aged participants and the ineligible CaMOS mid-aged participants (those who did not undergo a BMD at baseline, were not followed up at Year 3, or had missing data for their feedback diagnosis), as well as comparisons to an equivalent age- and gender-matched sample from the 1996 NPHS, were made using the Chi-squared test for homogeneity (for the categorical data) or the T-test (for continuous data). The agreement between the "feedback" diagnosis and the WHO diagnosis based on the raw T-scores from the BMD was investigated using the Kappa statistic.

The analyses of correct knowledge of test results and of osteoporosis-related health behaviour began with a descriptive analysis of the main explanatory variables, the potential confounders or effect modifiers and the outcome variable(s). This was followed by univariate

[24] Copies of individual letters were considered essential in all centres where the diagnostic criteria or hip site for hip diagnosis varied between participants, where the diagnostic criteria were unclear or the content of the feedback was not identical for all participants or family physicians.

analyses of the relationships between the potential explanatory variables and the relationships between each explanatory variable and the outcome variable(s) to assess the potential for confounding and collinearity. Correlations were determined for the pairs of continuous variables. Associations between the pairs of categorical or discrete variables were estimated with the Chi-square test. Comparison of the means of the continuous variables between subgroups was carried out with the t-test (for variables with two subgroups) or one-way analysis of variance (for variables with three or more subgroups).

Multiple regression modelling was used to assess the associations between the explanatory variables and each of the knowledge and health behaviour outcomes, while taking into account other variables that were associated with both the explanatory variables and the outcome. Logistic regression models were used for the binary outcomes; knowledge of test results, information seeking, calcium supplement use, Vitamin D supplement use, exercise participation, osteoporosis-related medication use, smoking status, high alcohol intake, and high caffeine intake. Linear regression models were used for the continuous outcomes (dietary and total calcium intake and caffeine intake) with transformations of the data, where necessary, as discussed below.

The main focus of this study was the relationships among the diagnosis as a result of the BMD tests, the destination of the feedback, and the outcome variables: knowledge of test results and osteoporosis-related health behaviour after three years. For this reason, these main explanatory variables of interest were included in all models, whether or not they made a significant contribution to the model. In addition, age group was included in all models because it was seen as an important potential effect modifier; physicians and participants may have taken the risk of osteoporosis more seriously, or acted on it, if the participant was older (in the 50- to 60-year-old age group). The inclusion of any form of recommendation for treatment or for further referral, in the feedback sent to the FP or the participant, was considered to be an important potential confounder of the association between the diagnosis, the destination of the feedback and the knowledge and behavioural outcomes; a recommendation for action was included in all models. Finally, to control for baseline health behaviour (i.e., before feedback of BMD test results), all models of osteoporosis-related health behaviour included the baseline measure of the behaviour as an explanatory variable when available.[25]

[25] The exception was the information seeking variable where no baseline assessment was available. Participants were not asked about their previous information seeking behaviour at baseline.

To determine which other explanatory variables should be entered into the multivariable regression analysis (in addition to those listed in the paragraph above), a cut-off of $p < 0.2$ in the univariate analysis was used as a criterion for consideration of variables for the multivariable model (378). Manual backwards stepwise multivariate regression was performed using those variables found to be significantly associated with the outcome in the univariate analyses. Starting with all of the variables that met the above criteria, the variable with the weakest, non-significant association with the outcome variable was removed and the impact of removal of the variable was evaluated by calculating the difference between the Chi-squared value for the model with the variable and the model with the variable removed. If this difference was not significant ($p > 0.05$) the variable's contribution to the model was considered to be non-significant and the variable was removed. In addition, the effect of removal of the variable on the coefficients remaining in the model and their standard errors was considered. Finally, the multivariable model was estimated with only those variables included that contributed significantly to the model so that all cases with data for these variables were taken into consideration. The aim was to achieve the most parsimonious models possible while including all important and significant variables as well as the explanatory variable of interest.

The analyses of the association between the feedback diagnosis and correct knowledge of the BMD test results are presented in Chapter 6. Descriptive information about correct awareness of test results is presented first, and is followed by the results of univariate analyses between the explanatory variables as well as the potential confounders and correct awareness. The results of the multivariable modelling are then presented followed by an examination of potential effect modification by diagnosis and then by age group. For the assessment of potential effect modification, the analyses were repeated in each of the three diagnostic subgroups (normal, osteopenia and osteoporosis) and in each of the two age groups (40 to 50 years and 51 to 60 years) for women and men, separately. All explanatory variables that were included in the main models were included as covariates except for those that were not relevant to the subgroup analyses (i.e., "diagnosis" in the diagnostic subgroup analyses and "age group" in the age group subgroup analyses). The separate analysis of the older age group includes the assessment of the potential effects of a report of a significant fracture from the X-ray on correct awareness of test results (see below). Chapter 6 ends with the sensitivity analyses (also described below).

The associations among the feedback diagnosis and each of the behavioural outcomes are presented in Chapter 7. Both the feedback diagnosis and the *recalled* diagnosis, as reported at Year 3 by the participants (see Table 4.1), were considered, in separate models, as potential

explanatory variables for these behavioural analyses. The associations between the feedback diagnosis and the behavioural outcomes are presented as the main analyses so that the effectiveness of a diagnosis reported from a BMD test by DXA can be estimated. Analyses were repeated with the recalled diagnosis (which represents the diagnosis that participants believed that they had received three years earlier) as the main explanatory variable. The results of these subsequent analyses of "perceived" diagnosis and behavioural change pertains to the question of what the participants who had a correct "awareness" or "perception" of their test results did with this knowledge. These results are compared with those from the main analysis of the feedback diagnosis.

A description of the health behaviour at Year 3 is presented first for each set of analyses of the association between diagnosis and health behaviour in Chapter 7. This is followed by the results of univariate analyses between the explanatory variables as well as the potential confounders and the behavioural outcomes. The results of the multivariable modelling are then presented. Subsequently, examination of the potential effects of the results of the X-ray test on those aged 50 to 60 years (as described below) are presented by subgroup analyses of the older age group of women and men who attended the X-ray test. The results of the sensitivity analyses of these models are also included in Chapter 7 (also described below).

4.5.3 Further Analyses, Sensitivity Analyses and Diagnostics

As previously mentioned, only two thirds of the participants in this study were eligible to attend the spinal X-ray and receive the X-ray results because spinal X-ray was only offered to those CaMOS participants who were aged 50 year or older at baseline. All participants who attended the X-ray (or their physicians) received a report indicating whether a significant prevalent fracture was evident on the X-ray. The effect of a report of a significant prevalent fracture from the X-ray was examined by multivariable regression in the subgroups of women and men who were aged 50 to 60 years at baseline and attended the X-ray test. The question of interest was whether the report of a significant fracture increased the participants' knowledge of a diagnosis of osteopenia or osteoporosis, or contributed to osteoporosis related health-behaviour change.

Because some of the centres followed the same protocol for their feedback of BMD results for all participants within their centre, the destination variable was partially nested within the centre. For this reason, analyses with "Centre" as an explanatory variable were conducted separately from those with the "Destination" variable and the models were compared.

For the knowledge outcome, sensitivity analyses were performed using the three alternative versions of correct awareness, as described above. Further, the analyses were repeated for all models (knowledge and behaviour outcomes) while excluding those cases in any centre where the feedback was not sent according to the protocol. The purpose of this sensitivity analysis was to examine the potential effects of a bias in the destination of the test results in those centres where the intended protocol deviated for some cases.

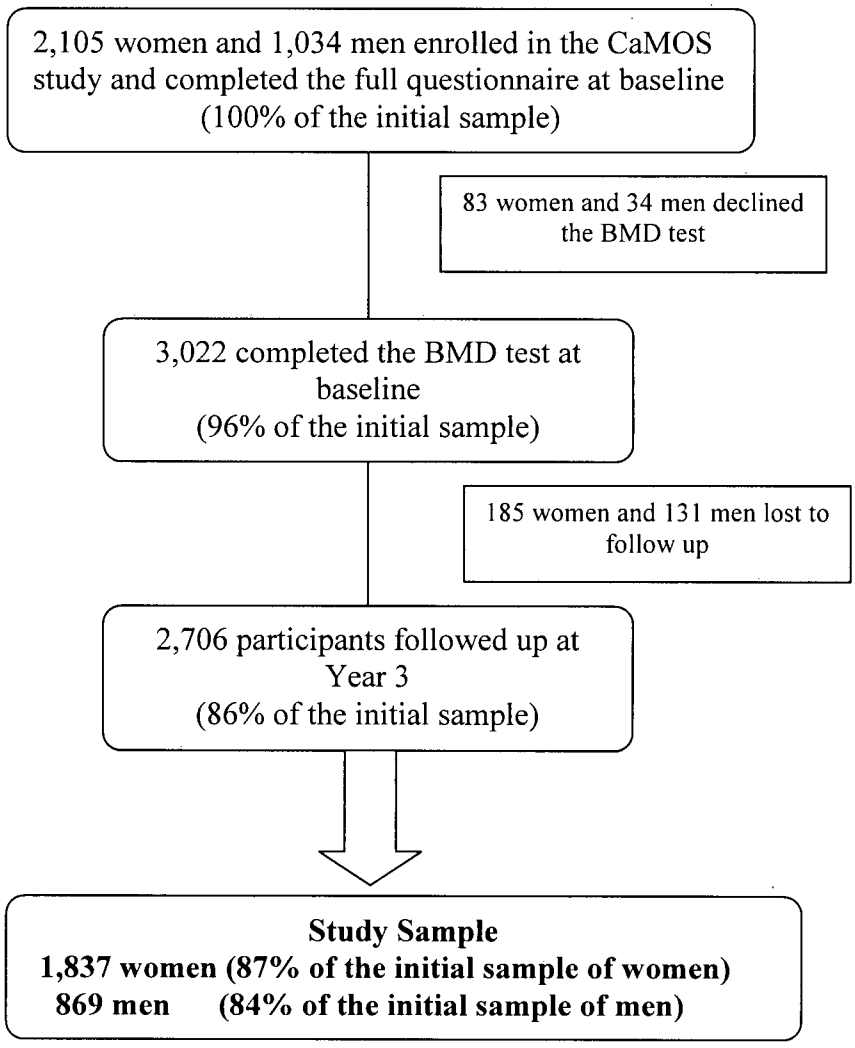
Model diagnostics were performed on the final logistic and linear multivariate models to identify potentially influential cases and to determine whether the model's assumptions had been met. Predicted values were plotted against standardised residuals and the regression analyses were repeated after influential cases had either been removed, or their values modified by applying a maximum ceiling value or by transformation.

CHAPTER 5: Results I. The Study Sample and the Explanatory Variables

5.1 The Study Sample

The selection of participants for this study is demonstrated in Figure 5.1. There were 3,139 full[26] participants aged 40 to 60 years at baseline in the CaMOS study. Of these, 1,837 women and 869 men (86% of the original CaMOS mid-aged sample) met the selection criteria of completion of a baseline BMD test in addition to the questionnaire and follow-up at Year 3.

Figure 5.1: Selection of the Study Sample from the 40- to 60-year-old CaMOS Participants



[26] A "full" participant is classified as an eligible person who was invited to participate and who completed the full version of the CaMOS questionnaire.

5.1.1 Missing Data

In a few cases, copies of the reports that were sent to the participants and/or their family physicians were not available at the centres and the feedback destination or diagnosis could not be derived from other information. Consequently, there were 18 women and 4 men in the study sample for whom the feedback diagnosis was missing and 5 women and 4 men with missing information on the destination of their feedback. Responses were missing to some questions on the CaMOS questionnaire, but the proportion did not exceed 5% for any one variable, and was typically much less than 1%. These responses, or the variables that were derived from them, were left as missing because they could not be inferred. All selected participants were included in all analyses except when there was a missing value for an included variable. Missing information on specific variables is noted below (see Tables 5.1a and 5.1b).

Missing data on the outcome variables, and the self-recalled bone density test results (which was part of the outcome variable "correct" as well as an explanatory variable in the behavioural analyses), are addressed in the following chapters.

5.1.2 Baseline Characteristics and Generalisability of the Study Sample

The baseline characteristics of the women and men who participated in this study are listed in Tables 5.1a and Table 5.1b, respectively. For comparison purposes, the distributions of the same characteristics are shown in the second column of the table for the 40-60 year-old participants from the CaMOS study that were "excluded" because of a missing BMD test or loss to follow-up at Year 3. The last column in the table compares the distributions of the gender- and age-matched sample of subjects from the 1996 NPHS for those variables that were comparable between the two studies.

Table 5.1a: Comparison of Baseline Characteristics between Included Women, Excluded CaMOS Women and a Matched Sample of Women from the NPHS

	STUDY SAMPLE OF WOMEN N = 1837[a]	EXCLUDED WOMEN N = 268[b]	NPHS WOMEN N = 8383
	Mean (SD)	Mean (SD)	Mean (SD)
Body Mass Index[c]	**27.1 (5.4)**	27.3 (5.2)	25.3 (4.7)***

		STUDY SAMPLE OF WOMEN N = 1837[a]	EXCLUDED WOMEN N = 268[b]	NPHS WOMEN N = 8383
		N (%)	N (%)	N (%)
Diagnosis in Feedback	Normal	**943 (52%)**	92 (50%)	
	Osteopenia	**563 (31%)**	60 (32%)	------
	Osteoporosis	**313 (17%)**	33 (18%)	
Significant Prevalent Fracture[d]		**92 (8%)**	14 (11%)	------
Destination of Feedback				
	To Family Physician	**382 (21%)**	52 (28%)*	
	To Participant	**935 (51%)**	79 (43%)	------
	To Both	**515 (28%)**	53 (29%)	
Recommendation for Referral or Treatment		**135 (7%)**	19 (10%)	------
Age Group	40-49 years	**562 (31%)**	60 (22%)**	------
	50-60 years	**1275 (69%)**	208 (78%)	
"Non-white" Race/Ethnicity		**107 (6%)**	21 (8%)	701 (8%)***
Reproductive Status				
	Premenopausal	**638 (35%)**	75 (28%)	-----
	Naturally Menopausal	**704 (38%)**	104 (39%)	
	Surgically Menopausal	**140 (8%)**	28 (10%)	
	Premenopausal hysterectomy	**354 (19%)**	61 (23%)	
Education				
	Incomplete High School	**458 (25%)**	98 (37%)***	1999 (24%)***
	Complete High School	**338 (18%)**	45 (17%)	2982 (36%)
	Postsecondary Education	**708 (39%)**	92 (34%)	1987 (24%)
	University Degree	**333 (18%)**	33 (12%)	1344 (16%)
Estimated Neighbourhood Income Quintile	Lowest	**303 (17%)**	62 (23%)	-----
	Second Lowest	**331 (18%)**	48 (18%)	
	Middle	**323 (18%)**	49 (19%)	
	Second Highest	**389 (22%)**	52 (20%)	
	Highest	**456 (25%)**	54 (20%)	
Centre	Calgary	**212 (12%)**	19 (7%)***	
	Hamilton	**190 (10%)**	26 (10%)	-----
	Halifax	**192 (11%)**	45 (17%)	
	Kingston	**190 (10%)**	35 (13%)	
	Quebec City	**239 (13%)**	37 (14%)	
	Saskatoon	**205 (11%)**	12 (5%)	
	St. John's	**196 (11%)**	22 (8%)	
	Toronto	**194 (11%)**	39 (15%)	
	Vancouver	**219 (12%)**	33 (12%)	
Awareness of Family History		**312 (17%)**	44 (17%)	-----

	STUDY SAMPLE OF WOMEN N = 1837[a]	EXCLUDED WOMEN N = 268[b]	NPHS WOMEN N = 8383
Previous Diagnosis of Osteoporosis	**83 (5%)**	21 (8%)*	-----
History of Comorbidity	**95 (5%)**	21 (8%)	-----
History of "High Risk" Medication Exposure	**227 (12%)**	42 (16%)	-----
General Health Poor/ Fair/ Good	**639 (35%)**	118 (44%)**	3450 (41%)***
Very Good/ Excellent	**1197 (65%)**	150 (56%)	4933 (59%)
Current Cigarette Smoker	**304 (17%)**	66 (25%)**	1834 (22%)***
Current Ca Supplement Use	**772 (42%)**	105 (39%)	-----
Current Vitamin D Supplement Use	**594 (32%)**	75 (28%)	-----
Current Regular Exercise	**1013 (55%)**	137 (51%)	-----
High Alcohol Intake	**82 (5%)**	9 (3%)	175 (2%)**
High Coffee Intake	**297 (16%)**	47 (18%)	-----
Current Osteoporosis Medication Use	**8 (<1%)**	4 (2%)	-----
Current OHT Use	**637 (35%)**	91 (34%)	1541 (19%)***
	Mean (SD)	**Mean (SD)**	
Calcium (supplements and diet); mg/day	**1023 (604)**	1004 (619)	-----
Calcium (diet alone); mg/day	**785 (476)**	807 (509)	
Total Caffeine	**311 (293)**	311 (269)	-----

* $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$ when compared with the study sample.

[a] The denominator for the study sample of women is less for some variables due to the following missing data: BMI (n = 4), Reproductive Status (n = 1), Estimated Neighbourhood Income Quintile (n = 35), Awareness of Family History (n = 6), Previous Diagnosis of Osteoporosis (n = 1), General Health (n = 1), History of Comorbidity (n = 1), Dietary and Total Calcium (n = 39), Total Caffeine (n = 11) and High Alcohol Intake (n = 2); Significant Prevalent Fracture (n = 2; the contents of the X-ray report were missing for 2 women who attended the X-ray).

[b] The denominator for the excluded women is less for some variables due to the following missing data: BMI (n = 33), Estimated Neighbourhood Income Quintile (n = 3), Awareness of Family History (n = 1), Dietary and Total Calcium (n = 3), Total Caffeine (n = 1) and High Alcohol Intake (n = 1).

[c] The women were divided into quartiles of BMI for all the analyses: Lowest quartile = 16.53–23.25; second lowest quartile = 23.26–26.07; second highest quartile = 26.08-29.84; highest quartile = 29.86-64.30

[d] Significant fracture is only relevant to the women who were eligible for an X-ray (those aged 50 years and over), and who attended the X-ray. The proportion of women aged 50 years and over who agreed to an X-ray was greater in the study sample (92%) than in the excluded group of participants (64%) (Chi-Square = 133.9; df = 1; $p < 0.001$); those who refused the DXA test were more likely to refuse the X-ray.

Table 5.1b: Comparison of Baseline Characteristics between Included Men, Excluded CaMOS Men and a Matched Sample of Men from the NPHS

		STUDY SAMPLE OF MEN N = 869[a]		EXCLUDED MEN N = 165		NPHS MEN N = 7838	
Body Mass Index[b]		**Mean 27.3**	**(SD) (4.2)**	Mean 27.6	(SD) (4.2)	Mean (SD) 26.6	(3.9)***
		N	**(%)**	N	(%)	N	(%)
Diagnosis in Feedback	Normal	**392**	**(45%)**	60	(46%)		
	Osteopenia	**300**	**(35%)**	40	(31%)	-----	
	Osteoporosis	**173**	**(20%)**	30	(23%)		
Significant Prevalent Fracture[c]		**67**	**(13%)**	8	(11%)		
Destination of Feedback							
	To Family Physician	**188**	**(22%)**	29	(22%)*		
	To Participant	**456**	**(52%)**	76	(59%)	-----	
	To Both	**221**	**(26%)**	24	(19%)		
Recommendation for Referral or Treatment		**72**	**(8%)**	7	(5%)	------	
Age Group	40-49 years	**313**	**(36%)**	60	(36%)		
	50-60 years	**556**	**(64%)**	105	(64%)	------	
"Non-white" Race/Ethnicity		**65**	**(8%)**	20	(12%)	696	(9%)
Education							
	Incomplete High School	**179**	**(21%)**	39	(24%)	1795	(23%)***
	Complete High School	**132**	**(15%)**	23	(14%)	2592	(33%)
	Postsecondary Education	**296**	**(34%)**	65	(39%)	1824	(23%)
	University Degree	**262**	**(30%)**	38	(23%)	1551	(20%)
Estimated Neighbourhood Income Quintile	Lowest	**158**	**(19%)**	37	(23%)		
	Second Lowest	**155**	**(18%)**	31	(19%)		
	Middle	**169**	**(20%)**	36	(22%)	-----	
	Second Highest	**166**	**(20%)**	26	(16%)		
	Highest	**204**	**(24%)**	32	(20%)		
Centre	Calgary	**92**	**(11%)**	16	(10%)*		
	Hamilton	**99**	**(11%)**	11	(7%)	-----	
	Halifax	**90**	**(10%)**	20	(12%)		
	Kingston	**81**	**(9%)**	26	(16%)		
	Quebec City	**101**	**(12%)**	24	(15%)		
	Saskatoon	**104**	**(12%)**	13	(8%)		
	St. John's	**98**	**(11%)**	16	(10%)		
	Toronto	**97**	**(11%)**	26	(16%)		
	Vancouver	**107**	**(12%)**	13	(8%)		
Awareness of Family History		**77**	**(9%)**	17	(10%)	-----	

	STUDY SAMPLE OF MEN N = 869[a]	EXCLUDED MEN N = 165	NPHS MEN N = 7838
Previous Diagnosis of Osteoporosis	**7 (<1%)**	6 (4%)**	-----
History of Comorbidity	**21 (2%)**	3 (2%)	-----
History of "High Risk" Medication Exposure	**69 (8%)**	18 (11%)	-----
General Health			
Poor/ Fair/ Good	**286 (33%)**	78 (47%)**	3015 (39%)**
Very Good/ Excellent	**583 (67%)**	87 (53%)	4823 (62%)
Current Cigarette Smoker	**185 (21%)**	54 (33%)**	2172 (28%)***
Current Ca Supplement Use	**181 (21%)**	29 (18%)	-----
Current Vitamin D Supplement Use	**167 (19%)**	31 (19%)	-----
Current Regular Exercise	**464 (54%)**	84 (51%)	-----
High Alcohol Intake	**137 (16%)**	21 (13%)	714 (9%)***
High Coffee Intake	**241 (28%)**	44 (27%)	-----
Current Osteoporosis Medication	**1 (<1%)**	1 (<1%)	-----
	Mean (SD)	**Mean (SD)**	
Calcium (supplements and diet); mg/day	**886 (604)**	937 (554)	-----
Calcium (diet alone); mg/day	**816 (538)**	885 (522)	-----
Total Caffeine; mg/day	**399 (335)**	415 (390)	-----

* $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$ when compared with the study sample.

[a] The denominator for the study sample of men is less for some variables due to the following missing data: BMI (n = 1), Estimated Neighbourhood Income Quintile (n = 17), Awareness of Family History (n = 3), Previous Diagnosis of Osteoporosis (n = 5), History of Comorbidity (n = 2), History of "High Risk" Medication Exposure (n = 1), Current Smoking Status (n = 1), Dietary and Total Calcium (n = 26), Current Regular Exercise (n = 1), High Coffee Intake and Total Caffeine Intake (n = 3), High Alcohol Intake (n = 2).

[b] The men were divided into quartiles of BMI for all of the analyses except for these comparisons: Lowest quartile = 17.14–24.66; second lowest quartile = 24.67–26.90; second highest quartile = 26.91-29.35; highest quartile = 29.36-62.24

[c] Significant fracture is only relevant to the proportion of men who were eligible for (the protocol allowed for only those aged 50 years and over), and had the X-ray. As with the women, the proportion of men aged 50 and over who agreed to the X-ray was greater in the study sample (90%) than in the excluded participants (72%) (Chi-Square = 23.54; df = 1; p <0.001); those who refused a DXA test were more likely to refuse the X-ray.

Due to the stratified gender, age and centre recruitment strategy employed by CaMOS, two thirds of the sample were women, two thirds were aged 50 to 60 years, and there were approximately equal numbers of participants in each of the nine geographical centres. Eighty

seven percent of the original CaMOS mid-aged women and 84% of the original CaMOS mid-aged men were included in this study; women were somewhat less likely than men to be lost to follow up and older women (aged 50 to 60 years) were more likely to be lost to follow up than were younger women (aged 40 to 49 years), but neither of these differences was substantial. Although inclusion in this study was not completely consistent across the centres, there was good representation from every centre; at least 81% of the CaMOS baseline participants from each centre were included and the inclusion rate was as high as 93% for Saskatoon. The study samples of both the women and the men were evenly distributed across education levels and across estimated neighbourhood income quintiles, although a significantly greater number of women from the lowest education level (incomplete high school) were excluded.

Approximately one fifth of the women and men were smokers and the majority of them (approximately two thirds) perceived themselves to be in very good or excellent general health. Both women and men who indicated that they were healthier, as measured by a response of "excellent" or "very good" to the "In general" health question on the SF-36, were more likely to be included, however, compared with those who stated that their health was only "good", "fair" or "poor". Likewise, men and women who were smokers at baseline were more likely to be excluded from the study because of refusal to take part in the DXA test or follow-up at Year 3.

Only 5% of the women and <1% of the men had previously received a diagnosis of osteoporosis or osteopenia and the participants who had already received a diagnosis of osteopenia or osteoporosis were more likely to be excluded due to a higher refusal rate for participation in DXA examination amongst those with a previous diagnosis, rather than a greater loss to follow up (most likely because they were already having regular BMD screening tests outside of the study).

Just over one third of the women were taking ovarian hormone therapy (OHT) at baseline. Only a very small proportion of the women and men were taking a medication indicated for the treatment or prevention of osteoporosis at baseline (other than OHT). All of these medication users were taking either etidronate or alendronate.

For both women and men, the proportions of participants in each of the diagnostic categories (normal, osteopenia or osteoporosis) from their baseline feedback were similar in the study sample and in those lost to follow-up.[27] Small differences were evident amongst the

[27] The destination of the feedback and the feedback diagnosis were only relevant for those "excluded" participants who had a DXA test but were then lost to follow-up; 186 (69%) of the excluded women and 131 (79%) of the excluded men. Comparisons on these variables therefore only apply to a subgroup of the excluded original CaMOS participants.

feedback destination categories when the study sample was compared with those excluded; relatively more women who received their feedback directly (to participant only) were included and relatively more women whose feedback went to the FP only were excluded. For men, this pattern was different; relatively fewer men whose feedback was sent to the participant only were included and relatively more men whose feedback went to both the participant and the FP were included. None of these differences in the distribution across the destination of feedback groups was substantial, however.

With the exception of current smoking status, the baseline behavioural measures were mostly comparable between the participants who were excluded and the study sample. The mean total daily calcium intake, based on self reported diet and supplement use, was low overall (particularly in men), although there was a very large range and variance in individual intakes. Fewer then one half of the participants (43% of the women and 30% of the men) were consuming the lowest minimum recommended daily intake of at least 1,000 mg per day.[28] Although the women and the men had comparable calcium intakes from their diets alone, the mean overall calcium intake was greater in women because of the higher frequency of supplement use. More women than men were taking calcium supplements (42% *v.* 21%) and Vitamin D supplements (32% *v.* 19%).

There were some additional differences between the women and men in this study. More men than women reported that they were drinking two or more alcoholic drinks per day (16% *v.* 5%) and that they consumed four or more cups of coffee per day (28% *v.* 16%). Similar proportions (just over one half) of men and women, however, reported participation in a regular program of exercise.

Overall, the men had completed a higher level of education than the women; 30% of the men had a university degree compared to only 18% of the women. The women were more likely to report a positive family history of osteoporosis than were the men (17% of women *v.* 9% of men), which suggests that women of this age group may be more aware of a family history of osteoporosis than are men or that women with a family history were more likely to join the CaMOS study than were men with a similar family history.

Compared with the mid-aged women and men from the NPHS, the participants in this study were less likely to be smokers, were more likely to report a higher level of self rated health and were more likely to report high alcohol intakes. The women in the CaMOS sample were

[28] The recommended daily intake of calcium for both prevention and management according to the 2002 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada (85) is 1,000 mg/day for women and men aged 31 to 50 years and 1,500 mg/day for women and men aged 51 to 70 years.

much more likely to be taking OHT compared with the NPHS sample; this difference between the samples was evident between the two populations of women within every five year age range, except for the youngest (40 to 44 years) where few women in either sample were taking OHT. Women and men in the CaMOS sample were larger on average that those in the NPHS sample (i.e., they had a higher mean body mass index). Although there was a statistically significant difference between the proportions of women who reported that they were "non-white"[29] between the two samples, the actual percentages were not substantially different. The distributions of "white" and "non-white"[30] men in the two populations were comparable. Finally, the CaMOS sample had a higher level of education than the NPHS sample overall; the majority of the men and women in the CaMOS sample had completed further education beyond high school whereas the majority of the NPHS sample did not report education past high school.

It should be noted that not all of the variables on the NPHS were directly comparable with those on the CaMOS questionnaire, and these variations may explain some of the differences observed in the population characteristics. Direct comparison could be made between the race, education and self reported general health variables only; the questions relating to these variables were essentially the same on the two questionnaires.

Smoking status in CaMOS referred to whether the participant had smoked daily for at least six months, and was currently smoking; participants who had not smoked cigarettes daily for at least six months were not asked if they were current smokers. The comparable measure on the NPHS included individuals who indicated that they currently smoked cigarettes daily. People who were current occasional smokers (as long as they had smoked daily for at least six months at some time) were included in the CaMOS estimate as a smoker but equivalent subjects could not be identified from the NPHS questions; NPHS subjects were not asked a question about former daily smoking (unless they were not current smokers). Inclusion of the "occasional current smoker" definition of smokers in the NPHS sample increased the estimate of the number of smokers and increased the difference between the two samples on this variable. The conclusion would be the same however; the CaMOS sample is under-representative of current smokers in the general Canadian population.

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[29] The "non-white" group of women was predominantly represented by women who described themselves as "Chinese" (54% of "non-white" women) or "South Asian" (16% of "non-white" women).

[30] The "non-white" group of men was predominantly represented by men who described themselves as "Chinese" (40% of "non-white" men) or "South Asian" (31% of "non-white" men).

The average daily consumption of alcohol was estimated based on a time frame of the past seven days on the NPHS, whereas the CaMOS estimate was based on average alcohol consumption over the past year.

Likewise, the time frames for the estimate of current OHT use in women were not identical, although they were very similar: CaMOS participants were asked about current use of OHT and NPHS participants were asked about any use during the past month. The NPHS question would therefore be expected to be more inclusive and the measurement difference in time frames would not explain the higher proportion of women taking OHT in the CaMOS sample.

Body mass index was calculated from self reported height and weight for the NPHS participants, whereas the height and weight of CaMOS participants were measured by the interviewers and were not based on self report. This may be expected to lead to underestimates of weight in the NPHS sample because people tend to underestimate, more often than overestimate, their weight. The difference observed in the body mass index between the two groups is in this direction; the CaMOS sample was larger on average, larger individuals may have been more likely to take part in the CaMOS study and/or the difference in the methods of measurement methods between the two studies led to a lower (possibly underestimated) average BMI in the NPHS sample.

It should also be noted that the CaMOS sample included people from nine mostly urban centres, located in only seven provinces. The NPHS participants were sampled from a more diverse and widespread geographical area across Canada. Differences between the two samples may be expected to be due to variations in geographical distribution of certain factors as well as to uneven recruitment of specific subgroups to the CaMOS study within those geographical areas. Still, the comparison of the CaMOS sample to the NPHS sample provides a means of assessing the generalizability of the results of this study to the general Canadian population.

5.1.3 Reasons for a Missing BMD Test

To further assess the potential representativeness of the selected sample, the original baseline questionnaires and interviewers' notes were reviewed for specific notations related to the omission of the BMD test at either the hip or spine at baseline (and hence exclusion from this study). Explanations included: a body weight that exceeded the maximum valid weight for a

DXA test of 300 lbs.[31] (2 women, 1 man), a recent BMD test or an upcoming scheduled BMD test outside of the CaMOS protocol (9 women), an illness or disability that made a BMD test too uncomfortable (3 women and 2 men), and technical errors with the DXA machine (results were not generated for two women who attended the BMD test). Of the remaining 67 women and 31 men who had no BMD test at baseline, those who offered a reason for declining the test cited a lack of time or an unwillingness to be exposed to radiation.

5.2 Content of Feedback to Study Participants

The general content of the information that was provided to the participants or their physicians as a follow-up to the DXA test was found to be similar across the centres; in all cases at least one hip and one spine bone density value was provided and there was a reference to how the participant's values compared to a standard population (a T score or Z score). The lower of the hip and spine values was interpreted as the "diagnosis". The bone density values were interpreted using the diagnostic criteria as described below, based on either three (7 centres) or two (2 centres) diagnostic categories. If the participant also had a spinal X-ray, the results were interpreted and included as part of the feedback. All participants were either given or sent a short pamphlet (provided by Osteoporosis Canada), which included brief information about osteoporosis, its risk factors and treatments as well as the importance of adequate calcium, vitamin D and exercise for healthy bones.

In addition to the diagnostic information, the reports sent to 57% of the participants (or their physicians) in the Vancouver centre and 7% of those in the Saint John's centre included a recommendation for some further action aimed at prevention or treatment. Most often, the recommendation was to refer the participant to a local osteoporosis clinic, but in a few other cases there was a specific recommendation for treatment by medication. No such recommendation was included in the feedback from the other seven centres, or for the remaining 43% of participants in Vancouver and 93% of participants in Saint John's. This type of recommendation may well be expected to have an impact on awareness, information seeking and health behaviour. Consequently, the potential effect of such a recommendation for referral or treatment was taken into account in all of the multivariable analyses.

[31] Participant file notes indicated that three participants, from the Halifax and Saskatoon centres, did not attend the BMD test because their weight exceeded the maximum valid weight for this test. Not all centres used these criteria however, to exclude participants from BMD tests: Four participants from the Kingston, Hamilton and Calgary centres who weighed >300 lbs. did attend the test and are included in the sample.

5.2.1 Criteria Used by Each Centre for Diagnosis of Osteoporosis or Osteopenia

The bone density of each participant was measured at three hip sites: the neck, the trochanter and Ward's triangle. For 80% of the participants,[32] the femoral neck measurement was used for the hip diagnosis, as recommended by the WHO at the time of baseline reporting. For the spine diagnosis, either the average bone density of vertebrae L2 - L4 (Hamilton and Saint John's), or the average of vertebrae L1 - L4 (all other centres) was used.

The standardised values used as criteria for a diagnosis varied; some centres strictly adhered to the WHO guidelines for cut-off values of T-scores while other centres employed a different approach to their interpretation.

Two centres did not use the "osteopenia" diagnosis at all; it was decided at these centres that because normal subjects had been recruited for the CaMOS study, it was not desirable to give the participants labels that referred to borderline risk. All T-scores within the range defined as osteopenia by the WHO (-1 to -2.5), were therefore reported as normal results in Quebec City and as either normal or consistent with osteoporosis in Kingston.[33] All three diagnostic categories were used in the other seven centres.

In three of the CaMOS centres (Quebec City, Saskatoon and Kingston), exact copies of the feedback given or sent to the participants were not available for every case and thus the diagnosis that was delivered was extrapolated from the diagnostic criteria that were utilized within the centres. Because these three centres followed the same diagnostic cut-offs throughout the baseline data collection, the diagnosis provided in the feedback could be reliably determined by the BMD test results.

5.2.2 Comparison of the Feedback Diagnosis and the Diagnosis Generated from WHO Criteria

Because the WHO guidelines for interpreting DXA results were available to family physicians at the time of the baseline testing there is some possibility that the participants' physicians "re-interpreted" the reported BMD values for their participants in the event that the WHO diagnosis differed from the interpretation provided by CaMOS. To assess the discrepancy

[32] Exceptions were in the Saskatoon centre where the lowest of two values (the femoral neck or average of the three measured sites) was reported for all participants (12% of the overall study sample) and in the first two thirds of recruited participants at the Vancouver centre where the lowest of three values (neck, trochanter or Ward's area) was reported (8% of the overall study sample).

[33] In Kingston, the percentage of young adult peak bone density, rather than the T score was used as the diagnostic measurement. Osteoporosis was considered to be present if the percentage was 75% or lower than young adult norms. This cut off is close to, but not exactly equivalent to, a t-score of -2.5; accordingly, a few cases that would have been diagnosed with osteopenia by the WHO criteria were diagnosed with osteoporosis.

between the reported feedback and WHO diagnoses, WHO diagnostic values were generated using the femoral neck and the L1 - L4 T-scores from the DXA reports. The relative frequencies of the reported diagnosis of osteopenia or osteoporosis, as well as the WHO diagnosis, reported by centre, are provided in Table 5.2.

Table 5.2: Comparison of Relative Frequencies of Reported Diagnosis and WHO Diagnosis by Centre

		Diagnosis by Feedback (%)		Diagnosis by WHO criteria[a] (%)	
Centre	**(N)**	**Osteopenia**	**Osteoporosis**	**Osteopenia**	**Osteoporosis**
Vancouver	(326)	41.1	38.0	53.4	23.0
Calgary	(304)	52.3	14.1	53.0	14.1
Saskatoon	(309)	57.0	15.5	56.3	15.5
Hamilton	(289)	38.4	6.6	38.8	5.9
Toronto	(290)[b]	51.7	16.6	52.1	17.2
Kingston	(271)	0	17.7	43.5	12.9
Quebec City	(340)	0	17.9	52.4	17.9
Halifax	(280)	22.9	16.1	48.9	15.0
St John's	(274)	24.8	18.2	44.9	9.1
Total	(2683)	32.1	18.1	49.5	14.8

[a] Note that the rates of these diagnoses cannot be strictly compared between centres because they are generated from the raw T-scores from different DXA machines and not from standardized T scores. Standardized scores should be used for comparisons of bone densities across different machines; whereas the purpose here is to compare the information that was reported and may have been interpreted by family physicians or others using the WHO criteria.
[b] Information on WHO diagnosis was missing for one woman (the original DXA results were missing although the participant received a feedback diagnosis).

There is particularly poor congruence between the different diagnostic methods in both Quebec City and Kingston as would be expected, due to the absence of the osteopenia diagnostic category reported in the feedback. There is also fairly low agreement between the diagnosis derived by the centre and the WHO diagnosis in St. John's (Kappa = 0.57), Halifax (Kappa = 0.57) and Vancouver (Kappa = 0.70). In each of the former two centres, one of several radiology consultants at the hospital where the BMD test took place was responsible for the interpretation of test results and the generation of the report; each radiologist used different criteria. In Vancouver, there was variation in the hip site used for diagnosis. The remaining

centres had close agreement between the diagnosis reported in the feedback and that derived from the WHO recommendations.

The Kappa value for the agreement between the diagnoses for all subjects across the nine centres is 0.69. Given this relatively low agreement, the analyses of correct awareness of test results were repeated using correct awareness of the WHO diagnosis (and correct awareness of either the WHO or the feedback diagnosis) instead of correct awareness of the feedback diagnosis, as a sensitivity analysis, to determine whether the variation in diagnostic criteria may have affected the awareness of test results (as previously described).

5.3 Destination of the Feedback

For every participant, the BMD results and their interpretation were sent or given to the participant directly, to the participant's family physician (FP), or to both the participant and the FP. The destination variable was incompletely nested within the CaMOS centres because some of the centres used the same protocol for all participants (Hamilton, Saskatoon and Halifax), while the other centres varied their protocol. In Kingston, the protocol was varied for only one participant and in St. John's for only three participants. There was more variation in the feedback protocols in the remaining four centres. The actual feedback destination of the BMD results by centre for all study participants is shown in Table 5.3.

The reasons for the variation in the intended protocols were examined to identify any potential sources of bias in the selection of the destination of feedback within any of the centres. For the few cases in Toronto where the results were sent only to the FP, the participants had requested that this be done at the time of their interview and before the results of the BMD test were known. The protocol changed over time in Toronto; in general, the results were sent to both the participant and the FP earlier in the study and to only the participant later in the study.

As shown in Table 5.3, all of the participants in Hamilton received direct reports of their test results. In addition, a package that included a copy of the BMD report, an explanatory letter intended for the FP, and an interpretation of the X-ray (if relevant) was enclosed in a separate envelope addressed to the FP. The accompanying letter to all the participants in Hamilton included the following line: "We have enclosed a copy of the results for you to mail to your Family Doctor".

Separate physician packages also were enclosed with the participants' feedback for a few cases in Vancouver (n = 47) and in Quebec (n = 6). In these two centres, the reports for the physicians were included with the participants' feedback because the participant requested that

they not be sent directly to the physician or because no family physician information was provided to the interviewer by the participant, before the BMD test results were known.

In Vancouver, the reports were sent only to the participant if there was a specific request to do so by the participant, if there was no contact information for the FP or, in a few cases, if the results were normal. In all other centres, variations to the protocol were by participant request before the BMD results were known.

Table 5.3: Frequency of Destination of Feedback by Centre

		Destination of BMD Results and Feedback N (% within each centre)			
		FP only	Participant only	Both FP and Participant	Total
CaMOS Centre	Vancouver	--	61 (18.7)	265 (81.3)	326
	Calgary	--	42 (13.8)	262 (86.2)	304
	Saskatoon[a]	--	309 (100.0)	--	309
	Hamilton	--	289 (100.0)	--	289
	Toronto	5 (1.8)	100 (35.5)	177 (62.8)	282
	Kingston	--	270 (99.6)	1 (0.4)	271
	Quebec City	--	312 (91.8)	28 (8.2)	340
	Halifax	282 (100.0)	--	--	282
	St John's	283 (96.3)	8 (2.7)	3 (1.0)	294
Total (% within each destination)		570 (21.1)	1390 (51.5)	737 (27.3)	2697

[a] BMD printouts were handed to all participants and verbally explained in the Saskatoon centre. Participants who received feedback directly in all other centres received letters giving explanations by mail, as did all the family physicians who received feedback.

To account for the possibility that selective variations in the destination may have biased the results of the analysis of the effects of feedback destination, the analyses were repeated after excluding those participants whose feedback destination varied from the intended within-centre protocol.[34] These sensitivity analyses were carried out as a precaution against potential bias

[34] Both feedback to the family physician and the participant, and to the participant only were considered to be the intended protocols for the Toronto centre.

caused by deliberate reporting of particular test results to a particular destination or any other reasons for deviations from the protocols.

5.4 Diagnosis and its Relationship with the Other Explanatory Variables

The feedback diagnoses that participants received are shown in Tables 5.4 (women) and 5.5 (men) stratified by the feedback destination, by the other potential explanatory variables and by the baseline behavioural variables. Almost one half of the women received a feedback diagnosis that indicated that their BMD results were low or very low and more than one half of the men were told that they had a low BMD test result. There were slightly more men than women with an "abnormal" diagnosis; these differences however were not substantial in the sample overall, or within any one centre.

Table 5.4: Feedback Diagnosis and its Association with the Other Explanatory Variables in Women

		NORMAL N = 943 (52%)	OSTEOPENIA N = 563 (31%)	OSTEOPOROSIS N = 313 (17%)
Total N = 1819[a]		*N (%)*	*N (%)*	*N (%)*
[b]**Significant Prevalent Fracture*** **		23 (4.3)	42 (10.7)	27 (11.6)
Destination* **	To FP only	230 (24.4)	73 (13.0)	61 (19.6)
	To participant only	550 (58.4)	245 (43.7)	140 (45.0)
	To both	162 (17.2)	243 (43.3)	110 (35.4)
Recommendation for Referral or Treatment* **		3 (0.3)	46 (8.2)	86 (27.6)
Age Group* **	40 to 49 years	342 (36.3)	156 (27.7)	56 (17.9)
	50 to 60 years	601 (63.7)	407 (72.3)	257 (82.1)
Body Mass Index* **	Lowest Quartile	182 (19.4)	145 (25.8)	127 (40.6)
	Second Lowest Quartile	216 (23.0)	154 (25.8)	93 (29.7)
	Second Highest Quartile	242 (25.7)	152 (27.0)	61 (19.5)
	Highest Quartile	300 (31.9)	120 (21.4)	32 (10.2)
Race/Ethnicity* **	"White"	917 (97.2)	518 (92.0)	277 (88.5)
	"Non-white"	26 (2.8)	45 (8.0)	36 (11.5)
Reproductive Status* **	Premenopausal	384 (40.7)	179 (31.8)	64 (20.5)
	Naturally Menopausal	291 (30.9)	238 (42.3)	172 (55.1)
	Surgically Menopausal	79 (8.4)	44 (7.8)	17 (5.4)
	Premenopausal Hysterectomy	189 (20.0)	102 (18.1)	59 (18.9)
Education	Incomplete High School	247 (26.2)	121 (21.5)	86 (27.5)
	Complete High School	161 (17.1)	115 (20.4)	58 (18.5)
	Postsecondary Education	364 (38.6)	221 (39.3)	117 (37.4)
	University Degree	171 (18.1)	106 (18.8)	52 (16.6)

		NORMAL N = 943 (52%)	OSTEOPENIA N = 563 (31%)	OSTEOPOROSIS N = 313 (17%)
Estimated Neighbourhood Income Quintile	Lowest	161 (17.3)	86 (15.6)	54 (17.8)
	Second Lowest	163 (17.5)	111 (20.2)	54 (17.8)
	Middle	178 (19.1)	94 (17.1)	44 (14.5)
	Second Highest	200 (21.5)	111 (20.2)	76 (25.0)
	Highest	229 (24.6)	148 (26.9)	76 (25.0)
Centre* **	Calgary	76 (8.1)	109 (19.4)	27 (8.6)
	Hamilton	104 (11.0)	73 (13.0)	13 (4.2)
	Halifax	124 (13.1)	37 (6.6)	29 (9.3)
	Kingston	157 (16.6)	0 (0.0)	33 (10.5)
	Quebec City	200 (21.2)	0 (0.0)	39 (12.5)
	Saskatoon	60 (6.4)	113 (20.1)	32 (10.2)
	St. John's	109 (11.6)	36 (6.4)	35 (11.2)
	Toronto	63 (6.7)	100 (17.8)	31 (9.9)
	Vancouver	50 (5.3)	95 (16.9)	74 (23.6)
Awareness of Family History*		137 (14.6)	110 (19.6)	62 (19.9)
Previous Diagnosis of Osteoporosis* **		24 (2.5)	25 (4.4)	34 (10.9)
History of Comorbidity		37 (3.9)	37 (6.6)	18 (5.8)
History of Medication Exposure		124 (13.1)	60 (10.7)	39 (12.5)
General Health	Poor/Fair/Good	320 (34.0)	190 (33.7)	124 (39.6)
	Very Good/Excellent	622 (66.0)	373 (66.3)	189 (60.4)
Current Cigarette Smoker		141 (15.0)	98 (17.4)	61 (19.5)
Current Ca Supplement Use* **		339 (35.9)	284 (50.4)	147 (47.0)
Current Vit. D Supplement Use* **		267 (28.3)	221 (39.3)	104 (33.2)
Current Regular Exercise		505 (53.6)	314 (55.8)	185 (59.1)
High Alcohol Intake		38 (4.0)	31 (5.5)	12 (3.8)
High Coffee Intake		153 (16.2)	94 (16.7)	46 (14.7)
Current Osteoporosis Medication Use* **		0 (0)	0 (0)	8 (2.6)
Current OHT Use		348 (36.9)	184 (32.7)	100 (31.9)
		Mean (SD)	***Mean (SD)***	***Mean (SD)***
**Total Calcium (mg/day) ** **		973 (568)	1098 (636)	1036 (633)
Dietary Calcium (mg/day)		798 (487)	782 (455)	742 (471)
Total Caffeine (mg/day)		311 (263)	309 (292)	314 (372)

* $p \leq 0.05$ ** $p \leq 0.01$ ***$p \leq 0.001$.

[a] Feedback diagnosis information was missing for 18 women.

[b] Only relevant to the women aged 50 to 60 years who attended the X-ray and for whom reports were available (N = 1170).

Table 5.5: Feedback Diagnosis and its Association with the Other Explanatory Variables in Men

		NORMAL N = 392 (45%)		OSTEOPENIA N = 300 (35%)		OSTEOPOROSIS N = 173 (20%)	
Total N = 865[a]		*N*	*(%)*	*N*	*(%)*	*N*	*(%)*
[b] **Significant Prevalent Fracture**		19	(9.4)	28	(15.1)	20	(18.3)
Destination* **	To FP only	93	(23.9)	61	(20.3)	31	(18.0)
	To participant only	241	(62.0)	141	(47.0)	74	(43.0)
	To both	55	(14.1)	98	(32.7)	67	(39.0)
Recommendation for Referral or Treatment* **		3	(0.8)	18	(6.0)	51	(29.5)
Age Group*	40 to 49 years	153	(39.0)	109	(36.3)	49	(28.3)
	50 to 60 years	239	(61.0)	191	(63.7)	124	(71.7)
Body Mass Index* **	Lowest Quartile	66	(16.8)	75	(25.0)	76	(44.2)
	Second Lowest Quartile	91	(23.2)	80	(26.7)	43	(25.0)
	Second Highest Quartile	105	(26.8)	77	(25.7)	35	(20.3)
	Highest Quartile	130	(33.2)	68	(22.7)	18	(10.5)
Race/Ethnicity*	"White"	372	(94.9)	273	(91.0)	155	(89.6)
	"Non-white"	20	(5.1)	27	(9.0)	18	(10.4)
Education	Incomplete High School	76	(19.4)	66	(22.0)	37	(21.4)
	Complete High School	67	(17.1)	38	(12.7)	25	(14.5)
	Postsecondary Education	135	(34.4)	98	(32.7)	61	(35.3)
	University Degree	114	(29.1)	98	(32.7)	50	(28.9)
Estimated Neighbourhood Income Quintile	Lowest	61	(16.0)	57	(19.4)	40	(23.1)
	Second Lowest	64	(16.8)	55	(18.7)	36	(20.8)
	Middle	84	(22.0)	54	(18.4)	29	(16.8)
	Second Highest	73	(19.2)	60	(20.4)	33	(19.1)
	Highest	99	(26.0)	68	(23.1)	35	(20.2)
Centre* **	Calgary	26	(6.6)	50	(16.7)	16	(9.2)
	Hamilton	55	(14.0)	38	(12.7)	6	(3.5)
	Halifax	47	(12.0)	27	(9.0)	16	(9.2)
	Kingston	66	(16.8)	0	(0.0)	15	(8.7)
	Quebec City	79	(20.2)	0	(0.0)	22	(12.7)
	Saskatoon	25	(6.4)	63	(21.0)	16	(9.2)
	St. John's	47	(12.0)	32	(10.7)	15	(8.7)
	Toronto	29	(7.4)	51	(17.0)	17	(9.8)
	Vancouver	18	(4.6)	39	(13.0)	50	(28.9)
Awareness of Family History		30	(7.7)	30	(10.0)	17	(9.8)
Previous Diagnosis of Osteoporosis		3	(0.8)	1	(0.3)	3	(1.7)
History of Comorbidity		6	(1.5)	8	(2.7)	7	(4.1)
History of Medication Exposure		32	(8.2)	20	(6.7)	17	(9.8)
General Health **	Poor/Fair/Good	112	(28.6)	99	(33.0)	73	(42.2)
	Very Good/Excellent	280	(71.4)	201	(67.0)	100	(57.8)
Current Cigarette Smoker*		78	(19.9)	57	(19.0)	49	(28.3)
Current Ca. Supplement Use		73	(18.6)	61	(20.3)	46	(26.6)

	NORMAL N = 392 (45%)		OSTEOPENIA N = 300 (35%)		OSTEOPOROSIS N = 173 (20%)	
Current Vit. D Supplement Use	64	(16.3)	65	(21.7)	37	(21.4)
Current Regular Exercise*	213	(54.3)	173	(57.9)	78	(45.1)
High Alcohol Intake**	79	(20.2)	35	(11.7)	23	(13.3)
High Coffee Intake	100	(25.5)	98	(32.7)	42	(24.3)
Current Osteoporosis Medication	1	(0.3)	0	(0.0)	0	(0.0)
	Mean	***(SD)***	***Mean***	***(SD)***	***Mean***	***(SD)***
Total Calcium (mg/day)	909	(586)	896	(625)	810	(602)
Dietary Calcium (mg/day)	848	(535)	819	(545)	732	(523)
Total Caffeine (mg/day)	387	(335)	423	(347)	387	(317)

* $p \leq 0.05$ ** $p \leq 0.01$ ***$p \leq 0.001$.

[a] Feedback diagnosis information was missing for 4 men.
[b] Only relevant to the men aged 50 to 60 years who attended the X-ray (n = 499).

In women, a diagnosis of a low BMD was associated with being in the lowest quartile for body mass index, in the older age group, naturally menopausal, previously diagnosed with osteoporosis or osteopenia, of a family with a history of osteoporosis and "non-white".

Smaller men (the lowest quartile for body mass index), men in the older age group and those who reported that they were current smokers or regarded themselves to be in poorer health in general, were more likely to be diagnosed with osteoporosis. As with the women, the diagnosis was associated with race or ethnicity; the few men who described themselves as "non-white" were more likely to receive a diagnosis of osteoporosis or osteopenia. There were too few men in this sample who had received a previous diagnosis of osteoporosis (n = 7) to adequately explore associations with this variable. Consequently "previous diagnosis" in men was not included in any of the analyses, although it was included throughout for descriptive purposes.

Women who received a low BMD diagnosis were already more likely to be taking calcium and Vitamin D supplements at baseline, consequently the estimated daily total calcium intake was higher for those women who received a diagnosis of osteopenia or osteoporosis. In contrast, there was no difference in supplement use, or in total or dietary calcium intake, between the diagnostic groups at baseline in the men. There were small differences in other baseline behavioural variables in the men, however; those who reported high alcohol use were more likely to receive a normal diagnosis while those who reported no participation in regular exercise were more likely to receive a diagnosis of osteoporosis.

For both men and women, the diagnosis was associated with the destination of the feedback, a recommendation for referral or treatment, and with Centre; participants with an abnormal diagnosis (osteopenia or osteoporosis) were more likely to be in the group where feedback was sent to both the participant and the FP, compared with the "FP only" group or the "participant only" group. Because the feedback destination was dependent on the centre, these differences are expected to be related to a combination of demographic effects such as variation in bone density between centres (i.e., geographical variation) and procedural effects, such as variation in diagnostic criteria between centres, as well as differences between the DXA machines in each centre. Almost all of the participants in Vancouver who received a diagnosis of osteoporosis also received a recommendation for a referral (to an osteoporosis clinic) or for treatment, as did approximately one quarter of the men and one third of the women in Saint John's who received a diagnosis of osteoporosis.

Within the subgroup of women who had an X-ray, the women who received a report of a significant prevalent vertebral fracture were significantly more likely to also receive a diagnosis of osteopenia or osteoporosis. This same association was not significant in the men, although there was a trend towards a higher rate of significant fractures amongst the men who received a low BMD diagnosis ($\chi^2 = 5.61$; df = 2; p = 0.06).

To determine whether diagnosis and the destination of the feedback were associated with each other because of an increased likelihood of reporting abnormal results or a decreased likelihood of reporting normal results to family physicians (which would potentially bias the interpretation of the effects of Destination), the association between diagnosis and the feedback destination was examined within those centres where the protocol was allowed to vary for more than a few cases between "to participant" and "to both" (Toronto, Vancouver, Quebec City and Calgary). No significant association was found between the feedback destination and the diagnosis within any one of these four centres, which suggests that the diagnosis did not influence the destination of the results measurably. As mentioned above, there was, however, documentation of a selective bias in the destination of the test results by diagnosis in the files of a few cases in the Vancouver centre. To ensure that a selective bias in the destination of the feedback did not influence the estimation of any of the statistical models, all of the analyses were repeated after removal of the participants whose feedback was not sent by the prescribed within-centre protocol; these models were compared with those in which all participants were included.

5.5 Destination, Centre and their Relationships with the Other Explanatory Variables

In Appendix E, Table E.1 summarizes the relationships between the feedback destination and all of the remaining explanatory variables for women and Table E.2 summarizes the same relationships for men. Tables E.3 and E.4 show the distributions of the same explanatory variables by CaMOS centre for women and for men, respectively.[35]

Because Destination was partially nested in CaMOS centre (see Table 5.3), uneven distributions of variables across the destination categories also tended to be distributed unevenly across the CaMOS centres, and it was not possible to separate the effects of these two variables. There are factors that are likely to be associated with Centre that were not measured, such as cultural differences between the populations and regional differences among the approaches of the health-care providers. Any effects of Centre on the outcome variables would be expected to be due to these unmeasured differences, as well as to the effects of Destination because of the partial nesting.

Although there were statistically significant associations between Centre and some of the other explanatory variables, most of these differences were small in magnitude. The most notable variations in distribution between the centres were in race and education (for both men and women), and amongst the women, in family history of osteoporosis and menopausal status.

The participants who classified themselves as "non-white" were concentrated in the Vancouver and Toronto centres. These urban centres are more ethnically diverse than the other relatively smaller urban centres. Furthermore, interviews were offered in Mandarin and Cantonese at only these two centres; more than two thirds of the participants in Vancouver and approximately one half of the participants in Toronto who described themselves as "non-white" also identified themselves as belonging to the Chinese ethnic or cultural group. As a result of the uneven distribution of "non-white" participants across the centres, a greater proportion of this subgroup received their feedback by the "to both" method because this was the dominant method of feedback in the Vancouver and Toronto centres.

Educational level was unevenly distributed across the centres. There were fewer women and men who represented the two higher educational levels (trades or professional certificate and diploma or university degree) in the Quebec City and Hamilton centres. Because of this uneven distribution, the feedback was more likely to be sent directly to the "participant only" for

[35] Feedback Diagnosis was not included in these tables because its association with destination and centre was discussed above.

women, and to a lesser extent for men, in the lower education groups; both Quebec City and Hamilton used a "direct-to-participant" feedback protocol.

Nineteen percent of the women in this study had a hysterectomy while they were premenopausal; this proportion was as high as 27% and 28% in the east coast centres of Saint John's and Halifax, respectively. In contrast, the rate of premenopausal hysterectomy was only 11% and 12% in Toronto and Kingston, respectively. Women who had experienced surgically induced menopause[36] represented almost 8% of the sample, but there were somewhat higher rates of women in Kingston (11%) and Hamilton (14%). The rates of surgical menopause in the remaining seven centres ranged from 4.7% to 8.3%. Because Halifax and Saint John's were the two centres where most of the participants had their results reported "to family physician" only, and both Kingston and Hamilton adopted the "to participant only" protocol, the uneven distribution of menopausal status between these centres resulted in an uneven distribution between Destination and menopausal status.

The Saskatoon centre had a relatively large proportion of participants with an awareness of a family history of osteoporosis. While only 14% of the participants overall were aware of at least one relative who had been diagnosed with osteoporosis, 24% of those in the Saskatoon centre (28% of the women and 15% of the men) reported a family history. Again, this had a small effect on the distribution of family history across the centres.

The frequency of a history of exposure to corticosteroids or anticonvulsants was particularly high in the Halifax centre, where 21% of the women and 19% of the men reported a history of exposure (compared to 9% of the women and 8% of the men combined).

There were differences between the centres in participants' dietary and total calcium intakes, calcium and Vitamin D supplement use, caffeine intake and exercise participation, as well as current ovarian hormone therapy use in women. The frequency of calcium supplement use in women ranged from 18% in Saint John's to 60% in Saskatoon, for example, while the frequency of current ovarian hormone therapy use ranged from 27% in Vancouver to 44% in Quebec City. Other associations between Destination or Centre, and the remaining variables were not substantial.

[36] Removal of both ovaries prior to menopause.

5.6 Prevalent Fractures from the Spinal X-rays

In the study sample, 1831 men and women were eligible for a spinal X-ray (i.e., they were aged between 50 and 60 years inclusively at baseline). Most of these participants (1669; 91%) had the X-ray; the remaining 9% declined the test, usually because they preferred not to be exposed to ionizing radiation.

Copies of the reports that were sent to participants or to the family physicians regarding the X-ray results were available for all except 2 of these 1669 cases; copies of X-ray reports for 2 women were missing. One hundred and fifty nine of the 1667 participants for whom documentation was available received an indication in their feedback that there was evidence of a significant vertebral fracture on their X-ray (8% of the women and 13% of the men).

A report of a significant fracture was associated with both Destination and Centre in the men and the women (see Tables E.1 to E.4 in Appendix E). As with the interpretation of the DXA tests, different criteria were used at each centre to diagnose prevalent spinal fractures, which would account for at least some of this variation. The number of reported significant fractures amongst women ranged from 1.3% (in Kingston) to 22.3% (in Calgary). Women who were told that they had a significant prevalent fracture were also more likely to receive a diagnosis of osteopenia or osteoporosis as a result of their BMD test, although this association was not significant in men (see Table 5.4 and 5.5).

A report of a significant spinal fracture, based on the X-ray report, may have influenced the participants' knowledge of their BMD results; participants who were told that their BMD results were low may have paid more attention to these results if they were also told that they had a significant spinal fracture, or they may have been more likely to visit their FP for interpretation and discussion of their results. The influence of a report of a fracture on correct self-reports of the feedback diagnosis, information seeking, and osteoporosis related health behaviour change were examined in the subgroup of participants who had X-rays.

5.7 Associations among the Remaining Explanatory Variables

There were associations between age group and education level in both women and men and between age group and menopausal status in women (as would be expected). In both men and women, lower education level was associated with lower neighbourhood income quintile and with poorer self reported health status. In turn, poorer self-reported health status was associated with other health markers, particularly a previous diagnosis of osteoporosis in women

and a history of exposure to corticosteroids or anticonvulsants in both women and men. Participants who described themselves as "non-white" were more likely to be in the lowest quartile for body mass index (BMI) than those who described themselves as "white". A lower BMI was also associated with the younger age group, premenopausal status and no history of "high risk" medication exposure in women. Both men and women who reported a lower level of general health (fair, poor or good) were more likely to be in the highest quartile for BMI compared with those who reported a very good or excellent level of health.

Patterns also were evident in the behavioural measures at baseline. Men and women in the higher income quintiles more frequently reported participation in a regular program of exercise and women in the higher income quintiles were more likely to report high alcohol consumption. Older men and women were more likely to use calcium and Vitamin D supplements; younger women were more likely to report a high coffee intake. Women in the highest quartile of the BMI distribution had the lowest use of calcium and Vitamin D supplements and the least participation in regular exercise. Women in the older age group (and women who were menopausal) were more likely to be taking ovarian hormone therapy as were those with a previous diagnosis of osteoporosis. Women with a previous diagnosis of osteoporosis more frequently used calcium and vitamin D supplements, although they consumed comparable amounts of *dietary* calcium to women without a history of osteoporosis. The participants who identified themselves as "non-white" and the men who reported a history of exposure to relevant medications (corticosteroids or anticonvulsants) were less likely to be "heavy coffee drinkers". "Non-white" women were also less likely to be taking ovarian hormone therapy than those who were "white", and "non-white" men had a lower average total calcium intake than had "white" men. Compared with non-smokers, female smokers were less likely to take calcium supplements and both male and female smokers were less likely to participate in regular programs of exercise, more frequently reported high coffee and alcohol consumption and reported poorer general health. Smoking was most frequent in men with the lowest neighbourhood income quintile. All eight women who were taking a medication for the treatment or prevention of osteoporosis at baseline reported a previous diagnosis of osteoporosis, were in the older age group and reported taking calcium supplements.

As is evident from the results of the univariate analyses presented in this chapter, the interrelationships among the many potential explanatory variables that have been measured and considered in this study are numerous and complex. Thus it was considered essential that all of these variables be taken into account as potential explanatory variables in the multivariable

analyses that are described in the following two chapters. These demographic and risk factor variables were considered not only for their important potential confounding influences on the relationships between the key explanatory variables of interest (diagnosis from the DXA test and destination of the feedback of the test results) and correct awareness of test results, information seeking and health behaviour, but also to explore any modifying role that they may play in these relationships.

Although there were many significant statistical associations, none of the correlations among the explanatory variables was large except for that between Centre and Destination. This suggested that including these variables in the same models to determine their effects, if any, on the outcomes of interest was feasible.

Diagnosis (either the "feedback" diagnosis or the diagnosis as recalled by the participant at Year 3), Destination or Centre, as well as a recommendation for referral or treatment and age group were included in all multivariable models, regardless of their univariate associations with the outcome (as described in Chapter 4). Centre was not considered in the models with the destination variable however because the two variables explained almost all of the same variance, as described above. The models that included Destination as an explanatory variable were compared with equivalent models in which Destination was replaced with Centre.

CHAPTER 6: Results II. Correct Awareness of Bone Density Test Results

6.1 "Correct" Awareness of Feedback Diagnosis: Outcome Variable

This chapter describes the participants' correct awareness at Year 3 of the BMD test results provided by the CaMOS centres at baseline. Participants were considered to have a correct "awareness" of their results rather than a correct "recall" because it was not possible to determine whether diagnostic information reached all of the participants; participants could not be expected to recall information that they may never have received.

The responses to question 1.5 of the CaMOS Year 3 questionnaire (See Appendix B) are summarized by feedback diagnosis and for women and men separately in Table 6.1. The exactly correct ("Correct") responses are those that appear in the darker shaded sections of the table (i.e., the response exactly matched the diagnosis that was provided in the feedback). The lighter shaded areas, together with the darker shaded areas, represent those responses that are classified as "closely correct" (i.e., they were exactly correct or had an "abnormal" diagnosis of osteopenia or osteoporosis and described their results as either one of these diagnoses).

About one half (54%) of the women were able to report the exact diagnosis provided in their feedback; 24% responded that they did not know their diagnosis and 23% provided an incorrect diagnosis. Less than one half of the men (42%) were able to provide the exact diagnosis, while 34% responded that they did not know and 24% provided an incorrect response. The men were more likely than the women to be incorrect ($\chi^2 = 31.02$; df = 1; $p < 0.001$), and compared with the women, the men were more likely to respond with "I don't know" than to provide a diagnosis ($\chi^2 = 30.89$; df = 1, $p < 0.001$).

Both women and men were more likely to be correct if their feedback diagnosis was normal. As shown in Table 6.1, approximately one third of the women with a feedback diagnosis of osteoporosis were able to recall this correctly. Amongst the women who received a diagnosis of osteoporosis however, two thirds knew that their results were low, even though one half of them stated that the results indicated osteopenia or a low result without osteoporosis. Fifty nine percent of the men who were told that they had osteoporosis were at least "closely correct" (reported their results as abnormal), but only one quarter of the men with osteoporosis were exactly correct about their diagnosis.

Table 6.1: Participants' Self Reports of their Diagnosis by Feedback Diagnosis

WOMEN	**BMD Feedback Diagnosis**			
What were the results of your bone density test, 3 years ago?	Normal N (%)	Osteopenia N (%)	Osteoporosis N (%)	**Total**
"Don't know or unsure"	224 (23.8)	137 (24.4)	68 (21.7)	**429 (24%)**
"High or Normal"	659 (69.9)	189 (33.6)	34 (10.9)	**882 (49%)**
"Low without osteoporosis"[a]	46 (4.9)	213 (37.9)	104 (33.2)	**363 (20%)**
"Low or osteoporosis"	14 (1.5)	23 (4.1)	107 (34.2)	**144 (8%)**
Total Women	**943 (52%)**	**562 (31%)**	**313 (17%)**	**1818**[b]
MEN	**BMD Feedback Diagnosis**			
What were the results of your bone density test, 3 years ago?	Normal N (%)	Osteopenia N (%)	Osteoporosis N (%)	**Total**
"Don't know or unsure"	139 (35.8)	108 (36.1)	45 (26)	**292 (34%)**
"High or Normal"	232 (59.8)	94 (31.4)	26 (15)	**352 (41%)**
"Low without osteoporosis"[a]	14 (3.6)	89 (29.8)	59 (34.1)	**162 (19%)**
"Low or osteoporosis"	3 (0.8)	8 (2.7)	43 (24.9)	**54 (6%)**
Total Men	**388 (45%)**	**299 (35%)**	**173 (20%)**	**860**[c]

[a] Includes responses of "borderline" or "osteopenia."
[b] Missing responses to this question for 1 woman and the feedback diagnosis for 18 women.
[c] Missing responses to this question for 5 men and the feedback diagnosis for 4 men.

Amongst the women who were told that they had osteopenia, 42% knew that their results were low (either osteopenia or osteoporosis) and 38% were exactly correct about this diagnosis. Nearly 30% of the men with a feedback diagnosis of osteopenia were exactly correct about their diagnosis and a further 3% were aware that their result was abnormal, but described it as osteoporosis.

6.2 Factors Associated with Correct Awareness: Univariate Analyses

The frequencies of providing an exactly correct diagnosis are presented within the levels of each of the potential explanatory variables, stratified by gender, in Table 6.2

Table 6.2: Distribution of Correct Awareness of Baseline BMD Results within each Explanatory Variable Stratified by Gender.

	Women; N = 1818 Number Correct			Men; N = 860 Number Correct		
	N	(%)[a]	p[b]	N	(%)[a]	p[b]
Feedback Diagnosis						
Normal	659	(69.9%)	**<0.001**	232	(59.8%)	**<0.001**
Osteopenia	213	(37.9%)		89	(29.8%)	
Osteoporosis	107	(34.2%)		43	(24.9%)	
Significant Prevalent Fracture[c] Yes	44	(47.8%)	0.6	34	(50.7%)	0.1
No	550	(51.4%)		33	(49.3%)	
Destination						
To FP only	179	(49.2%)	**<0.001**	63	(34.6%)	**<0.001**
To participant only	549	(58.7%)		223	(49.1%)	
To both	250	(48.6%)		77	(35.0%)	
Recommendation for Referral or Treatment Yes	57	(42.2%)	**0.006**	24	(33.3%)	**0.1**
No	922	(54.8%)		340	(43.1%)	
Age Group 40 to 49 years	320	(57.9%)	**0.03**	134	(43.2%)	0.7
50 to 60 years	659	(52.1%)		230	(41.8%)	
Body Mass Index						
Lowest Quartile	223	(49.1%)	**0.02**	91	(42.3%)	0.9
Second Lowest Quartile	236	(52.0%)		93	(43.5%)	
Second Highest Quartile	267	(58.7%)		87	(40.5%)	
Highest Quartile	251	(55.5%)		92	(42.8%)	
Race/Ethnicity						
"White"	929	(54.3%)	0.1	339	(42.6%)	0.6
"Non-white"	50	(46.7%)		25	(38.5%)	
Reproductive Status						
Premenopausal	384	(61.3%)	**<0.001**			
Naturally Menopausal	340	(48.5%)				
Surgically Menopausal	74	(52.9%)				
Premen. Hysterectomy	180	(51.4%)				
Education						
Incomplete High School	240	(52.9%)	0.3	59	(33.1%)	**0.01**
Complete High School	175	(52.4%)		63	(49.2%)	
Postsecondary Education	371	(52.8%)		120	(41.1%)	
University Degree	193	(58.8%)		122	(46.6%)	

		Women; N = 1818 Number Correct			Men; N = 860 Number Correct		
		N	(%)[a]	p[b]	N	(%)[a]	p[b]
Neighbourhood Income Quintile	Lowest	164	(54.5%)	0.6	66	(42.3%)	**0.04**
	Second lowest	168	(51.2%)		60	(38.7%)	
	Middle	174	(55.1%)		71	(42.5%)	
	Second highest	220	(56.8%)		55	(33.5%)	
	Highest	238	(52.7%)		99	(49.3%)	
Centre	Vancouver	105	(47.9%)	**<0.001**	44	(41.1%)	**<0.001**
	Calgary	92	(43.4%)		23	(25.0%)	
	Saskatoon	111	(54.1%)		44	(42.3%)	
	Hamilton	133	(70.0%)		56	(56.6%)	
	Toronto	109	(56.5%)		38	(39.2%)	
	Kingston	109	(57.4%)		45	(57.0%)	
	Quebec City	141	(59.0%)		50	(49.5%)	
	Halifax	86	(45.3%)		24	(26.7%)	
	Saint John's	93	(51.7%)		40	(44.0%)	
Awareness of Family History	Yes	183	(59.2%)	**0.04**	35	(46.1%)	0.6
	No or DK	792	(52.7%)		327	(41.9%)	
Self-reported Previous Diagnosis	Yes	34	(41.0%)	**0.02**	2	(28.6%)	---
	No or DK	945	(54.5%)		362	(42.4%)	
History of Comorbidity	Yes	37	(40.2%)	**0.01**	8	(38.1%)	0.9
	No	941	(54.6%)		355	(42.4%)	
History of Medication Exposure	Yes	112	(50.2%)	0.3	19	(27.5%)	**0.01**
	No	867	(54.4%)		344	(43.5%)	
General Health	Poor/Fair/Good	305	(48.1%)	**<0.001**	116	(41.0%)	0.6
	Very Good/Excellent	673	(56.9%)		248	(43.0%)	
Current Cigarette Smoker	Yes	137	(45.7%)	**0.002**	69	(38.1%)	0.2
	No	842	(55.5%)		295	(43.4%)	

[a] Represents percentage correct within each level of the explanatory variable.
[b] Significance level of the association between "Correct" *vs.* "Incorrect" and the levels of each explanatory variable by Chi Square analysis.
[c] Relevant only to the women (n = 1161) and men (n = 494) aged 50 to 60 years, who attended the X-ray and for whom data were available.

The most substantial association with having a correct response was seen with the respondents' feedback diagnosis. Participants with a normal diagnosis were almost twice as likely to give the exact diagnosis that was provided in their feedback when compared with those who had received a diagnosis of osteoporosis or osteopenia. In addition, women and men were more likely to be correct about their test results, in the unadjusted analysis, when their feedback

was sent directly to them, rather than to the FP alone or to both the FP and the participant. The inclusion of a recommendation for treatment or a referral to the osteoporosis clinic in the feedback of a small group of participants was not associated with a higher rate of correct awareness of the test results; in fact, the women in this subgroup were less likely to provide the correct diagnosis (because a recommendation for treatment or referral was associated with a low DXA test result).

Correct responses were more frequent in women who were premenopausal and younger. Although women with a family history of osteoporosis or osteopenia were somewhat more likely to be correct about their results, those with a previous diagnosis of osteopenia or osteoporosis were less likely to provide the correct diagnosis according to their feedback (which may indicate that their diagnosis in the past did not always match that sent out in the CaMOS feedback). The women who reported poor, fair or good general health, were current smokers, were in the lowest quartile for body mass index, or had a history of rheumatoid arthritis or an eating disorder were less likely to be correct about their test results.

Men with a history of exposure to significant medications were less likely to be correct. Men residing in the highest neighbourhood income quintile were more likely to be correct compared with those in the lower quintiles and those in the lowest education level (incomplete high school) had a lower rate of correct responses compared with those with higher education. The associations between correct awareness and sociodemographic markers were not significant for women.

Finally, there were significant differences between the centres; women's rates of correct awareness ranged from 43% in Calgary to 70% in Hamilton, while those for men ranged from 25% in Calgary to 57% in both Hamilton and Kingston. The centres with the highest rate of incorrect awareness were the same for men and for women (Calgary and Halifax).

6.3 Potential Explanatory Factors Associated with Correct Awareness: Multivariable Modelling

All of the potential explanatory variables that were associated, in the univariate analysis, with correct awareness of test results with a p value ≤ 0.2 (see Table 6.2) were considered in the multivariable logistic models for their association with correct awareness of test results. A manual backward elimination (stepwise) procedure was used to derive the most parsimonious model; all variables that were not significant at a level of $p < 0.05$ were removed. Diagnosis and Destination (as the primary variables of interest), any recommendation included in the feedback

(because of its potential confounding influence on the Destination variable) and age group (considered as an important variable in all analyses) were, however, included as explanatory variables irrespective of the strength of their association. Other explanatory variables were kept in the model only if they made a significant improvement to the fit of the model. All models were derived separately for women and men.

Table 6.3: Multiple Logistic Regression Analysis of the Effects of Destination, Diagnosis and Other Explanatory Variables on Correct Awareness for Women and Men

	WOMEN (N = 1805)[a]		MEN (N = 855)[b]	
	OR (95% C.I.)	**p**	**OR (95% C.I)**	**p**
Feedback Diagnosis				
Normal	*Referent*	-----	*Referent*	-----
Osteopenia	0.24 (0.19 - 0.30)	**<0.001**	0.28 (0.20-0.39)	**<0.001**
Osteoporosis	0.20 (0.15 - 0.27)	**<0.001**	0.20 (0.13-0.31)	**<0.001**
Destination To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.71 (1.31 - 2.23)	**<0.001**	2.00 (1.36-2.92)	**<0.001**
To both	1.52 (1.12 - 2.07)	**0.007**	1.40 (0.88-2.23)	0.2
Recommendation Yes	1.37 (0.91 – 2.07)	0.1	1.46 (0.79 – 2.68)	0.2
No	*Referent*		*Referent*	
Age Group 40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	0.99 (0.79-1.23)	0.9	1.12 (0.83 – 1.53)	0.5
Education				
Incomplete High School			0.51 (0.33-0.78)	**0.002**
Complete High School			0.95 (0.60-1.49)	0.8
Postsecondary Education			0.72 (0.50-1.04)	0.08
University Degree			*Referent*	----
FH of Osteoporosis Yes	1.52 (1.16 - 1.99)	**0.002**		
No or DK	*Referent*	-----		
History of Medication Exposure Yes			0.50 (0.28-0.91)	**0.02**
No			*Referent*	-----
General Health				
Poor/Fair/Good	*Referent*	-----		
Very Good/Excellent	1.44 (1.17-1.78)	**0.001**		
Current Smoker Yes	0.73 (0.55-0.95)	**0.02**		
No	*Referent*	-----		
Nagelkerke's R^2	0.17		0.18	

[a] Missing data on included variables for 32 women.
[b] Missing data on included variables for 14 men.

The most parsimonious model for women included the following variables: Destination, diagnosis, smoking status, self-rated health status and family history of osteoporosis or osteopenia. Neither age group nor a recommendation in the feedback made a significant contribution to the model and their removal or inclusion did not change the coefficients of the other variables. This multivariable model is presented in the left side of Table 6.3, with the odds ratios for the each level of the explanatory variables compared with the noted referent, with 95% confidence intervals.

Women with a normal diagnosis were about 4 times more likely to be correct about their diagnosis as were women who had received an abnormal diagnosis (of either osteopenia or osteoporosis), even when other significant explanatory variables were accounted for. Compared to women whose results were sent only to the FP, those whose results were sent directly to them (whether or not they were also sent to the FP), were more likely to be correct about their results. Current smokers and those who reported poorer health were less likely to report their diagnosis correctly. Women with a self-reported family history of osteoporosis, on the other hand, were 1.5 times more likely to be correct.

The most parsimonious model for men is shown on the right side of Table 6.3. The associations of both the destination of the feedback and the diagnosis with correct awareness of test results in men were similar to those seen in women; men were much less likely to be aware of their test results if the results were low compared with normal. Although the association between feedback "to both participant and FP" was only marginally different from "to the FP only" destination (and not significant), men were significantly more likely to know their test results if the feedback went to the "participant only" compared with those whose feedback went "to the FP only". Similar to the women's model, the association between age group and correct awareness and between a recommendation in the feedback and correct awareness were not significant in the adjusted model. Other predictors that were important in the women's model were not found to be associated with correct awareness in men (current smoking, family history or self rated health). Significant predictors of men's poor awareness of their diagnosis were lower education and a history of exposure to relevant medications.[37] When the destination variable was replaced by the centre variable in the above multivariable models, the effects of diagnosis, family history, smoking status and self-rated health on correct awareness of their test

[37] The association between medication exposure and correct awareness was not changed by the exclusion from the analysis of the 7 men who reported a previous diagnosis of osteoporosis. (Three of these 7 men had a history of medication exposure, whereas only 8% of the men with no reported previous diagnosis had a history of medication exposure).

results, by the women, remained essentially the same. Likewise, the results remained essentially the same when Destination was replaced by Centre in the multivariable analysis of men's correct awareness. All variables that were significantly associated with correct awareness in the models presented above remained significantly associated when the models were adjusted for Centre instead of Destination of the feedback.

6.4 Subgroup Analyses of Correct Awareness

6.4.1 Potential Effect Modification of the Explanatory Factors Associated with Correct Awareness of BMD Results by Feedback Diagnosis

Subgroup analysis of only those women who received a normal diagnosis (n = 943)[38] resulted in similar regression coefficients to those in the model which included all of the women. The coefficients for Destination were smaller in this "normal" subgroup, but Destination remained significantly associated with a correct awareness of test results. In addition, the regression coefficient for a family history of osteoporosis was in the same direction and similar to that in the main model but the confidence interval was wide and the association was not significant. Otherwise, the model for correct awareness in women with normal test results was essentially the same as that for the original analysis of all women.

The results of multivariable analyses in the subgroups of the women who received a diagnosis of osteopenia and of osteoporosis are shown in Table 6.4. The explanatory variables from the model of all women have been included in these subgroup models for comparison. In the subgroup of women who received a diagnosis of osteopenia (see the left side of Table 6.4), the regression coefficients for the destination variables were increased somewhat compared with those in the main analysis. Amongst women with a diagnosis of osteopenia, those who received their diagnosis directly were much more likely to be correct about their diagnosis compared with those whose feedback went to the FP only. This was the case, whether the feedback went "to the participant only" or "to both the participant and the FP". A recommendation for a referral or treatment was associated with a greater likelihood of correct awareness of osteopenia test results; this variable was not associated with correct awareness in the full sample, as shown in Table 6.3. As in the main analysis, women with a diagnosis of osteopenia were more likely to be correct about their diagnosis if they had a family history of osteopenia or osteoporosis, or if they reported very good or excellent general health status; the coefficients for these two variables were comparable to those in the main analysis. Smoking status, on the other hand, was not

[38] Six women with a normal diagnosis had incomplete data on the included variables.

associated with correct awareness of test results, and its removal or inclusion in the model for this subgroup did not change the associations between the other variables and correct awareness. No other explanatory variables under consideration[39] had a significant association with a correct awareness of osteopenia except for Centre ($\chi^2 = 36.03$; df = 6; $p < 0.001$); correct awareness ranged from a frequency of 16% in the Halifax and Saint John's centres to 51% and 56% in Vancouver and Hamilton respectively (note that this is only relevant to the seven centres that used the "osteopenia" diagnosis and does not take into account other significant confounders).

In contrast to the above models, none of the variables in the main model was significantly associated with correct awareness in the subgroup of women who received a diagnosis of osteoporosis (see right side of Table 6.4). Women whose feedback was sent to the participant only or to both the participant and to the FP were no more likely to be correct about their diagnosis of osteoporosis than were women whose feedback was sent to the FP only. Women who were not current smokers and who reported very good or excellent general health status were also no more likely to be correct. The regression coefficient for a family history of osteoporosis was in the same direction as that in the main model but the association was not significant in the osteoporosis subgroup. Further, no other explanatory variables under consideration[39] had a significant association with a correct awareness of osteoporosis except for Centre ($\chi^2 = 20.59$; df = 8; $p = 0.008$); correct awareness ranged from a frequency of 18% and 21% in Kingston and Quebec City, respectively to 54% and 56% in Hamilton and Saskatoon, respectively.

In the model for the 384 men who received a normal diagnosis in their feedback (and for whom complete data were available), the regression coefficients were very similar to those in the model that included all of the men. Men whose feedback was sent directly to them and only to them were more likely to be correctly aware of a normal diagnosis than were men whose feedback went to the FP only; there was no difference in correct awareness between the men whose feedback went to both the participant and the FP and those whose feedback went to the FP only. As seen in the main model, men in the lowest level of education compared with those in the highest level and men with a history of exposure to relevant medications were significantly less likely to be correct about a normal diagnosis. Age group was not associated

[39] Other variables that were considered were BMI, race, menopausal status, level of education, estimated neighbourhood income quintile, previous diagnosis of osteopenia or osteoporosis, history of comorbidity of rheumatoid arthritis or eating disorder and history of exposure to significant medications. A report of a significant fracture was considered in the subgroup analysis of the older age group (see below).

with correct awareness of a normal diagnosis. The model for correct awareness in men with normal test results was therefore essentially the same as that for the original analysis that included all of the men.

Table 6.4: Results of Subgroup Analysis of the Effects of Destination and the Other Explanatory Variables on Correct Awareness in Women with Diagnoses of Low BMD

WOMEN	OSTEOPENIA DIAGNOSIS (N = 559)[a] OR (95% C.I.)	p	OSTEOPOROSIS DIAGNOSIS (N = 309)[b] OR (95% C.I)	p
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	3.55 (1.82 – 6.90)	**<0.001**	0.94 (0.49 – 1.79)	0.8
To both	2.63 (1.34 – 5.17)	**0.005**	0.96 (0.47 – 1.95)	0.9
Recommendation				
Yes	2.21 (1.34 – 5.17)	**0.02**	1.04 (0.56 – 1.93)	0.9
No	*Referent*	-----	*Referent*	-----
Age Group				
40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	0.70 (0.47 – 1.03)	0.07	1.35 (0.71 – 2.57)	0.4
FH of Osteoporosis				
Yes	1.83 (1.18 – 2.82)	**0.007**	1.27 (0.71 – 2.27)	0.4
No or DK	*Referent*	-----	*Referent*	-----
General Health				
Poor/Fair/Good	*Referent*	-----	*Referent*	-----
Very Good/Excellent	1.82 (1.23 – 2.69)	**0.003**	0.76 (0.46 – 1.24)	0.3
Current Smoker Yes	0.99 (0.62 – 1.60)	1.0	1.02 (0.56 – 1.87)	0.9
Current Smoker No	*Referent*	-----	*Referent*	-----
Nagelkerke's R^2	0.10		0.01	

[a] There were 4 women who received a diagnosis of osteopenia with incomplete data on included variables.
[b] There were 4 women who received a diagnosis of osteoporosis with incomplete data on included variables.

The results of multivariable analyses in the subgroups of the men who received a diagnosis of osteopenia and of osteoporosis are shown in Table 6.5. The explanatory variables included in the model for all the men were included in these subgroup models for comparison. In the men who received a diagnosis of osteopenia, the regression coefficients for the destination of the feedback and for the lowest education level compared with the highest education level, were comparable to those in the main analysis (see left side of Table 6.5). As seen in the subgroup of women with osteopenia, a recommendation for a referral or treatment was associated with a greater likelihood of correct awareness of osteopenia test results, although the confidence interval was wide because there were only 18 men with a diagnosis of osteopenia

who received a recommendation for referral or treatment. This variable was not associated with correct awareness in the full sample of men as shown in Table 6.3. A history of exposure to significant medications was not associated with correct awareness in this subgroup, although it was associated with correct awareness in the entire group of men. As seen in the main model, age group was not associated with correct awareness of an osteopenia diagnosis. Removal of age group or history of significant medication exposure did not change the relationships between the remaining variables in the model, and no other explanatory variables[40] under consideration were significantly associated with correct awareness of a diagnosis of osteopenia except for Centre. There was significant variation in correct awareness of a diagnosis of osteopenia between the seven centres that reported this diagnosis to their participants ($\chi^2 = 20.79$; df = 6; p = 0.002), ranging from 15% in Halifax to 54% in Vancouver.

When the subgroup of men who received a diagnosis of osteoporosis was analysed separately (see right side of Table 6.5), the destination of the test results, a recommendation for referral or treatment and the men's level of education were not associated with a correct awareness of an osteoporosis diagnosis. The only variable that was found to be significantly associated with correct awareness in this subgroup of men was age group; even though age was not associated with correct awareness in the entire sample. Older men were approximately 2.5 times more likely to be correct about their diagnosis of osteoporosis as were men in the younger age group. There was a trend that suggested that men with a history of exposure to significant medications were less likely to be correct about their diagnosis of osteoporosis, but the confidence interval was very wide due to small numbers (only 17 men in this subgroup had a history of exposure to significant medications), and included the value 1.0. Removal of the variables that were not associated with correct awareness of a diagnosis of osteoporosis did not change the relationships between the remaining variables, and no other explanatory variables[40] under consideration were significantly associated with correct awareness of a diagnosis of osteoporosis except for Centre. There was significant variation in correct awareness of a diagnosis of osteoporosis among the centres ($\chi^2 = 25.44$; df = 8; p = 0.001), with a wide range; from 5% (Quebec City) and 6% (Halifax and Calgary) correct to 50% (Hamilton) and 53% (Saint John's) correct.

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[40] Other variables that were considered included: BMI quartile, race, family history, self-reported general health, smoking status, history of comorbidity of rheumatoid arthritis or eating disorder and estimated neighbourhood income quintile. A report of a significant fracture was included in the subgroup analysis of the older age group (see below).

Table 6.5: Results of Subgroup Analysis of the Effects of Destination and the Other Explanatory Variables on Correct Awareness in Men with Diagnoses of Low BMD

MEN	OSTEOPENIA DIAGNOSIS (N = 299)[a] OR (95% C.I.)	p	OSTEOPOROSIS DIAGNOSIS (N = 172)[b] OR (95% C.I.)	p
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	2.28 (1.07 – 4.87)	**0.03**	0.90 (0.33 – 2.43)	0.8
To both	1.91 (0.85 – 4.31)	0.1	0.75 (0.24 – 2.30)	0.6
Recommendation Yes	4.05 (1.43 –11.50)	**0.009**	0.80 (0.32 – 2.01)	0.6
No	*Referent*	-----	*Referent*	-----
Age Group				
40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	0.71 (0.42 – 1.21)	0.2	2.65 (1.06 – 6.59)	**0.04**
Education				
Incomplete High School	0.46 (0.21 – 0.98)	**0.04**	0.52 (0.18 – 1.49)	0.2
Complete High School	1.27 (0.56 – 2.85)	0.6	0.59 (0.19 – 1.82)	0.4
Postsecondary Education	0.73 (0.39 – 1.36)	0.3	0.68 (0.29 – 1.62)	0.4
University Degree	*Referent*	-----	*Referent*	----
History of Medication Exposure Yes	1.33 (0.47 – 3.81)	0.2	0.16 (0.02 – 1.26)	0.08
No	*Referent*	-----	*Referent*	-----
Nagelkerke's R^2	0.10		0.10	

[a] There was one man who received a diagnosis of osteopenia with incomplete data on included variables.
[b] There was one man who received a diagnosis of osteoporosis with incomplete data on included variables.

The results of these subgroup analyses therefore revealed that the destination of the feedback was not associated with a correct awareness of a diagnosis of ***osteoporosis*** in women or men, nor were any of the other variables from the main analysis. Men who were older (aged 50 to 60 years) were more likely to be correct about their diagnosis of osteoporosis compared with younger men (aged 40 to 49 years).

The destination of the feedback, however, was strongly associated with a diagnosis of ***osteopenia***; women and men whose results were sent to them directly (*only* to the participant in the case of men) were more likely than those whose results went "to the FP only" to know that their diagnosis was osteopenia. Men and women with a normal diagnosis were also more likely to be correct if they had received their results directly.

In women, self reported general health was associated with a correct awareness of a normal diagnosis or a diagnosis of osteopenia, a family history was associated with a correct awareness of osteopenia and current smoking status was associated with a correct awareness of a

normal diagnosis only. In men, the level of education was associated with a correct awareness of a normal diagnosis or of a diagnosis of osteopenia while a history of exposure to significant medications was associated with correct awareness of normal results only.

Finally, a recommendation for either referral or for treatment in the feedback was associated with correct awareness of a diagnosis of osteopenia, specifically, in both women and men.

6.4.2 Subgroup Analyses: Age Group and Report of a Prevalent Spinal Fracture within the Older Age Group

Multivariable logistic regression models were estimated for the subgroups of women and men aged 40 to 49 years and aged 50 to 60 years, separately. All variables[41] that were associated with correct awareness in the main models for all participants (see Table 6.3) were included and, in addition, the report of a significant fracture was considered as a potential explanatory variable in the older aged participants who attended the X-ray.

All covariates from the main model were significantly associated with correct awareness of test results amongst women in the younger age group of women (n = 625). Younger women with a diagnosis of osteopenia (OR: 0.27; 95% CI: 0.18 – 0.42) or osteoporosis (OR: 0.10; 95% CI: 0.04 – 0.21) were less likely to be correct about their diagnoses, although lower numbers of abnormal diagnosis within this age group resulted in large confidence intervals. Likewise, destination of the feedback "to participant only" (OR: 1.87; 95% CI: 1.14 – 3.01) and "to both" (OR: 2.06; 95% CI: 1.14 – 3.70), higher self-reported general health (OR: 2.02; 95% CI: 1.36 – 3.00), and a family history of osteopenia or osteoporosis (OR: 2.34; 95% CI: 1.38 – 3.05) were associated with a higher likelihood of correct awareness in the younger age group. While the regression coefficient for current smoking was of a similar magnitude and in the same direction as that in the main model, the confidence interval included 1.0 (OR: 0.66; 95% CI: 0.40 – 1.10). Inclusion of a recommended referral or treatment in the feedback was associated with correct awareness in the younger age group of women (OR: 3.39; 95% CI: 1.22 – 9.48), although this was not the case in the main analysis.

Results of the multivariable logistic regression analyses of the older subgroup of women who attended the X-ray are shown on the left side of Table 6.6. The prediction of correct awareness of BMD test results in this subgroup of women was comparable to that of the entire group of women: Feedback destination to the participant only and having a normal diagnosis

[41] Except for age group because it was not relevant to these subgroups analyses.

were the most important predictors of correct awareness, together with a better self reported health status. Although there was a trend towards correct awareness by the women who were non-smokers and who had a family history of osteoporosis, these influences were less important in this subgroup of women than those seen in the entire sample. A report of a significant fracture was not associated with correct awareness and its removal did not change the contribution of any other variables. Further, there was no significant interaction between fracture and diagnosis; a report of a significant fracture did not make a substantial difference to the likelihood of a correct response within any diagnostic category.

As seen for the entire group of men, the men in the 40- to 49-year age group (n = 308),[42] were less likely to be correct about their test results if their diagnosis was osteopenia (OR: 0.38; 95% CI: 0.22 – 0.65) or osteoporosis (OR: 0.12; 95% CI: 0.04 – 0.30) compared to normal. Men in this age group were also more likely to be correct if their feedback was delivered to both themselves and their FP (OR: 2.67; 95% CI: 1.14 – 6.21) or to themselves only (OR: 3.76; 95% CI: 1.91 – 8.38), rather than to the FP only. As in the main analysis, a recommended referral or treatment was not associated with correct awareness in the younger age group of men (OR: 1.21; 95% CI: 0.37 – 3.96). A history of significant medication use (OR: 0.71; 95% CI: 0.21 – 2.33) and the lowest level of education compared with the highest level (OR: 0.57; 95% CI: 0.26 – 1.26) were not associated with correct awareness of test results, although the regression coefficients for these variables were in the same direction as seen in the main model; small numbers of men in this age group within certain strata resulted in wide confidence intervals for all coefficients. In this younger subgroup of men, the diagnosis (normal) and the destination of the test results (directly to the participant) were the greatest predictors of correct awareness of test results.

Results of the multivariable logistic regression analyses of the older subgroup of men who attended the X-ray are shown on the right side of Table 6.6. Unlike the women, a report of a significant fracture was associated with men's correct awareness of their BMD test results, both in the univariate and multivariable models; men who received a report of a significant fracture were twice as likely to be correct about their test results. The destination of the feedback, however, made no difference to the correct awareness of the older group of men. Diagnosis remained significant; men in this subgroup were much less likely to correctly report their results if they were low. Men aged 50 to 60 years with a history of exposure to relevant medications, or with the lowest education, were less likely to be correct.

[42] Missing data on included variables for 5 men in the younger age group.

Table 6.6: Results of Multiple Logistic Regression Analysis of the Effects of a Report of a Significant Fracture on Correct Awareness in Women and Men Aged 50 Years and Older

	WOMEN (N = 1156)[a]		MEN (N = 493)[b]	
	OR (95% C.I.)	**p**	**OR (95% C.I)**	**p**
Feedback Diagnosis				
Normal	*Referent*	-----	*Referent*	-----
Osteopenia	0.22 (0.17 - 0.30)	**<0.001**	0.21 (0.14 - 0.34)	**<0.001**
Osteoporosis	0.21 (0.15 - 0.31)	**<0.001**	0.19 (0.11 - 0.35)	**<0.001**
Significant Fracture No	*Referent*	-----	*Referent*	-----
Yes	1.21 (0.76 - 1.91)	0.4	2.14 (1.20 – 3.79)	**0.01**
Destination To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.72 (1.24 - 2.38)	**0.001**	1.33 (0.81 - 2.19)	0.3
To both	1.36 (0.94 - 1.97)	0.1	0.92 (0.51 - 1.65)	0.8
Recommendation				
Yes	1.24 (0.77 - 2.01)	0.4	1.50 (0.70 – 3.20)	0.3
No	*Referent*	----	*Referent*	----
Education				
Incomplete High School			0.53 (0.31 - 0.92)	**0.03**
Complete High School			0.66 (0.36 - 1.22)	0.2
Postsecondary Education			0.70 (0.43 - 1.15)	0.2
University Degree			*Referent*	----
FH of Osteoporosis Yes	1.23 (0.89 - 1.71)	0.2		
No or DK	*Referent*	-----		
History of Medication Exposure Yes			0.44 (0.21 - 0.93)	**0.03**
No			*Referent*	-----
Self Rated Health				
Poor/Fair/Good	*Referent*	-----		
Very Good/Excellent	1.31 (1.01 - 1.70)	0.04		
Current Smoker Yes	0.79 (0.56 - 1.10)	0.2		
No	*Referent*	-----		
Nagelkerke's R^2	0.17		0.20	

[a] Includes only those women who attended the X-ray and for whom complete data were available; missing data on included variables for 4 women.

[b] Includes only those men who attended the X-ray and for whom complete data were available; missing data on included variables for 6 men.

The influence of a reported fracture in the older group of men was not the same in all diagnostic categories (i.e., there was an interaction between reported fracture and diagnosis). The men who received a diagnosis of osteoporosis or osteopenia were more likely to be correct if they also received a report of a significant prevalent fracture. The men with a normal diagnosis,

on the other hand, were no more likely to be correct or incorrect if they had also received a report of a fracture, as would be expected.

6.5 Sensitivity Analyses of Correct Awareness

"Closely Correct": It could be argued that specific awareness of a diagnosis is not necessary, and simply knowing that a BMD test result was below normal is sufficient. An alternative outcome of "closely correct" (participants who knew their diagnosis was "abnormal" were considered to be correct) was therefore substituted for the exactly correct outcome analyzed in the above models. The coding for this variable and the frequencies of the "closely correct" responses are shown for men and women in the shaded areas of Table 6.1.

In the multivariable model, with closely correct as the response variable, the men and women with ***osteoporosis*** were just as likely to know that their results were low (even though they may have thought of them as "low but not osteoporosis" or as "osteopenia") as were the men and women who had normal results were to know that their results were "normal". Participants who were told that they had ***osteopenia***, however, were much less likely to report an abnormal result and were therefore more likely to be coded as incorrect by these criteria. This indicates that although many participants who were classified with osteoporosis did not know that their results were reported as osteoporosis, they still knew that their results were low. This was not however, true for those classified with osteopenia.

As in the model of exactly correct awareness, correct awareness of the result ("closely correct") in both women and men was more frequent when the results were sent directly to the participant only (for both women and men) or to both the participant and the FP (for women). The only variable whose association with correct awareness changed by substituting closely correct for exactly correct was a recommendation for referral or treatment; such a recommendation was associated with a greater likelihood of a closely correct awareness of the diagnosis in both women (OR: 2.41; 95% CI: 1.53 – 3.78) and in men (OR: 2.76; 95% CI: 1.49 – 5.08). The other variables in the above models did not change substantially when closely correct was substituted for the outcome variable.

"Correct" by WHO Diagnostic Criteria: Because the diagnosis received from the CaMOS study centres was not always identical to the diagnosis generated by the WHO criteria, the results may have been re-interpreted by the participant's physician. This would potentially bias the "correct" data because women and men who received a diagnosis that was incongruent with

their WHO diagnosis may have had a higher chance of being classified as "incorrect" based on the diagnosis received in their feedback. A variation of correct awareness of test results based on the WHO diagnostic criteria was substituted in the models to determine whether the results were influenced by the variation in diagnostic criteria in some of the centres: A response that described *either* the feedback diagnosis *or* the WHO diagnosis correctly was scored as correct. The feedback diagnosis and the WHO diagnosis were each included, separately, as the "diagnosis" variable in models together with the other explanatory variables from the main models.

There were no substantial changes to the models or their interpretation for either women or men when this alternative form of "correct" awareness was substituted for the outcome variable, whether the feedback diagnosis or the WHO diagnosis was included as a covariate.

Exclusion of Participants Whose Feedback Destination Varied from the Intended Within-centre Protocol: The exclusion of all cases (42 in Calgary, 1 in Kingston, 28 in Quebec City, 11 in Saint John's, 61 in Vancouver and 5 in Toronto) for whom the feedback was not provided according to the established within-centre protocol did not change the results of the adjusted models on correct awareness of feedback diagnosis. All of the associations remained the same in the men's and women's models.

6.6 Summary of the Results of the Analyses of Correct Awareness

In summary, correct awareness of their baseline BMD results, in both men and women, was strongly associated with the diagnosis; participants were much less likely to correctly report a low BMD result than a normal result and the proportion of women and men who were aware of their abnormal results three years after testing was low overall. Younger men (aged 40 to 49 years) were less likely than older men (aged 50 to 60 years) to know that their results provided a diagnosis of "osteoporosis". Women of all ages and men in the younger age group (40 to 49 years) were less likely to recall their normal or osteopenia results correctly if the feedback was sent only to their family physician. Higher education was associated with correct awareness of "normal" or "osteopenia" test results in the men, but not in the women.

Women with a family history of osteoporosis or osteopenia were more likely to be correct about their diagnosis if it were osteopenia and men with a history of exposure to relevant medication were less likely to be correct about their normal test results. Women who were current smokers were less likely to be correct about their normal results and women who

reported a lower level of general health were less likely to be correct about their results if they were normal or reported to be osteopenia.

Finally, for men aged 50 years and over, a report of a significant spinal fracture from the X-ray was associated with increased correct awareness of low test results (osteopenia or osteoporosis). Report of a significant fracture had no effect on the awareness of their test results by the women.

CHAPTER 7: Results III: Bone Density Test Results and Health Behaviour

The diagnosis that the participants received was the main explanatory variable in all of the following analyses to examine the relationship between bone density test results and health related behaviour. The relationships between received (feedback) diagnosis, together with important potential confounders, and each of the behaviours of interest (information seeking, calcium intake, vitamin D supplement use, exercise, osteoporosis-related medication use, alcohol intake, smoking status and caffeine intake) were examined in univariate and multivariable analyses.

After analyses of the received diagnosis, all analyses were repeated with *recalled diagnosis* as the main explanatory variable of interest. These analyses were performed to explore the relationships between the health behaviours and the *perceived* diagnosis for comparison with the main analysis of *received diagnosis*. The recalled diagnosis (i.e., the response to Question 1.5 of the Year 3 questionnaire (see Appendix B)) represents the diagnosis that the participants believed that they had received at baseline, but also includes the response "I don't know", which represents no awareness of a particular diagnosis. These further analyses with recalled diagnosis were undertaken with the assumption that individuals must be aware of their diagnosis, or risk, before behavioural changes associated with that perceived risk can be made. Again, all modeling was stratified by gender.

Recalled Diagnosis: Alternative Explanatory Variable

The main explanatory variable, feedback diagnosis, and its associations with the potential covariates were discussed earlier in Chapter 5 and shown in Tables 5.4 and 5.5.

The frequency of the recalled diagnosis is shown in Table 6.1 in Chapter 6. Six percent of the men and 8% of the women recalled a diagnosis of "low or osteoporosis" at Year 3 when asked what the results of their bone density test was when completed three years previously. A higher frequency recalled a diagnosis of "osteopenia" (or "low without osteoporosis"): 19% of the men and 20% of the women recalled a low or "osteopenia" diagnosis. The majority recalled a diagnosis of "normal"; 41% of the men and 49% of the women recalled a normal test result. The remaining one third of the men and one quarter of the women stated that they did not know their diagnosis.

7.1 Information seeking about Osteoporosis

7.1.1 Information Seeking about Osteoporosis: Outcome Variable

The frequencies of reported information seeking from at least one source during the three years between baseline and follow-up, as well as the description of the sources cited by the study participants, were derived from the responses to question 1.6 on the Year 3 CaMOS questionnaire (see Appendix B). These responses are summarized in Table 7.1. Note that because some participants reported seeking information from more than one kind of source, the categories are not mutually exclusive.

Table 7.1: Frequencies of Reported Information Seeking by Gender

	Women N[a] (%)	Men N[b] (%)
Health-Care Professional Nutritionist	46 (2.5)	16 (1.8)
Physiotherapist/exercise specialist	42 (2.3)	13 (1.5)
Nurse	43 (2.4)	13 (1.5)
Physician	349 (19.0)	120 (13.8)
Other Health Care Professional	21 (1.1)	1 (0.1)
At least one health professional	**373 (20.3)**	**128 (14.7)**
Local Public Health Resource	99 (5.4)	24 (2.8)
The Osteoporosis Society of Canada	79 (4.3)	20 (2.3)
"Other Sources"		
Literature and media[c]	791 (43.3)	217 (25.0)
Internet	40 (2.2)	23 (2.6)
Friends, relatives, work	17 (0.9)	4 (0.5)
Seminars and workshops	19 (1.0)	2 (0.2)
Information sought from at least one source	**1018 (55.4)**	**322 (37.1)**

[a] Missing responses amongst women for "Physiotherapist/exercise specialist" and "At least one health professional" (n = 5), for "Nutritionist", "Nurse", "Other Health Care Professional" and "Osteoporosis Society of Canada" (n = 4), for "Physician" and "Local Public Health Resource" (n = 3) , for "Other Sources" (n = 2).
[b] Missing responses amongst men for "Osteoporosis Society of Canada" (n = 2), for "Other Health Care Professional" and "At least one health professional" (n = 1).
[c] Includes books, pamphlets, magazines, newspaper, television and radio.

Literature and media were the most frequently cited sources of information; information was reportedly sought from at least one such source by 43% of the women and 25% of the men.

Further, such "independent" sources of information (i.e., not health-care professional, Osteoporosis Canada or a public health resource) were cited as the *only* source of information by 31% of the women and 20% of the men (not shown in the Table). Amongst the health-care professionals from whom information was sought, physicians were the most commonly cited; other health-care professionals were infrequently cited as sources of information seeking about osteoporosis. Overall, more women than men reported seeking information about osteoporosis from all sources (the only exception was the internet, from which similar, small proportions of men and women sought information). Fifty five percent of the women reported that they had sought information about osteoporosis from at least one source, compared to only 37% of the men ($\chi^2 = 79.09$; df = 1; $p < 0.001$).

7.1.2 Factors Associated with Information seeking: Univariate Analyses

Table F.1 in Appendix F summarizes the associations among self-reported information seeking from at least one source and feedback diagnosis as well as the other explanatory variables of interest. The diagnosis received in the feedback was significantly associated with information seeking behaviour in both men and women. Although 48% of the women who received a normal diagnosis reported that they had sought information about osteoporosis, a larger proportion of the women who received a diagnosis of osteopenia had sought information (58%). A larger proportion still of those who received a diagnosis of osteoporosis had sought information about osteoporosis (75%). Similarly, the men with an abnormal diagnosis were more likely to have sought information compared with the men who had received a normal diagnosis (26%); 42% of the men who received a diagnosis of osteopenia and 54% of the men who received a diagnosis of osteoporosis had sought information.

Recalled diagnosis was also significantly associated with information seeking about osteoporosis; 83% of the women and 78% of the men who reported a diagnosis of osteoporosis had sought information. Thus, although significantly fewer men with a feedback diagnosis of osteoporosis reported information seeking than did the women with the same diagnosis, there was no significant difference between the men and women with a *self-reported* diagnosis of osteoporosis.

Both women and men whose results were provided directly reported that they had sought information more frequently than did those whose results were sent only to the physician. The participants whose feedback was sent only to the FP were less likely to have sought information from any source, as shown in the table, and they were less likely to have sought information

from at least one health-care professional or from physicians, specifically (not shown). A recommendation for a referral or for treatment was associated with more reported information seeking in both women and men.

Other personal factors associated with increased information seeking by the women included a previous diagnosis of osteopenia or osteoporosis and a family history of osteoporosis. Women who had surgically-induced menopause were significantly less likely to report seeking information. Information seeking amongst both the men and women varied significantly by centre (with particularly high rates of information seeking reported in the Vancouver centre). Men who described themselves as "non-white" were more likely to have sought information about osteoporosis than were men described as "white"; this association was not observed in the women. Those in the lower quartiles of the body mass index distribution were significantly more likely to report information seeking than were those in the higher quartiles, in both women and in men. Information seeking was not associated with age group, level of education, neighbourhood income, current smoking, self-rated health status, a history of significant comorbidity, or relevant medication use.

7.1.3 Potential Explanatory Factors Associated with Information seeking: Multivariable Modelling

The most parsimonious models for information seeking from at least one source for women and men are shown in Table 7.2. In the final multivariable model, the women who received a diagnosis of osteoporosis in their feedback diagnosis were more than twice as likely as were women who reported a normal diagnosis to have sought information on osteoporosis. Women who directly received their feedback, which was not also sent to the FP, were more likely to have sought information compared with those whose feedback went only to their FP, even when the diagnosis was taken into account. A recommendation for referral or treatment in the feedback report was a strong indicator of whether the women sought information about osteoporosis. As in the univariate analysis, having experienced surgically-induced menopause and having a history of significant comorbidity were associated with less likelihood of information seeking. By contrast, a previous diagnosis of osteoporosis and being in the lowest quartile of body mass index (compared with the highest quartile) were associated with greater likelihood of information seeking. Women in both age groups were equally likely to seek information when the above variables were taken into account. The removal of age group from the model did not change the associations among the other variables. Family history, smoking

status, general health status and race were removed from the model when the above variables were included; they did not contribute significantly to the adjusted model. Further, there were no significant interaction effects between diagnosis, or age group, and the included variables.

Table 7.2: Multiple Logistic Regression Analysis of Factors Associated with Information Seeking about Osteoporosis for Women and Men

	WOMEN (N = 1805)[a]		**MEN** (N = 861)[b]	
	OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Feedback Diagnosis				
Normal	*Referent*	-------	*Referent*	-----
Osteopenia	1.33 (1.06 – 1.67)	**0.02**	2.08 (1.49 – 2.90)	**<0.001**
Osteoporosis	2.00 (1.45 – 2.77)	**<0.001**	2.65 (1.75 – 4.01)	**<0.001**
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.67 (1.29 - 2.15)	**<0.001**	2.07 (1.39 – 3.07)	**<0.001**
To both	1.06 (0.79 - 1.43)	0.7	1.64 (1.03 - 2.60)	**0.04**
Recommendation				
Yes	9.55 (4.83 - 18.90)	**<0.001**	2.90 (1.61 – 5.24)	**<0.001**
No	*Referent*	-----	*Referent*	-----
Age Group 40 to 49 years	0.94 (0.74 - 1.21)	0.6	1.04 (0.77 - 1.40)	0.8
50 to 60 years	*Referent*	-----	*Referent*	-----
BMI Lowest Quartile	1.45 (1.09 – 1.93)	**0.01**		
Second Lowest Quartile	1.31 (0.99 – 1.73)	0.06		
Second Highest Quartile	0.88 (0.67 – 1.16)	0.4		
Highest Quartile	*Referent*	-----		
Reproductive Status				
Premenopausal	*Referent*	-----		
Naturally Menopausal	0.99 (0.75 - 1.29)	0.2		
Surgically Menopausal	0.57 (0.38 - 0.86)	**0.007**		
Premen. Hysterectomy	1.20 (0.89 - 1.61)	0.2		
Previous Diagnosis of Osteoporosis Yes	2.18 (1.27-3.72)	**0.004**		
No or DK	*Referent*	-----		
History of Comorbidity				
Yes	0.61 (0.39 – 0.97)	**0.04**		
No or DK	*Referent*	-----		
Nagelkerke's R^2	0.14		0.11	

[a] Missing information on included variables for 32 women.
[b] Missing information on included variables for 8 men.

In the multivariable model for men, diagnoses of osteoporosis or osteopenia were significantly associated with a greater likelihood of information seeking (men who received a

diagnosis of osteoporosis were approximately 2.5 times more likely to have sought information compared with those who received a normal diagnosis). Men who had received the diagnostic information directly were more likely to seek information than were those whose feedback went to the FP only. Men whose feedback included a recommendation for referral or treatment were 2.9 times more likely to report having sought information, even when their diagnosis was taken into account. As with the women, the men's age group was not associated with information seeking in the multivariable model, and its removal did not change the relationships among the other variables. Family history, history of significant comorbidity and race were all removed from the model when the above variables were included. No significant interactions were found between feedback diagnosis, or age group, and the other variables in the model.

The multivariable models for information seeking for women and men were similar; a diagnosis of osteoporosis or osteopenia had a significant association for both genders, as did a recommendation for referral or treatment. Direct receipt of feedback information was associated with an increased likelihood of information seeking in both genders. A lower body mass index in men was associated with a higher frequency of information seeking in univariate analyses (see Table F.1, Appendix F), but there was no significant association when diagnosis and the other significant covariates were taken into account. Unlike the women's model, a history of a significant comorbidity was not associated with information seeking in men, in the unadjusted or adjusted analyses. Reproductive status was not relevant to the analysis of the men's data and there were insufficient men with a previous diagnosis of osteoporosis in the sample to include this variable in the analyses.

When the CaMOS centre was included in the models, in place of feedback destination, there was significant variation in the participants' information seeking between the centres, but the associations between the other variables and information seeking were no different from the models in Table 7.2.

The Association between Recalled Diagnosis and Information seeking

The model building process was repeated with self-reported diagnosis (a self report of "normal; see Table 6.1) in place of the feedback diagnosis. Women and men who self reported a diagnosis of "osteopenia" or "osteoporosis", or who responded that they did not know their diagnosis, were compared with those who reported a "normal" diagnosis (see Table 6.1). These equivalent multivariable models for self reported diagnosis and information seeking in women and men are shown in Appendix G.

The final models for information seeking for both women and men were found to be very similar to those shown in the previous section, but the odds ratios for a recalled diagnosis of osteoporosis or osteopenia were larger than those seen in the model for feedback diagnosis, particularly for the men. Men who believed that their diagnosis was osteoporosis, for example, were 9.7 times more likely to seek information as were those who recalled a normal diagnosis and the equivalent women were 3.4 times more likely to seek information. Women who reported that they did not know their diagnosis were less likely to report seeking information than were those who recalled a normal diagnosis. The relationships between information seeking and all of the remaining variables in the models in Table 7.2 remained virtually unchanged when feedback diagnosis was replaced with recalled diagnosis.[43]

7.2 Calcium Intake from Diet and Supplements

The main outcome for the assessment of a change in calcium intake was whether participants reported current, regular use of calcium supplements, at baseline and Year 3. Further, linear regression analysis of the total calcium intake from diet alone and from diet and supplements combined is presented below. The results of these linear regression analyses are limited, however, and must be interpreted with caution due to limitations in the measurement of dietary intake of calcium at Year 3 in the CaMOS study, as discussed in Chapter 3.

7.2.1 Calcium Intake: Outcome Variables

a. Use of Calcium Supplements

The proportions of women and men who were using calcium supplements at Year 3 are shown in Table 7.3 stratified by whether they were using calcium supplements at baseline.

The frequency of calcium supplementation had increased between baseline and Year 3 amongst the women from 42% to 56% and amongst the men from 21% to 33%. There was a strong association between baseline use of supplements and Year 3 use of supplements (for women: $\chi^2 = 444.30$; df = 1; $p < 0.001$ and for men: $\chi^2 = 147.68$; df = 1; $p < 0.001$). Approximately one third of the women and one quarter of the men "took up" calcium supplementation, while 15% of the women and more than one quarter of the men who were taking supplements at baseline were no longer taking them at Year 3.

[43] Although a history of comorbidity was not significantly associated with information seeking in women in the model adjusted for recalled diagnosis (the association was "borderline"), the odds ratio and 95% confidence intervals were very similar to the equivalent measures of association in the model for women in Table 6.2.

Table 7.3: Frequency of Use of Calcium Supplements at Year 3 by Use of Calcium Supplements at Baseline

WOMEN	**Use of Calcium Supplements at Baseline**		
Use of Calcium Supplements at Year 3	No N (%)	Yes N (%)	Total N (%)
No	691 (65%)	119 (15%)	810 (44%)
Yes	374 (35%)	653 (85%)	1027 (56%)
Total Women; N	1065	772	1837
MEN	**Use of Calcium Supplements at Baseline**		
Use of Calcium Supplements at Year 3	No N (%)	Yes N (%)	Total N (%)
No	527 (77%)	52 (29%)	579 (67%)
Yes	161 (23%)	129 (71%)	290 (33%)
Total Men; N	688	181	869

b. Total Calcium Intake

The distribution of total calcium intake at Year 3 is shown in Figures 7.1 and 7.2 for women and men, respectively. In both distributions, there were some particularly high reported calcium intakes causing the distribution to be skewed to the right.[44] The highest value for women was 8,537 mg/day and for men was 5,511 mg/day.

[44] The distributions of total calcium intakes at Year 3 were not only skewed to the right for both women (skewness statistic = 1.72) and for men (skewness statistic = 1.83), but also had stronger peaks than the normal distribution (i.e., positive kurtosis). The kurtosis statistic was 10.02 for women and 5.12 for men. Adjustment of the total calcium values at Year 3 for each of the 7 women and 7 men with reported intakes > 3,500mg per day to a value of 3,500mg per day improved the "normality" of the distributions, as did a square root transformation of total calcium. The skewness and kurtosis values for Year 3 total calcium intake, in women after the former adjustment, for example, were 0.84 and 0.76, respectively, and in men, these values were 1.44 and 2.26, respectively. It was considered possible that the results of the linear models would be improved if the Year 3 calcium values were manipulated by either of these methods. For the multivariable analysis, all models were re-estimated with the extreme values adjusted to a maximum of 3,500mg/day for total calcium (baseline values were similarly adjusted to this maximum value, although there were fewer baseline intakes over 3,500mg; 5 women and 5 men). Models were re-estimated using the square root of total Year 3 calcium (adjusted for the square root of baseline calcium). Although both of these subsequent analyses led to minor improvements in the multivariable regression diagnostics there were no meaningful changes in the associations between any of the explanatory variables and the response variables in the models for women or for men, consequently the models with the original untransformed calcium values, including the extreme values have been presented here to simplify interpretation.

Figure 7.1: Distribution of Total Calcium Intake at Year 3 in Women

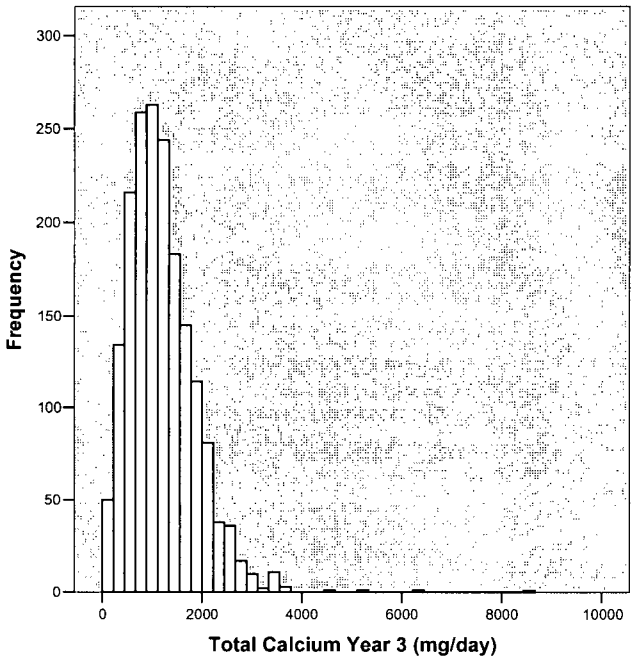
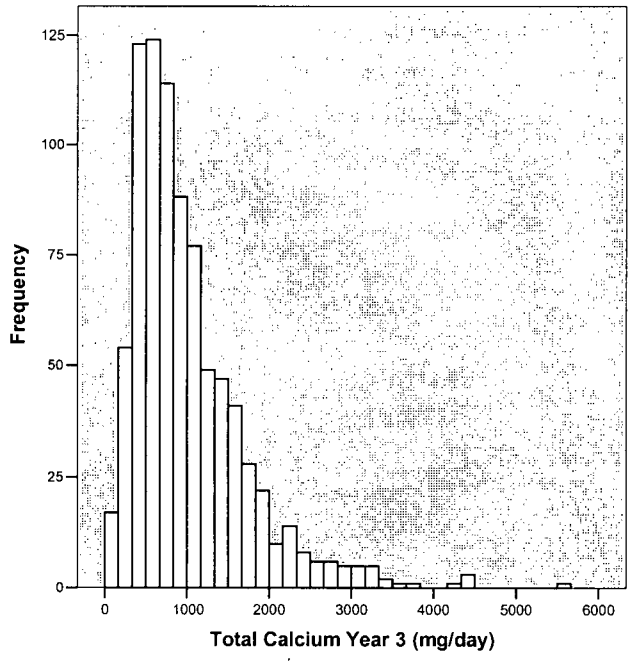


Figure 7.2: Distribution of Total Calcium Intake at Year 3 in Men



The estimated intake of calcium from all sources (diet and supplements) and from diet alone over the previous 12 months, as measured at baseline and Year 3, for women and men is shown in Table 7.4. The average amount of total calcium had increased for both women and

men by Year 3 when compared with their intake at baseline, by an average of approximately 166 mg/day in women (Paired t = -10.12; df = 1770: $p < 0.001$), and an average of approximately 123 mg/day in men (Paired t = -5.27; df = 828; $p < 0.001$). Accordingly, the proportion of participants who were consuming at least 1,000 mg per day was still low, but had increased to 55% of the women and 38% of the men.

Table 7.4: Total and Dietary Calcium Intake for Women and Men at Baseline and Year 3

	WOMEN (n = 1771)[a]	
Estimated daily intake over previous 12 months	Total Calcium (mg) Mean (SD)	Dietary Calcium (mg) Mean (SD)
Baseline	1024 (606)	786 (478)
Year 3	1190 (672)	820 (517)
	MEN (n =829)[b]	
Estimated daily intake over previous 12 months	Total Calcium (mg) Mean (SD)	Dietary Calcium (mg) Mean (SD)
Baseline	888 (607)	818 (540)
Year 3	1011 (697)	861 (618)

[a] Missing data on calcium intake for 66 women.
[b] Missing data on calcium intake for 40 men.

c. Dietary Calcium Intake

As shown in Table 7.4, there was a small, but statistically significant increase in the average calcium intake from diet alone for both women (Paired t = -2.85; df = 1770; p = 0.004) and men (Paired t = -2.20; df = 828; p = 0.03).

7.2.2 Factors Associated with Calcium Intake: Univariate Analyses

a. Use of Calcium Supplements

As mentioned above, supplementation at Year 3 was strongly associated with supplement use at baseline. Accordingly, supplement use at Year 3 was associated with most of the factors

that were associated with baseline use. In women, these factors were family history of osteoporosis, previous diagnosis, older age group, being in the lowest quartile for body mass index and being menopausal. Calcium supplementation at Year 3 was associated with feedback to the participant directly and with a diagnosis of, as well as a self report of, osteopenia or osteoporosis; the use of calcium supplements at baseline, however, was unevenly distributed between the "Destination" subgroups (see Table E.1, Appendix E) and the feedback diagnosis subgroups (see Table 5.4). Supplement use at Year 3 in women varied by Centre as it did at baseline. In men, Year 3 supplement use was associated with older age, feedback to the participant directly, receipt, as well as self report, of a diagnosis of osteopenia or osteoporosis and Centre. Older age was associated with baseline use of calcium supplements in men and supplement use was not evenly distributed across the Destination categories; men who received their feedback directly were already more likely to be taking supplements at baseline (see Table E.2, Appendix E).

In women, there was no difference between the reported use of supplements at Year 3 between non-smokers and smokers (56% of female smokers and non-smokers reported supplement use at Year 3), although there was a difference in reported supplement use at baseline between these two groups (43% of non-smokers and 36% of smokers reported supplement use at baseline). Amongst the men, a higher frequency of non-smokers reported supplement use at Year 3 compared to smokers (36% v. 25%); this association was not observed in the baseline use of supplements (21% of non-smokers reported use at baseline and 19% of smokers reported such use). Thus, supplement use amongst male non-smokers increased relative to male smokers, whereas the opposite was observed in women; supplement use amongst female smokers increased relative to non-smokers.

Although the number of men who were taking calcium supplements at baseline was evenly distributed across the categories of diagnosis received in the feedback, there was a significant association between calcium supplementation at Year 3 and a diagnosis of osteopenia or osteoporosis. In addition, men who reported that they were "white" were more likely to report supplement use at Year 3 (35% of men who reported that they were "white" took supplements) compared with men who reported that they were "non-white" (17% of men who reported they were "non-white" took supplements at Year 3). This association was not seen in baseline supplement use.

Although significantly fewer men than women with a diagnosis of osteoporosis were taking calcium supplements at Year 3 ($\chi^2 = 30.85$; df = 1; $p < 0.001$), there was no difference

between the proportion of men and women taking calcium supplements amongst those who *recalled* a diagnosis of osteoporosis (χ^2= 0.0; df = 1; p = 1.0).

b. Total Calcium Intake

The average amount of daily calcium reported at Year 3 was correlated with that reported at baseline (women; $r = 0.43$, $p < 0.001$ and men; $r = 0.48$; $p < 0.001$).

For both women and men, a higher calcium intake at Year 3 was associated with a diagnosis of osteopenia or osteoporosis (both by feedback and by self report), a family history of osteoporosis and a recommendation for referral or treatment in the feedback. In addition, a higher intake of total calcium at Year 3 was associated with a higher education level, not being premenopausal, older age group, being in the lowest quartile of BMI, a previous diagnosis of osteoporosis and direct receipt of feedback in women.

Men who described themselves as "non-white" reported a considerably lower overall mean intake of calcium at Year 3. The intake of calcium at Year 3 was unevenly distributed across the centres for both genders.

c. Dietary Calcium Intake

In women, dietary calcium intake at Year 3 was correlated with the amount of calcium in the diet at baseline ($r = 0.47$; $p < 0.001$). In unadjusted models, a higher amount of Year 3 dietary calcium was associated with a higher education level, being "white", Centre and feedback to the FP; education and race also were associated with a higher dietary calcium intake at baseline, however, and baseline dietary calcium intake was not evenly distributed across the Centres or the Destination subgroups (see Table E.1 and E.3, Appendix E). A family history of osteoporosis in women was associated with a higher intake of dietary calcium at Year 3, although it was not associated with baseline intake. Dietary calcium intake was lower in men that were "non-white" compared with those that were "white" and, as with baseline dietary calcium intake, Year 3 intake varied across the centres. No other associations between the variables of interest and dietary intake at Year 3 were significant in the univariate analyses for men.

7.2.3 Potential Explanatory Factors Associated with Calcium Intake: Multivariable Modelling

a. Use of Calcium Supplements

The results of multivariable regression modeling in which those variables that were associated with supplement use at Year 3 were examined in combination for each gender separately, are shown in Table 7.5.

Table 7.5: Multivariable Logistic Regression Analysis of Factors Associated with Calcium Supplement Use at Year 3 for Women and Men

		WOMEN (N = 1808)		**MEN** (N = 860)	
		OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Supplements at Baseline	Yes	10.24 (7.95 -13.18)	**<0.001**	8.50 (5.71 - 12.65)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis					
	Normal	*Referent*	-----	*Referent*	-----
	Osteopenia	1.58 (1.22 - 2.06)	**0.001**	1.63 (1.11 - 2.39)	**0.01**
	Osteoporosis	3.18 (2.21 - 4.57)	**<0.001**	3.11 (1.95 - 4.96)	**<0.001**
Destination	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	1.30 (0.97 - 1.74)	0.08	1.70 (1.09 - 2.64)	**0.02**
	To both	1.98 (1.41 - 2.78)	**<0.001**	1.69 (1.01 - 2.83)	**0.05**
Recommendation	Yes	3.67 (1.91 – 7.04)	**<0.001**	3.00 (1.57 – 5.75)	**0.001**
	No	*Referent*	-----	*Referent*	-----
Age Group	40 to 49 years	*Referent*	-----	*Referent*	-----
	50 to 60 years	1.24 (0.97 - 1.60)	0.08	0.95 (0.67 – 1.34)	0.8
BMI					
	Lowest Quartile	1.33 (0.95 – 1.85)	0.1		
	Second Lowest Quartile	1.44 (1.05 – 1.98)	**0.03**		
	Second Highest Quartile	0.99 (0.72 – 1.35)	0.9		
	Highest Quartile	*Referent*	-----		
Race/Ethnicity					
	"Non-white"			*Referent*	-----
	"White"			4.65 (2.13 –10.14)	**<0.001**
Previous Diagnosis of Osteoporosis	No	*Referent*	------		
	Yes	0.49 (0.28 - 0.88)	**0.02**		
Current Smoker	No			*Referent*	-----
	Yes			0.51 (0.33 - 0.77)	**0.002**
Nagelkerke's R^2		0.40		0.32	

Reported use of any calcium supplements at Year 3 was associated with a diagnosis of osteopenia or osteoporosis, in both women and men. In the adjusted model, both women and men who received a diagnosis of osteoporosis were 3 times more likely to report any supplement

use at Year 3 compared with those who received a normal diagnosis even when baseline supplement use was taken into account.

Direct-to-participant feedback was associated with a higher frequency of supplement use at Year 3, in men and women. Both women and men who received a recommendation for referral or treatment in their feedback were more likely to report calcium supplementation at Year 3. Amongst the men, smokers and those who described themselves as "non-white" were less likely to have used supplements at Year 3. Women in the older age group were somewhat more likely to use calcium supplements at Year 3 (although this difference between the age groups was not significant); there was no difference between the age groups in men. Women who had a previous diagnosis of osteoporosis were *less* likely to take supplements at Year 3 when baseline use was accounted for (because the use of supplements was already high in this subgroup at baseline). This same relationship could not be assessed in the men because of small numbers. Finally, women in the lower two quartiles for body mass index reported marginally more supplement use than those in the highest quartile, while body mass index was not associated with calcium supplementation in the men.

The addition of Centre to the above models in place of Destination did not change the direction of the associations between Year 3 supplement use and any of the other variables in the models. The odds ratios for the remaining variables in the model adjusted for Centre in women were of a similar magnitude to the model that included Destination, although they increased slightly for the lowest quartile of body mass index (OR: 1.44; 95% CI: 1.03 – 2.02) and for the older age group (OR: 1.29; 95% CI: 1.00 – 1.65), so that the 95% confidence intervals for these variables did not include one. Substitution of Centre for Destination in the model for men also resulted in similar odds ratios, although the association between a diagnosis of osteopenia and calcium supplementation decreased and was no longer significant when Centre was taken into account (OR: 1.29; 95% CI: 0.85 – 1.97). The association between a diagnosis of osteoporosis and calcium supplementation in men was essentially unchanged, however, by the substitution of Centre (OR: 3.24; 95% CI: 1.96 – 5.36). Supplement use at Year 3, relative to baseline, was lower overall for both men and women in Quebec City and for women in Saint John's, Halifax and Hamilton.

When self reported diagnosis was substituted in the models described above, in place of feedback diagnosis, women who reported their diagnosis as osteoporosis were 2.5 times as likely to be using calcium supplementation at Year 3 (OR: 2.55; 95% CI: 1.53 – 4.27), and those who reported a diagnosis of osteopenia were about 2 times as likely to be using supplements (OR:

2.15; 95% CI: 1.51 – 3.06). The associations between calcium supplement use at Year 3 and all of the other variables in the model shown on the left side of Table 7.5 were comparable to the model that included feedback diagnosis. Men who reported a diagnosis of osteoporosis were 14 times as likely to report calcium supplementation at Year 3 compared with those who believed that their diagnosis was normal (OR: 14.23; 95% CI: 6.20 – 32.71), although the confidence interval was wide because of small numbers. Men who self reported a diagnosis of osteopenia were 2.5 times as likely to report calcium supplement use (OR: 2.49; 95% CI: 1.54 – 4.02). Substitution of self reported diagnosis for feedback diagnosis in the model for men did not substantially change the associations between the other variables.

Investigation of Potential Effect Modification by Calcium Supplement Use at Baseline

Interactions between baseline use of calcium supplements and the feedback diagnosis were investigated in the models presented in Table 7.5, for men and women. No interactions were apparent; a low BMD test result was predictive of a greater likelihood of supplement use at Year 3 in women and men who were taking supplements at baseline and in those who reported no supplement use at baseline.

b. Total Calcium Intake

The results of multivariable linear regression modelling in which those variables that were associated with Year 3 calcium intake were examined in combination, for each gender separately, are presented in Table 7.6. The diagnosis received in the feedback together with Destination was included in all models because these were the main variables of interest. Baseline calcium intake was also included, as was age group because of the importance of these variables as potential confounders or effect modifiers. A recommendation for referral or treatment in the feedback was added to the model to adjust for its potential influence on the effect of the "Destination" variable. All other variables were included in the models if they had a significant association with the outcome in the multivariable model.

The results demonstrated that even when levels of baseline calcium intake and age group were taken into account, together with race and family history in men, women and men who reported that they had received a diagnosis of osteopenia or osteoporosis at baseline also reported a substantially higher intake of total calcium by Year 3. Participants who received a diagnosis of osteoporosis were taking approximately 228 mg/day (women) or 333 mg/day (men) more calcium than those who reported a normal diagnosis. The women and men who received a

diagnosis of osteopenia were taking approximately 96 mg/day and 131 mg/day more, respectively, than those who reported a normal diagnosis.

Table 7.6: Multivariable Linear Regression Analysis of Factors Associated with Total Calcium Intake at Year 3 for Women and Men

	WOMEN (N = 1745)		MEN (N = 818)	
	B (95% CI)	**p**	**B (95% CI)**	**p**
Intercept	543.0 (454.7; 632.2)		160.0 (-36.8; 356.7)	
Baseline Calcium	0.46 (0.41; 0.51)	**<0.001**	0.57 (0.50; 0.64)	**<0.001**
Feedback Diagnosis				
Normal	*Referent*	-------	*Referent*	-----
Osteopenia	96.4 (30.4; 162.4)	**0.004**	131.1 (37.2; 224.9)	**0.006**
Osteoporosis	227.7 (142.5; 313.0)	**<0.001**	332.6 (213.0; 452.2)	**<0.001**
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	60.1 (-14.2; 134.4)	0.1	68.3 (-37.6; 174.2)	0.2
To both	65.5 (-20.4; 151.5)	0.1	-26.7 (-155.2; 101.7)	0.7
Recommendation				
Yes	289.0 (168.2; 409.8)	**<0.001**	106.8 (-64.0; 277.7)	0.2
No	*Referent*	-----	*Referent*	-----
Age Group				
40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	55.3 (-5.9; 116.6)	0.08	-28.9 (-114.1; 56.3)	0.5
Race/Ethnicity				
"Non-white"			*Referent*	-----
"White"			223.4 (66.2; 380.6)	**0.005**
Family History of Osteoporosis Yes			149.3 (6.2; 292.4)	**0.04**
No or DK			*Referent*	-----
R^2	0.22		0.29	

Men who described themselves as "white" had a higher average intake of calcium at Year 3; they reported approximately 223 mg/day more than those who described themselves as "non-white". Men who reported a family history of osteoporosis or osteopenia were taking approximately 149 mg/day more calcium than those with no family history. Race and family history were not associated with calcium intake at Year 3 in women.

Neither destination of the feedback nor age group was significantly associated with a higher intake of calcium, in women and men. A recommendation for a referral or treatment[45] was significantly associated with a higher intake of total calcium in women, but not in men.

On average, for each 100 mg increase in baseline calcium intake there was a 41 to 51 mg/day increase in the estimated total amount of calcium intake at Year 3 in women and an increase of 50 to 64 mg/day in the estimated total calcium intake at Year 3 in men. The most important indicator of Year 3 calcium intake was reported calcium intake at baseline, as may be expected. The relative contribution[46] of baseline calcium as a predictor of Year 3 calcium intake was 0.79 in the model for women and 0.86 in the model for men. The other explanatory variables in both models each contributed less than 0.10; a diagnosis of osteoporosis was the next most important predictor of Year 3 calcium intake and contributed 0.09 of the total variance accounted for by each of the models (for women and for men).

Other variables that were found to be associated with Year 3 calcium intake in the univariate analyses did not make a contribution to the multivariable model, which indicates that baseline calcium intake and the feedback diagnosis were the stronger explanatory factors.

The models shown in Table 7.6 were essentially the same when Centre was substituted for Destination as an explanatory variable. The relationship between total calcium intake at Year 3 and the other explanatory variables in the models remained the same and there was little variation between the centres in Year 3 intake when baseline intake was taken into account.

When the model building process was repeated with self reported diagnosis in place of the feedback diagnosis, the final models for total calcium intake for both women and men were found to be very similar to those shown in the previous section. The regression coefficients for a recalled diagnosis of osteoporosis or osteopenia were larger than those seen for feedback diagnosis; women who believed that their diagnosis was osteoporosis, for example, reported approximately 293 mg/day more calcium than did women who believed that their diagnosis was normal; the equivalent men reported approximately 435 mg/day more calcium than did those who recalled a normal diagnosis. The relationships between the total calcium intake at Year 3 and all of the remaining variables from the models in Table 7.6 remained virtually unchanged when feedback diagnosis was replaced with recalled diagnosis.

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[45] All of these participants received an abnormal diagnosis or a report of a prevalent spinal fracture in their feedback and this variable was included mainly to adjust for potential confounding of the Diagnosis and Destination variables.
[46] A Relative Pratt Index (RPI) (379) was computed to partition the variance (R^2) and to determine the relative contribution of each of the explanatory variables in the models.

Investigation of Potential Effect Modification by Total Calcium Intake at Baseline

Because there was such a wide range of calcium intake at baseline, the potential for different associations between the diagnosis and the intake of total calcium at Year 3 was investigated within different levels of baseline calcium intake. The participants were divided into four different groups based on quartiles of baseline calcium intake (see Table 7.7) and the multivariable analyses including the explanatory variables in Table 7.6, were repeated within each of these four groups.

Table 7.7: Quartiles of Baseline Total Calcium Intake in Women and Men

		WOMEN			MEN		
		Mean mg/d	**(SD)**	***N***	**Mean mg/d**	**(SD)**	***N***
Quartiles of Baseline Calcium Intake	Lowest	387	(132)	449	334	(110)	210
	Second Lowest	742	(92)	450	610	(66)	211
	Second Highest	1116	(125)	450	902	(107)	211
	Highest	1849	(498)	449	1694	(631)	211
	Total	1023	(604)	1798	885	(604)	843

When the Year 3 calcium intake was compared with the baseline intake within each of these four groups, the intake was found to have increased on average in the three lower groups but to have decreased in the highest intake group. The decrease in calcium intake in this group, which includes extremely high values of baseline calcium, is not surprising due to ceiling effects and some regression to the mean as well as the possibility that participants may have intentionally reduced their high calcium intakes.[47]

When a separate multivariable analysis was carried out within each level of baseline calcium, while taking the actual baseline calcium into account, the relationship between diagnosis and calcium intake at Year 3 was greatest within the subgroup of women with the lowest intakes of calcium at baseline. Women in the lowest quartile of baseline calcium who received a diagnosis of osteoporosis reported a substantially higher intake of calcium at Year 3 compared with those in this subgroup who received a normal diagnosis (B = 388.9 mg/day; 95%

[47] The relationship between baseline calcium intake and Year 3 calcium intake was linear for both women and men and the intercept for this line is > 0 and the slope is < 1 (see Table 7.6). Thus, for lower values of baseline calcium, the average Year 3 calcium intake was greater than that at baseline, but for higher values of baseline calcium the Year 3 calcium value falls below the baseline calcium intake on average. The mean calcium intake at Year 3 of those in the highest quartile of baseline calcium intake (both women and men) was therefore higher than the mean Year 3 calcium intake of those in the lower three quartiles of baseline calcium intake.

CI: 245.0; 532.8 mg/day). Women in the second lowest quartile (B = 230.1; 95% CI: 73.11; 386.0) and the second highest quartile (B = 197.8 mg/day; 95% CI: 11.1; 384.5 mg/day) of baseline calcium intake also reported a significantly higher intake of calcium at Year 3 compared with those with a normal diagnosis. Although there was a trend towards a higher Year 3 calcium intake amongst the subgroup of women in the highest quartile of baseline calcium who received a diagnosis of osteoporosis, the difference when compared with women who received a normal diagnosis in this subgroup was not significant (B = 127.3 mg/day; 95% CI: -60.3; 314.8 mg/day). The effects of a low BMD diagnosis were therefore more notable at lower levels of baseline calcium intake. There were no substantive changes to the effects of the other factors in the model shown in Table 7.6 when the analyses were carried out within the subgroups of baseline calcium intake quartiles.

As seen in the women, the men in the highest quartile of baseline calcium intake showed a mean reduction in calcium by Year 3 overall, while those in the three lower quartiles showed an increase in calcium intake, on average. Still, in multivariable analysis within each quartile of baseline calcium, men with a diagnosis of osteoporosis also reported a higher intake of calcium at Year 3 and men with a diagnosis osteopenia reported somewhat higher intakes of calcium compared with those who received a normal diagnosis within each quartile of baseline calcium intake. The influence of a diagnosis of osteoporosis was comparable within each quartile of baseline calcium intake in the men.

c. Dietary Calcium

When baseline dietary calcium was taken into account, the other variables that were associated with dietary calcium at Year 3 in the univariate analyses were eliminated from the model. A feedback diagnosis of osteoporosis or osteopenia was not associated with Year 3 dietary calcium in women; further there was no association between age or destination of the feedback and Year 3 dietary calcium intake. Dietary calcium intake was no greater in the small group of women who received a recommendation of referral or treatment. The only significant predictor amongst those under consideration, of dietary calcium intake at Year 3 in women, was baseline dietary calcium intake.

In contrast to the women, an abnormal diagnosis was associated with a higher intake of dietary calcium at Year 3 by the men. In the model adjusted for baseline dietary calcium, the destination of the feedback, a recommendation for referral or treatment and age group, men who received a diagnosis of osteoporosis reported significantly higher levels of dietary calcium intake

(B =149 mg/day; 95% CI: 45; 253 mg/day) than men who received a normal diagnosis. Men who received a diagnosis of osteopenia also reported significantly higher intakes than did men who received a normal diagnosis, although these latter differences were small (B = 89 mg/day; 95% CI: 7; 170 mg/day). Except for baseline dietary calcium, none of the other variables was significantly associated with dietary calcium intake at Year 3 in men (including age group, the destination of the feedback and a recommendation for referral or treatment).

There were no substantive changes in the models when Centre was substituted for Destination as an explanatory variable in the model for women; feedback diagnosis was not associated with dietary calcium at Year 3 and there was little variation between Year 3 intake at the different centres when baseline dietary calcium was taken into account; there was a significantly lower mean dietary calcium intake in only one centre (Calgary) compared with the referent, St John's (B = -104 mg/day; 95% CI: -200; -7 mg/day).

Substitution of self reported diagnosis for the feedback diagnosis made no difference to the model for women; self reported diagnosis was not associated with the estimated dietary calcium intake at Year 3 when baseline dietary calcium was taken into account.

Substitution of Centre for Destination in the model for men led to a minimal increase in the strength of the association between the feedback diagnosis for both osteoporosis (B =169 mg/day; 95% CI: 65; 274 mg/day) and osteopenia (B = 119 mg/day; 95% CI: 29; 208 mg/day) and there was a statistically significant difference in the Year 3 dietary calcium intakes in the Kingston centre compared with the referent centre, Saint John's (B = 192 mg/day; 95% CI: -28; 357 mg/day). There were no changes to the association between the remaining variables and Year 3 dietary calcium intake.

Self-reported diagnosis (in place of feedback diagnosis) was not associated with dietary calcium in the adjusted model for men; men who reported that their diagnosis was osteoporosis (B = 99 mg/day; 95% CI: -60; 259 mg/day) or osteopenia (B = 65 mg/day; 95% CI: -38; 167 mg/day) did not report significantly different dietary intakes from those who believed that they had received a normal diagnosis.

7.3 Vitamin D Supplement Use

7.3.1 Vitamin D Supplement Use: Outcome Variable

Table 7.8: Frequency of Use of Vitamin D Supplements at Year 3 by Use of Vitamin D Supplements at Baseline

WOMEN	**Use of Vitamin D Supplements at Baseline**		
Use of Vitamin D Supplements at Year 3	No N (%)	Yes N (%)	Total N (%)
No	843 (68%)	134 (23%)	977 (53%)
Yes	400 (32%)	460 (77%)	860 (47%)
Total Women; N	1243	594	1837
MEN	**Use of Vitamin D Supplements at Baseline**		
Use of Vitamin D Supplements at Year 3	No N (%)	Yes N (%)	Total N (%)
No	569 (81%)	49 (29%)	618 (71%)
Yes	133 (19%)	118 (71%)	251 (29%)
Total Men; N	702	167	869

The proportions of participants who were taking Vitamin D supplements at Year 3 are shown in Table 7.8 stratified by whether they were using supplements at baseline. There was some uptake of Vitamin D supplements amongst those not taking them at baseline (32% in women and 19% in men), but nearly one quarter of the women and just over one quarter of the men who were taking supplements at baseline were no longer taking them at Year 3.

7.3.2 Factors Associated with Vitamin D Supplement Use: Univariate Analyses

There was a strong association between supplement use at baseline and supplement use at Year 3 for both women (χ^2= 330.7, df = 1; $p < 0.001$) and men (χ^2=175.6, df = 1; $p < 0.001$). There were also strong associations between receipt of a diagnosis of osteopenia or osteoporosis and supplement use at Year 3 in both women (χ^2= 84.6, df = 2; $p < 0.001$) and men (χ^2= 17.9, df

= 2; $p < 0.001$); use of Vitamin D supplements at baseline was evenly distributed across the diagnostic subgroups in men, but not in women (see Tables 5.4 and 5.5). In other univariate analyses, variables that were associated with baseline supplement use were associated with supplement use at Year 3 (older age, feedback to the participant directly and Centre for men and women, as well as being menopausal or having a lower body mass index in women).

Non-smoking status in men and being "non-white" in women, as well as higher education in both genders, were also associated with supplement use at Year 3; these same associations were not seen with baseline supplement use.

Self-reported diagnosis was significantly associated with Vitamin D supplement use at Year 3 in both women and men. It is notable that, although significantly fewer men than women with a diagnosis of osteoporosis were taking Vitamin D supplements at Year 3 ($\chi^2 = 25.95$; df = 1; $p < 0.001$), there was no significant difference between the proportion of men and women taking Vitamin D supplements amongst those who *recalled* a diagnosis of osteoporosis ($\chi^2 = 0.86$; df = 1; $p = 0.4$).

7.3.3 Potential Explanatory Factors Associated with Vitamin D Supplement Use: Multivariable Modelling

The results of multivariable regression modeling in which those variables that were associated with Vitamin D supplement use at Year 3 were examined in combination for each gender separately are presented in Table 7.9. The feedback diagnosis was included together with Destination (or Centre, see below) in all models together with baseline supplement use and age group. Finally, a recommendation for referral or treatment in the feedback was added to the model to adjust for any potential confounding effect on the association between the feedback Destination variable and Year 3 supplement use. All other variables were included in the models if they had a significant effect on the outcome in the multivariable model.

Table 7.9: Multivariable Logistic Regression Analysis of Factors Associated with Vitamin D Supplement Use at Year 3 for Women and Men

	WOMEN (N = 1813)[a]		MEN (N = 861)[b]	
	OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Baseline Vitamin D Supplement Use Yes	7.22 (5.71 – 9.14)	**<0.001**	10.58 (7.08 – 15.82)	**<0.001**
No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis				
Normal	*Referent*	-------	*Referent*	-----
Osteopenia	1.44 (1.13 – 1.85)	**0.003**	1.57 (1.05 – 2.32)	**0.03**
Osteoporosis	2.55 (1.86 - 3.50)	**<0.001**	1.86 (1.15 – 3.03)	**0.01**
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.19 (0.90 - 1.58)	0.2	0.94 (0.60 – 1.48)	0.8
To both	1.77 (1.29 - 2.44)	**< 0.001**	1.25 (0.75 – 2.32)	0.4
Recommendation Yes	2.42 (1.48 – 3.94)	**<0.001**	2.93 (1.56 – 5.52)	**0.001**
No	*Referent*	-----	*Referent*	-----
Age Group				
40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	1.17 (0.92 – 1.47)	0.2	1.15 (0.81 – 1.65)	0.4
Nagelkerke's R^2	0.29		0.30	

[a] Missing data on included variables for 24 women.
[b] Missing data on included variables for 8 men.

The results of the multivariable analysis demonstrated that even when Vitamin D supplement use at baseline and age group were taken into account, participants who received a low BMD diagnosis at baseline were more likely to report Vitamin D supplement use at Year 3. Women who received a diagnosis of osteoporosis were approximately 2.6 times more likely, and women who received a diagnosis of osteopenia were approximately 1.4 times more likely, to be taking Vitamin D supplements at Year 3 compared with those who received a normal diagnosis. Men who received a diagnosis of osteoporosis were 1.9 times more likely, and men who received a diagnosis of osteopenia were 1.6 times more likely to be taking Vitamin D supplements.

When the feedback was sent to both the participant and the FP, rather than only to the FP, there was a higher frequency of uptake by Year 3, in women. This same association was not seen in men. The subgroups of men and women who received a recommendation for referral to an osteoporosis clinic or for treatment were significantly more likely to report taking Vitamin D supplements at Year 3. Age group was not associated with Vitamin D supplement use at Year 3 in the adjusted model for women or men.

The most important indicator of Year 3 Vitamin D supplement use was baseline supplement use, as would be expected. Other variables that were found to be associated with Year 3 supplement use in the univariate analyses did not make a contribution to the multivariable model, which indicates that baseline supplement use and self-reported diagnosis are the stronger explanatory factors.

The association between a diagnosis of osteopenia and Vitamin D supplement use at Year 3 was reduced in both women (OR: 1.13; 95% CI: 0.86 – 1.48) and men (OR: 1.08; 95% CI: 0.70 – 1.66), and was not significant in models that were adjusted for Centre instead of Destination. The addition of Centre in place of Destination did not change the association between Year 3 supplement use and any of the other variables in the models, including that between a diagnosis of osteoporosis and Vitamin D supplement use. Overall, women in Toronto, Saskatoon and Calgary were more likely to take Vitamin D supplements when baseline use, diagnosis, age group and a recommendation for referral or treatment were taken into account. Vitamin D supplement use at Year 3, relative to their use at baseline, was lower in Quebec City and higher in Toronto than in the other centres for men.

When self reported diagnosis was substituted in the models above in place of feedback diagnosis, women who reported a diagnosis of osteopenia or osteoporosis were more than twice as likely to be using Vitamin D supplementation at Year 3. Men who reported a diagnosis of osteoporosis were 3.6 times as likely to report Vitamin D supplementation at Year 3 compared with those who believed that their diagnosis was normal. The confidence interval for the association between a self reported diagnosis of osteopenia and Vitamin D supplementation at Year 3 in men was larger than the equivalent confidence interval for a feedback diagnosis of osteopenia, and included the value 1.0 (OR: 1.54; 95% CI: 0.95 – 2.49), although the odds ratios were almost the same. The associations between Vitamin D supplementation at Year 3 and all of the other variables were comparable to the models that included feedback diagnosis shown in Table 7.9.

Investigation of Potential Effect Modification by Vitamin D Supplement Use at Baseline

When the model was estimated for only those women (N = 1,222) and men (N = 695) with data on all relevant variables who were *not* taking supplements at baseline, the association between diagnosis, destination of feedback, age group and a recommendation for referral or treatment with Year 3 Vitamin D supplement use remained the same as in the model above. Women and men who were not taking supplements at baseline and received a diagnosis of

osteoporosis or osteopenia were more likely to take Vitamin D supplements at Year 3; the odds ratios and confidence intervals for a recalled diagnosis of osteopenia or osteoporosis were very similar to those in the models with all participants included.

Amongst the smaller group of women who were taking Vitamin D supplements at baseline (N = 591), those who received a diagnosis of osteoporosis were significantly less likely to stop taking supplements by Year 3 (OR: 2.05; 95% CI: 1.06 – 3.96). There was no difference, however, between any of the "Destination" groups and no association between a recommendation for referral or treatment, or a feedback diagnosis of osteopenia and reported supplement use at Year 3 amongst those who were taking supplements at baseline.

The group of men who were taking supplements at baseline was relatively small (N =166), and some subgroups included very few men when the data were stratified by diagnosis, Destination and age group. Amongst the men who were taking Vitamin D supplements, there was a trend in univariate analyses towards less likelihood of stopping supplement use in men who received a diagnosis of osteoporosis, although the confidence interval was wide and included the value 1.0 (OR: 2.25; 95% CI: 0.85 – 5.93). As for the women, there was no association between a feedback diagnosis of osteopenia and reported Vitamin D supplement use for men who were taking supplements at baseline. There were too few numbers to assess these relationships by including the other variables in the model.

7.4 Participation in a Regular Exercise Program

7.4.1 Exercise Participation: Outcome Variable

The percentages of women and men who reported regular exercise participation at Year 3 are shown in Table 7.10 stratified by whether they reported participation at baseline. As can be seen from the table, there were approximately equal proportions (one third) of women in each of the baseline exercise participation groups who responded differently to the exercise question at Year 3. Thus, there was only a minor difference in the total number of women who reported participation in a regular exercise activity between baseline and Year 3; from 1013 women (55%) at baseline to 928 women (51%) at Year 3. Likewise, there was only a negligible difference between the percentages of men who reported regular exercise participation at baseline (53%) and regular participation at Year 3 (51%). It is notable that comparable percentages of men and women reported regular participation in an exercise program at Year 3.

Table 7.10: Frequency of Self-Reported Regular Exercise Participation at Year 3 by Baseline Self-Reported Exercise Participation

WOMEN	**Participation in Regular Activity or Program at Baseline**		
Participation in Regular Activity or Program at Year 3	No N (%)	Yes N (%)	Total N (%)
No	545 (66%)	364 (36%)	909 (49%)
Yes	279 (34%)	649 (64%)	928 (51%)
Total Women; N	824	1013	1837
MEN	**Participation in Regular Activity or Program at Baseline**		
Participation in Regular Activity or Program at Year 3	No N (%)	Yes N (%)	Total N (%)
No	292 (72%)	130 (28%)	422 (49%)
Yes	112 (28%)	334 (72%)	446 (51%)
Total Men; N	404	464	868

7.4.2 Factors Associated with Exercise Participation: Univariate Analyses

Participation in a regular program of exercise at Year 3 was strongly associated with such participation at baseline in both women (χ^2= 165.87; df = 1; $p < 0.001$) and men (χ^2= 169.35; df = 1; $p < 0.001$). Accordingly, exercise participation at Year 3 was associated with many of the same factors that were found to be associated with baseline exercise in women and men: Regular exercise at Year 3 was associated with non-smoking status, a university education and a higher self rated health status in both women and men. In women only, regular exercise at Year 3 was also associated with being in the lower quartiles for body mass index and being in the highest neighbourhood income quintile.

Exercise participation at Year 3 in women was associated with the 50-60 year age group, although there was no such association with baseline exercise participation. Further, participation in regular exercise at Year 3 was reported by 55% of the women who received a diagnosis of osteoporosis, 52% of those who received a diagnosis of osteopenia, and 48% of the

women who received a normal diagnosis. The exercise participation rates at Year 3 between the diagnostic groups were significantly different (χ^2= 5.87; df = 2; p = 0.05), which was not seen at baseline. Feedback to "FP only" and no recommendation for referral or treatment was associated with less exercise participation at Year 3 in women; these associations were different from those seen with baseline participation. The diagnosis received in the feedback was not associated with exercise participation at Year 3, in men, although there was a lower rate of exercise participation at baseline in those men who then received a diagnosis of osteoporosis (see Table 5.5). Exercise participation at Year 3 was not associated with the destination of the feedback or with a recommendation for referral or treatment in univariate analyses, nor was it associated with any of the remaining potential explanatory variables in men. As at baseline, exercise participation at Year 3 varied by Centre in men (from 36% participation in Quebec City to 70% participation in Halifax) and in women (from 36% participation in Saint John's to 69% participation in Vancouver).

7.4.3 Potential Explanatory Factors Associated with Exercise Participation: Multivariable Modelling

The results of multivariable regression modeling in which those variables that were associated with regular exercise participation at Year 3 were examined in combination for women and men separately are presented in Table 7.11. As with the other behavioural models, feedback diagnosis, destination of the feedback, a recommendation for referral or treatment and age group were included in all models together with any explanatory variables that were found to significantly improve the model.

Women in the older age group, those with a university education, those in the lowest quartile for body mass index, and current non-smokers, as well as those who may be considered "healthier" (by indicating very good or excellent self-rated health or indicating no history of rheumatoid arthritis or an eating disorder) were more likely to participate in a regular exercise program at Year 3 when baseline rates of participation were taken into account. In addition, those women who received their feedback directly, and those whose feedback included a recommendation for referral or treatment, were more likely to report exercise participation. There was no association in the adjusted model between a diagnosis of osteopenia or osteoporosis and regular exercise at Year 3.

Table 7.11: Multivariable Logistic Regression Analysis of Factors Associated with Exercise Participation at Year 3 for Women and Men

		WOMEN (N = 1807)[a] OR (95% C.I.)	p	MEN (N = 860)[b] OR (95% C.I.)	p
Regular Exercise Participation at Baseline					
	Yes	3.25 (2.65 – 3.99)	**<0.001**	6.43 (4.73 – 8.76)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis					
	Normal	*Referent*	-----	*Referent*	-----
	Osteopenia	1.05 (0.83 - 1.32)	0.7	0.98 (0.69 – 1.38)	0.9
	Osteoporosis	1.00 (0.73 - 1.36)	1.0	0.81 (0.52 – 1.26)	0.3
Destination	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	1.40 (1.08 - 1.83)	**0.01**	0.93 (0.63 – 1.37)	0.7
	To both	1.36 (1.01 – 1.84)	**0.05**	0.98 (0.62 – 1.56)	0.9
Recommendation	Yes	2.01 (1.29 –3.14)	**0.002**	1.86 (0.99 – 3.50)	0.06
	No	*Referent*	-----	*Referent*	-----
Age Group	40 to 49 years	*Referent*	-----	*Referent*	-----
	50 to 60 years	1.27 (1.02 – 1.59)	**0.03**	0.84 (0.61 – 1.15)	0.3
BMI	Lowest Quartile	1.44 (1.07 – 1.93)	**0.02**		
	Second Lowest Quartile	0.97 (0.72 – 1.29)	0.8		
	Second Highest Quartile	0.85 (0.64 – 1.12)	0.2		
	Highest Quartile	*Referent*	-----		
Education					
	Incomplete High School	0.51 (0.37 – 0.70)	**<0.001**	0.55 (0.36 – 0.85)	**0.008**
	Complete High School	0.59 (0.42 – 0.83)	**0.002**	0.54 (0.34 – 0.87)	**0.01**
	Postsecondary Education	0.66 (0.50 – 0.89)	**0.005**	0.56 (0.38 – 0.82)	**0.003**
	University Degree	*Referent*	-----	*Referent*	-----
History of Comorbidity	Yes	0.62 (0.39 – 0.98)	-----		
	No	*Referent*	**0.04**		
Self Reported Health					
	Poor/Fair/Good	*Referent*	-----		
	Very Good/Excellent	1.36 (1.10 – 1.68)	**0.02**		
Current Cigarette Smoker	Yes	0.71 (0.54 – 0.93)	**0.02**		
	No	*Referent*	-----		
Nagelkerke's R^2		0.17		0.27	

[a] Missing data on included variables for 30 women.
[b] Missing data on included variables for 9 men.

In men, the only significant predictors of exercise participation three years after BMD testing were whether they were participating in regular exercise at baseline and a higher education level (university education). The diagnosis received in the feedback was not associated with participation in exercise three years after their BMD testing in men and there

was no association between exercise participation and the destination of the feedback in the adjusted model.

The models for both women and men remained essentially the same when Centre was added in place of Destination. There was significant variation between the Centres in the adjusted models: Women in the Saint John's centre were the least likely, and women in the Vancouver centre were the most likely, to report exercise participation at Year 3 once baseline participation rates were taken into account (together with diagnosis, age group, quartile of body mass index, smoking status, self rated health status, history of comorbidity, education level and a recommendation for referral or treatment). Compared with those in Saint John's, men in Vancouver, Halifax, Hamilton and Calgary were more likely to report exercise participation at Year 3 even when baseline participation (as well as diagnosis, age group, education level and a recommendation for referral or treatment) was taken into account.

When self-reported diagnosis was substituted in the models above in place of feedback diagnosis, women who reported a diagnosis of osteoporosis (OR: 0.65; 95% CI: 0.44 – 0.97), or who did not know their diagnosis (OR: 0.71; 95% CI: 0.55 – 0.91), were *less* likely to participate in regular exercise at Year 3 compared with those who reported a normal diagnosis. There was no association between a self reported diagnosis of osteopenia and exercise participation at Year 3 in women and the associations between exercise participation at Year 3 and all of the other variables were comparable to the model that included feedback diagnosis shown on the left side of Table 7.11. No association between a self reported diagnosis of osteoporosis and exercise participation was observed in men; men who reported a diagnosis of osteoporosis or osteopenia, or who did not know their diagnosis, were no more or less likely to participate in exercise at Year 3 than those who reported a normal diagnosis. Likewise, all other associations between Year 3 exercise participation and the variables in the adjusted model were essentially the same when self reported diagnosis was substituted for feedback diagnosis.

Investigation of Potential Effect Modification by Exercise Participation at Baseline

No interactions were evident between baseline exercise participation and the other main variables in the model. The direction of all associations was the same for women and men who participated in regular exercise at baseline as they were for women and men who did not participate in regular exercise at baseline.

7.5 Current Use of Osteoporosis-Related Medications

7.5.1 Use of Osteoporosis-Related Medications: Outcome Variable

Amongst those participants who were taking a medication for the prevention or treatment of osteoporosis at baseline, the single man and one of the eight women were no longer taking medications at Year 3. The number of participants taking any bisphosphonate or raloxifene had increased by Year 3 to 109 (6%) of the women[48] and 28 (3%) of the men.[49] The following analyses of men provide an examination of medication use, measured at Year 3, amongst men not taking medication at baseline (the man who reported baseline use of a bisphosphonate was excluded from these analyses). Because there were so few men taking osteoporosis medication at Year 3, however, the analyses were limited to descriptive and univariate statistics.

Five hundred and sixty seven (89%) of the women who reported ovarian hormone therapy (OHT) at baseline were on therapy three years later, while 251 (21%) of those who had not been on OHT therapy at baseline were taking OHT at Year 3.[50] Because OHT therapy was a primary choice for the prevention or treatment of osteoporosis in menopausal women during the time of this study, reported use of OHT or the use of any other medication for the prevention or treatment of osteoporosis in women were combined into one variable.[51] One percent of the women who were classified as taking either OHT or osteoporosis medications at baseline were taking raloxifene or bisphosphonates with or without OHT. At Year 3, this proportion had increased to 12% of "current osteoporosis medication users". Table 7.12 shows the percentage of women who reported osteoporosis-related medication use at Year 3 stratified by osteoporosis-related medication use at baseline.

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[48] 41 were using alendronate, 60 used etidronate, 8 were taking raloxifene and 1 woman was taking clodronate.
[49] !0 men were using alendronate and 18 were using etidronate.
[50] Information is missing regarding OHT use at Year 3 for 3 women.
[51] OHT is and was often prescribed for reasons other than osteoporosis risk. Limited, mostly descriptive, analysis of the small number of women who were taking other osteoporosis medications has been provided, but OHT use has been included in this main analysis, because of its pervasive use in both the treatment and prevention of osteoporosis in this age group of women.

Table 7.12: Frequency of Osteoporosis Related Medication Use at Year 3 by Baseline Osteoporosis Related Medication Use in Women

WOMEN	**Use of OHT or Osteoporosis Medication at Baseline**		
Use of OHT or Osteoporosis Medication at Year 3	No N (%)	Yes N (%)	Total N (%)
No	893 (75%)	65 (10%)	958 (52%)
Yes	299 (25%)	577 (90%)	928 (48%)
Total Women; N	1192	642	1837

7.5.2 Factors Associated with Use of Osteoporosis-Related Medications: Univariate Analyses

As is clear from Table 7.12, use of osteoporosis-related medications at Year 3 was strongly associated with the use of such medications at baseline ($\chi^2 = 702.1$; df = 1; $p < 0.001$); most women who were taking OHT or medications for the prevention or treatment of osteoporosis continued to take these medications at Year 3, and one quarter of those who were not taking these medications at baseline were taking them at Year 3.

Consequently, use of medications in women at Year 3 was associated with many of the same factors that were associated with baseline use; older age group, menopausal status, a previous diagnosis of osteoporosis, a family history of osteoporosis and a history of exposure to corticosteroids or anticonvulsants.

Use of medication at Year 3 was lower in the group of women who fell in the highest quartile of the body mass distribution compared with the lighter women; this association was not evident at baseline. In addition, women who described themselves as "white" were more likely to be taking osteoporosis related medications at Year 3, than they were at baseline, although this was due to a specific association between OHT use and "white" race/ethnicity. In contrast, women who described themselves as "non-white" were more likely to be taking other medications related to osteoporosis prevention or treatment and less likely to be on OHT.

Medication use was the same at Year 3 across the Feedback Destination groups and across the centres, even though baseline use varied by Destination and by Centre, indicating that

changes in use of osteoporosis related medication were not consistent across the Destination groups and Centres. Medication use at Year 3 was significantly greater amongst women who had received a recommendation for referral or treatment in their feedback.

In univariate analysis there was evidence that women started osteoporosis therapy as a result of their diagnosis. A feedback diagnosis of osteoporosis at Year 3 was significantly associated with use of osteoporosis-related medication at Year 3. Likewise, such use was associated with a recalled diagnosis of osteoporosis. Osteoporosis-related current medication use at baseline was evenly distributed across the diagnostic groups (either feedback or recalled); women who received a diagnosis of osteoporosis at Year 3 were no more likely to have been taking any medications at baseline (although the eight women who were taking bisphosphonates, rather than OHT, at baseline all later received a feedback diagnosis of osteoporosis). Table 7.13 shows the continuation or uptake of osteoporosis related medications in women stratified by their BMD test results. Significantly more of those women who received a report of a diagnosis of osteopenia or osteoporosis had started a therapy by Year 3. There were no differences, on the other hand, between the diagnostic groups in the "continuation" of medications (women were no more likely to have stopped taking medication if their diagnosis was normal as opposed to low).

Table 7.13: Osteoporosis Related Medication Use at Year 3 in Women Stratified by Feedback Diagnosis and Baseline Use of Medications

	Feedback Diagnosis		
CONTINUATION **Osteoporosis Related Medication Use at Baseline** **N = 637**[a]	**Normal** N = 347 N (%)	**Osteopenia** N = 184 N (%)	**Osteoporosis** N = 106 N (%)
Osteoporosis-Related Medication Use at Year 3	311 (90%)	161 (88%)	101 (95%)
UPTAKE **No Osteoporosis Related Medication Use at Baseline** **N = 1179**[b]	**Normal** N = 595 N (%)	**Osteopenia** N = 378 N (%)	**Osteoporosis** N = 206 N (%)
Osteoporosis-Related Medication Use at Year 3	112 (19%)	91 (24%)	95 (46%)

[a] Data were missing for 6 of the women who were taking osteoporosis related medications at baseline.
[b] Data were missing for 15 of the women who were not taking osteoporosis related medication at baseline.

Men who were taking osteoporosis-related medications at Year 3 were more likely to be in the older age group, to be in the lowest quartile for body mass index or to have received a diagnosis of osteoporosis; the associations between age, size and medication uptake were due to the association between diagnosis and medication uptake, however (older, smaller men were more likely to be provided with an "abnormal" diagnosis). There was no association between the destination of the feedback and medication uptake and no other factors were associated with uptake of medications by men. The distribution of uptake of osteoporosis-related medication in men is shown in Table 7.14, stratified by diagnosis. Significantly more of the men who received a diagnosis of osteopenia or osteoporosis had started a therapy by Year 3.

Only 14% of the men who received a diagnosis of osteoporosis were taking any osteoporosis-related medications three years after BMD testing. As noted in Chapter 5, a large proportion of men who received a feedback diagnosis of osteoporosis were unable to recall this diagnosis correctly. Of the men who reported that they had received a diagnosis of osteoporosis in the feedback that was sent to their FP or to themselves directly, only 36% were taking osteoporosis-related medications at Year 3. The number of men with a feedback diagnosis or a recalled diagnosis of osteoporosis who were taking medications was too small to adequately investigate the potential influence of the destination of feedback on medication uptake in this group.

Table 7.14: Osteoporosis Related Medication Uptake at Year 3 in Men Stratified by Feedback Diagnosis

	Diagnosis		
UPTAKE of Osteoporosis Related Medication N = 864[a]	**Normal N = 391** N (%)	**Osteopenia N = 300** N (%)	**Osteoporosis N = 173** N (%)
Osteoporosis Related Medication use at Year 3	0 (0%)	4 (1%)	24 (14%)

[a] The one man who was taking osteoporosis medication at baseline was excluded and there were missing data for a further 4 men.

7.5.3 Potential Explanatory Factors Associated with Use of Osteoporosis-Related Medications in Women: Multivariable Modelling

The results of multivariable regression modelling in which those variables that were associated with OHT or osteoporosis medication use at Year 3 in women were examined in combination are presented in Table 7.15. Baseline osteoporosis-related medication use, the

feedback diagnosis, destination of the feedback, a recommendation for referral or treatment, and age group were included in the model together with any other explanatory variables that were found to significantly improve the model.

Table 7.15: Multivariable Logistic Regression Analysis of Factors Associated with Current Use of Medication at Year 3 for Women

		WOMEN (N = 1799)[a]	
		OR (95% C.I.)	**p**
Baseline OHT or Osteoporosis Medication Use	Yes	27.35 (19.82 – 37.34)	**<0.001**
	No	*Referent*	-----
Feedback Diagnosis	Normal	*Referent*	-------
	Osteopenia	0.94 (0.70 – 1.27)	0.6
	Osteoporosis	2.19 (1.51 – 3.18)	**<0.001**
Destination	To FP only	*Referent*	-----
	To participant only	0.91 (0.65 – 1.26)	0.6
	To both	1.14 (0.78 – 1.65)	0.5
Recommendation	Yes	1.71 (1.05 – 2.77)	**0.03**
	No	*Referent*	-----
Age Group	40 to 49 years	*Referent*	-----
	50 to 60 years	1.84 (1.35 – 2.51)	**<0.001**
Body Mass Index			
	Lowest Quartile	2.25 (1.55 – 3.27)	**<0.001**
	Second Lowest Quartile	2.11 (1.47 – 3.03)	**<0.001**
	Second Highest Quartile	1.65 (1.15 – 2.37)	**0.006**
	Highest Quartile	*Referent*	-----
Reproductive Status	Premenopausal	*Referent*	----
	Naturally Menopausal	0.91 (0.65 – 1.28)	0.6
	Surgically Menopausal	1.26 (0.71 – 2.23)	0.4
	Premenopausal Hysterectomy	1.64 (1.13 – 2.38)	**0.01**
Awareness of a Family History	Yes	1.56 (1.13 – 2.15)	**0.007**
	No	*Referent*	-----
	Nagelkerke's R^2	0.52	

[a] Missing data on included variables for 38 women.

The most parsimonious model for women's medication use at Year 3 indicated that they were more likely to be taking OHT or osteoporosis-related medication at Year 3 if they had received a diagnosis of osteoporosis from their baseline testing. Women with a diagnosis of osteoporosis were 2.2 times more likely than those who received a normal diagnosis to be taking some form of therapy, even when baseline use of medication and other significant confounders

(age group, menopausal status, quartile of body mass index, awareness of a family history of osteoporosis and a recommendation for referral or treatment) were taken into account.

Women in the older age group were more likely to be taking medication at Year 3, as were women with a family history of osteoporosis or osteopenia, women who had an average or smaller body mass index or those who had undergone a premenopausal hysterectomy. Women who received a recommendation for referral or treatment in their feedback were more likely to be taking medications at Year 3. The destination of the feedback was not associated with medication use, however, in univariate or multivariable analysis, and its removal or inclusion in the model did not change the coefficients of the remaining variables.

The model shown in Table 7.15 was not changed significantly by the substitution of Centre in place of Destination and there was no significant variation between the Centres in medication use at Year 3, in the adjusted models.

When self reported diagnosis was substituted in the model above in place of feedback diagnosis, women who reported that their diagnosis was osteoporosis were nearly 4 times more likely to be using osteoporosis-related medication at Year 3 compared with those who recalled a normal diagnosis (OR: 3.82; 95% CI: 2.40 – 6.09). Women who recalled a diagnosis of osteopenia were no more likely to be taking these medications at Year 3, and the associations between osteoporosis-related medication use at Year 3 and all of the other variables were comparable to the model that included feedback diagnosis shown in Table 7.15.

Investigation of Potential Effect Modification by Baseline Use of Osteoporosis Related Medication at Baseline in Women

No interactions were evident between baseline medication use and the other main variables in the model. The direction of all associations was the same for women who did and did not use osteoporosis-related medication at baseline.

7.6 Cigarette Smoking

7.6.1 Smoking Status: Outcome Variable

Few men and women changed their cigarette smoking status between baseline and Year 3. One fifth of the baseline smokers (22% of the women and 21% of the men) were not smoking at Year 3, while 1% of women and 2% of men who were not smoking at baseline were smoking at Year 3 (See Table 7.16). None of the men and women who were "non-smokers" at baseline

and then reported being current smokers at Year 3 had taken up smoking for the first time during the three years between baseline and follow up (i.e., they were all relapsed smokers).

Table 7.16: Smoking Status at Year 3 by Baseline Smoking Status

WOMEN	**Current Smoker at Baseline**		
Current Smoker at Year 3	No N (%)	Yes N (%)	Total N (%)
No	1511 (99%)	67 (22%)	1578 (86%)
Yes	20 (1%)	237 (78%)	257 (14%)
Total Women; N	1531	304	1835
MEN	**Current Smoker at Baseline**		
Current Smoker at Year 3	No N (%)	Yes N (%)	Total N (%)
No	671 (98%)	38 (21%)	709 (82%)
Yes	12 (2%)	147 (79%)	159 (18%)
Total Men; N	683	185	868

7.6.2 Factors Associated with Smoking Status: Univariate Analyses

As would be expected, there was a very strong association between baseline smoking status and current smoking status at Year 3, and the majority of the factors that were associated with Year 3 smoking status were the same as those that were associated with baseline status. In both women and men, those who reported very good or excellent health, those with the highest education level and those whose feedback went to both the participant and the FP were less likely to be current smokers at Year 3 (smokers were not evenly distributed across the Destination categories at baseline, see Tables E.1 and E.2, Appendix E). The women who reported that they were "white" or were premenopausal were more likely to be current smokers at Year 3. In men, smoking status at Year 3 varied across the neighbourhood income quintiles and in both men and women there was small variation between the centres.

Women who were smokers at Year 3 were more likely to have received a diagnosis of osteoporosis ($\chi^2 = 6.38$; df = 2; p = 0.04), although this association was not evident with baseline smoking status. There was no association between smoking status at Year 3 and the feedback

diagnosis in men, however, even though there was a greater frequency of male smokers at baseline amongst those who received a diagnosis of osteoporosis (see Table 5.5).

7.6.3 Potential Explanatory Factors Associated with Smoking Status: Multivariable Modelling

The results of multivariable regression modeling in which those variables that were associated with smoking status at Year 3 were examined in combination for each gender separately are presented in Table 7.17.

Table 7.17: Multivariable Logistic Regression Analysis of Factors Associated with Smoking Status at Year 3 for Women and Men

		WOMEN (N = 1811)[a]		MEN (N = 860)[b]	
		OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Baseline Current Smoker	Yes	298.04 (171.91-516.71)	**0.001**	220.62 (110.32-441.22)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis					
	Normal	*Referent*	------	*Referent*	-----
	Osteopenia	1.34 (0.78 – 2.33)	0.3	1.35 (0.65 – 2.80)	0.4
	Osteoporosis	2.13 (1.05 – 4.31)	**0.04**	0.94 (0.41 – 2.16)	0.9
Destination	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	0.77 (0.41 - 1.45)	0.4	1.59 (0.75 – 3.37)	0.2
	To both	0.82 (0.39 - 1.74)	0.6	1.05 (0.38 – 2.92)	0.9
Recommendation	Yes	0.20 (0.06 – 0.64)	**0.007**	1.71 (0.50 – 5.91)	0.4
	No	*Referent*	-----	*Referent*	-----
Age Group	40 to 49 years	*Referent*	-----	*Referent*	-----
	50 to 60 years	1.07 (0.63 – 1.80)	0.8	0.72 (0.38 – 1.36)	0.3
Nagelkerke's R^2		0.74		0.79	

[a] Missing data on included variables for 26 women.
[b] Missing data in included variables for 9 men.

Women who received a diagnosis of osteoporosis were *more* likely to be current smokers at Year 3 even when baseline smoking status was taken into account (while also controlling for Destination, age group and a recommendation for referral or treatment). This association was due to a smaller percentage of women stopping smoking between baseline and Year 3 in the osteoporosis group; the few women who relapsed to smoking were evenly distributed across the groups. Women who received a recommendation for referral or treatment were more likely to stop smoking by Year 3 than were those who did not receive such a recommendation; this observation is based on a small group of women, however, and should be interpreted cautiously

because of empty cells, and almost complete nesting of the variable within one centre and the low BMD diagnosis variables (osteoporosis and osteopenia).

The only significant predictor of whether men were current smokers at Year 3 was whether they reported that they were smoking at baseline, no other variables under consideration, including the diagnosis and the destination of the feedback, were associated with smoking status at Year 3 when baseline smoking status was taken into account.

The association between a diagnosis of osteopenia and smoking status at Year 3 was increased in women (OR: 1.93; 95% CI: 1.03 – 3.65) in models that were adjusted for Centre instead of Destination; women who received a diagnosis of osteopenia were less likely to give up smoking compared with those who received a normal diagnosis. The addition of Centre in place of Destination did not change the association between smoking status and any of the other variables in the models, including that between a diagnosis of osteoporosis and smoking status. There were no significant differences between the centres when baseline smoking status, the feedback diagnosis, a recommendation for referral or treatment and age group were taken into account and Centre was substituted for Destination in the model for women or for men. Furthermore, there were no substantive changes to the model for men when the destination variable was replaced by the Centre variable.

When self reported diagnosis was substituted in the models in place of feedback diagnosis, women who reported that their diagnosis was osteoporosis were less likely to have stopped smoking by Year 3 and the associations between the other variables in the model and smoking status at Year 3 were very similar to those shown in Table 7.17. As with feedback diagnosis, self-reported diagnosis was not associated with smoking status at Year 3 in men when baseline smoking status, Destination, a recommendation for referral or treatment and age group were taken into account.

7.7 High Alcohol Use

7.7.1 High Alcohol Use: Outcome Variable

At Year 3, 4% of the women and 16% of the men reported that they drank an average of two or more alcoholic drinks per day in the past year ("high alcohol users"). The frequency of "high alcohol use" stratified by baseline alcohol use is shown in Table 7.18. The greater changes were seen amongst those who were classified as high alcohol users at baseline; more than one half of the women and one third of the men were no longer drinking two or more drinks per day by Year 3.

Table 7.18: Frequency of High Alcohol Use at Year 3 by Baseline High Alcohol Use

WOMEN	**High Alcohol Use (2+ drinks/day) at Baseline**		
High Alcohol Use (2+ drinks/day) at Year 3	No N (%)	Yes N (%)	Total N (%)
No	1704 (98%)	48 (55%)	1752 (96%)
Yes	42 (2%)	40 (45%)	82 (4%)
Total Women; N	1746	88	1834
MEN	**High Alcohol Use (2+ drinks/day) at Baseline**		
High Alcohol Use (2+ drinks/day) at Year 3	No N (%)	Yes N (%)	Total N (%)
No	684 (93%)	46 (34%)	730 (84%)
Yes	48 (7%)	89 (66%)	137 (16%)
Total Men; N	732	135	867

7.7.2 Factors Associated with High Alcohol Use: Univariate Analyses

As can be seen from Table 7.18, high alcohol use at Year 3 was strongly associated with heavy use at baseline in both women ($\chi^2 = 363.5$; df = 1; $p < 0.001$) and men ($\chi^2 = 301.9$; df = 1; $p < 0.001$). Alcohol use (≥ 2 drinks/day) was also associated therefore with factors that were associated with baseline high alcohol use (current smoking at baseline in women and in men and a university education in women). High alcohol use at Year 3 was associated with a normal diagnosis from the BMD test in men ($\chi^2 = 10.26$; df = 2; $p = 0.006$), as was high alcohol use at baseline (see Table 5.5). Although there was no significant association between quartile of body mass index and high alcohol use at baseline in women, a lower frequency of high alcohol use at Year 3 was evident in the women who were in the highest quartile of the body mass index distribution ($\chi^2 = 7.80$; df = 3; $p = 0.05$). The frequency of Year 3 high alcohol use also showed some variation across the centres in men (but not in women); the pattern of variation across the centres was comparable to that seen with baseline high alcohol use. High alcohol use in women, or in men, was not associated with the destination of the feedback, age group or any of the remaining potential covariates.

7.7.3 Potential Explanatory Factors Associated with High Alcohol Use: Multivariable Modeling

The results of multivariable regression modeling in which those variables that were associated with high alcohol use at Year 3 were examined in combination for each gender separately are presented in Table 7.19.

Table 7.19: Multivariable Logistic Regression Analysis of Factors Associated with Alcohol Intake of Two or More Drinks per Day at Year 3 for Women and Men

	WOMEN (N = 1810)[a]		MEN (N = 859)[b]	
	OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Baseline Alcohol ≥ 2 drinks/day Yes	34.34 (19.71–59.82)	**<0.001**	29.73 (18.33–48.24)	**<0.001**
No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis				
Normal	*Referent*	-----	*Referent*	-----
Osteopenia	0.62 (0.33 - 1.14)	0.1	0.72 (0.42 – 1.22)	0.2
Osteoporosis	0.80 (0.37 – 1.70)	0.6	0.57 (0.28 – 1.19)	0.1
Destination To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.24 (0.61 – 2.53)	0.6	1.25 (0.69 – 2.26)	0.4
To both	1.13 (0.49 - 2.57)	0.8	1.94 (0.95 – 3.96)	0.07
Recommendation Yes	0.64 (0.24 – 2.05)	0.4	0.64 (0.23 – 1.78)	0.4
No	*Referent*	-----	*Referent*	-----
Age Group 40 to 49 years	*Referent*	-----	*Referent*	-----
50 to 60 years	1.33 (0.76 – 2.34)	0.3	0.78 (0.48 – 1.26)	0.3
Education				
Incomplete High School	0.25 (0.11 – 0.58)	**0.001**		
Complete High School	0.63 (0.31 – 1.28)	0.2		
Postsecondary Education	0.42 (0.22 – 0.79)	**0.007**		
University Degree	*Referent*	-----		
Current Cigarette Smoker Yes	2.10 (1.17 – 3.77)	**0.01**		
No	*Referent*	-----		
Nagelkerke's R^2	0.30		0.42	

[a] Missing data on included variables for 27 women.
[b] Missing data on included variables for 10 men.

Women who reported that they had been consuming two or more alcoholic drinks per day over the last year were more likely to be current smokers at baseline and to be in the highest education category even when "high alcohol intake" at baseline was taken into account (while also controlling for feedback diagnosis, Destination, age group and a recommendation for referral or treatment). This association was due to an increased likelihood that women who

smoked or women with a university degree would have passed the "two or more drinks per day" threshold at Year 3. It is important to note that these women reported higher average drinks per day at baseline overall, even amongst only those who were not classified as "high alcohol users". For this reason, although smokers and those within the highest education level were more likely to be "high alcohol users" at Year 3, they did not necessarily increase their total alcohol intake greater than did other subgroups (or decrease their intake less than other subgroups) because they were already using higher amounts of alcohol at baseline.

The diagnosis received in the feedback, destination of the feedback, a recommendation for referral or treatment and age group were not associated with high drinking status at Year 3 in women or men. The only significant predictor of high drinking status in men was whether they reported similarly high alcohol intake at baseline.

When "Centre" was added to the models in place of "Destination" there were no substantive changes to the models for women or men and there were no significant differences between high alcohol use rates at Year 3 between the centres when baseline high alcohol use was taken in to account. Likewise, when self reported diagnosis was added to the models in place of feedback diagnosis, the models were essentially unchanged; self reported diagnosis was not associated with high alcohol use at Year 3 in women or men. The only variables associated with high alcohol use at Year 3, other than high alcohol use at baseline, were a higher level of education and being a smoker at baseline in women.

7.8 Caffeine Intake

7.8.1 High Coffee Intake: Outcome Variable

At Year 3, 10% of the women and 22% of the men reported that they drank an average of four or more cups of coffee per day in the past year ("high coffee intake"). The frequency of women with a "high coffee intake" at Year 3 stratified by baseline high coffee intake is shown in Table 7.20. The greater changes were seen amongst those who were classified as high coffee drinkers at baseline; 55% these women and 39% of these men were no longer drinking four or more cups of coffee per day by Year 3.

Table 7.20: Frequency of High Caffeine Use at Year 3 by Baseline High Caffeine Use

WOMEN	**High Coffee Intake (≥ 4 cups of coffee/day) at Baseline**		
High Coffee Intake (≥4 cups of coffee/day) at Year 3	No N (%)	Yes N (%)	Total N (%)
No	1486 (96%)	162 (55%)	1648 (90%)
Yes	54 (4%)	135 (45%)	189 (10%)
Total Women; N	1540	297	1837
MEN	**High Coffee Intake (≥ 4 cups of coffee/day) at Baseline**		
High Coffee Intake (≥4 cups of coffee/day) at Year 3	No N (%)	Yes N (%)	Total N (%)
No	581 (93%)	94 (39%)	675 (78%)
Yes	46 (7%)	147 (61%)	118 (22%)
Total Men; N	627	241	868

7.8.2 Factors Associated with High Coffee Intake: Univariate Analyses

As can be seen from Table 7.20, high coffee intake at Year 3 was strongly associated with heavy use at baseline in both women ($\chi^2 = 474.7$; df = 1; $p < 0.001$) and men ($\chi^2 = 289.9$; df = 1; $p < 0.001$). High coffee use at Year 3 was also associated therefore with factors that were associated with baseline high coffee use (smoking status at baseline in women and men and feedback to the participant only, being "white", and Centre, in women). High coffee use at Year 3 was associated with a feedback diagnosis of osteopenia from the BMD test in men ($\chi^2 = 9.00$; df = 2; $p = 0.01$), this same association with a subsequent diagnosis of osteopenia was also evident at baseline, although it was only marginal ($\chi^2 = 5.64$; df = 2; $p = 0.06$). Although there was no significant association between either menopausal status or quartile of body mass index and high coffee use at baseline in women, high coffee use at Year 3 was less frequent in the women with a history of premenopausal hysterectomy or surgical menopause ($\chi^2 = 9.85$; df = 3; $p = 0.02$) and more frequent in those who were in the highest quartile of body mass index ($\chi^2 =$

19.5; df = 3; $p < 0.001$). The frequency of high coffee use at Year 3 also showed some variation across the centres in men ($\chi^2 = 15.5$; df = 8; $p = 0.05$), although the variation between the centres was not statistically significant at baseline. Likewise, race and a history of exposure to relevant medication in men and age group in women were not significantly associated with Year 3 high coffee intake, even though these factors were associated with high coffee intake at baseline. High coffee use was not associated with the diagnosis received in the feedback in women, or with the destination of the feedback in men, and was not associated with any of the remaining potential covariates.

7.8.3 Potential Explanatory Factors Associated with High Coffee Intake: Multivariable Modelling

The results of multivariable regression modelling in which those variables that were associated with high coffee intake at Year 3 were examined in combination for each gender separately are presented in Table 7.21.

Both women and men who reported at Year 3 that they had been consuming more than four cups of coffee per day over the last year were more likely to be current smokers at baseline even when "high coffee intake" at baseline was taken into account (while also controlling for feedback diagnosis, destination of the feedback, age group and a recommendation for referral or treatment as well as reproductive status and quartile of body mass index in women).

The diagnosis received in the feedback, destination of the feedback, a recommendation for referral or treatment and age group were not associated with high coffee intake at Year 3 in women. A high body mass index in women was however significantly associated with high coffee intake at Year 3 in the adjusted analysis. Women with a history of surgical menopause or premenopausal hysterectomy were less likely to have a high coffee intake at Year 3 in comparison with the premenopausal women.

Other than baseline high coffee intake and smoking status, the only factor that was associated with high coffee intake at Year 3 in the adjusted model for men was having received a diagnosis of osteopenia. Men in this diagnostic subgroup were more likely to have a high coffee intake at Year 3 than were those who received a normal diagnosis. A comparable association was not seen with a diagnosis of osteoporosis; the destination of the feedback, a recommendation for referral or treatment and age group were also not associated with high coffee intake at Year 3 in men.

Table 7.21: Multivariable Logistic Regression Analysis of Factors Associated with Drinking Four or More Cups of Coffee per Day at Year 3 for Women and Men

		WOMEN (N = 1808)[a] OR (95% C.I.)	p	MEN (N = 860)[b] OR (95% C.I.)	p
Baseline ≥ 4 Coffee drinks/day	Yes	20.25 (13.96-29.38)	**<0.001**	17.47 (11.64-26.20)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis					
	Normal	*Referent*	-----	*Referent*	-----
	Osteopenia	1.35 (0.89 - 2.06)	0.2	1.64 (1.04 - 2.58)	**0.03**
	Osteoporosis	0.82 (0.44 - 1.52)	0.5	1.08 (0.59 - 1.97)	0.8
Destination	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	1.32 (0.81 – 2.17)	0.3	1.24 (0.74 – 2.09)	0.4
	To both	0.71 (0.38 – 1.31)	0.3	1.16 (0.61 – 2.20)	0.7
Recommendation	Yes	0.91 (0.35– 2.34)	0.8	0.91 (0.53 – 1.23)	0.8
	No	*Referent*	-----	*Referent*	-----
Age Group	40 to 49 years	*Referent*	-----	*Referent*	-----
	50 to 60 years	1.02 (0.65 – 1.61)	0.9	0.81 (0.53 – 1.23)	0.3
Body Mass Index					
	Lowest Quartile	0.39 (0.23 – 0.66)	**0.001**		
	Second Lowest Quartile	0.54 (0.33 – 0.89)	**0.02**		
	Second Highest Quartile	0.42 (0.25 – 0.69)	**0.001**		
	Highest Quartile	*Referent*	-----		
Reproductive Status					
	Premenopausal	*Referent*	-----		
	Naturally Menopausal	0.88 (0.54 – 1.42)	0.6		
	Surgically Menopausal	0.42 (0.18 – 0.98)	**0.05**		
	Premenopausal Hysterectomy	0.40 (0.22 – 0.73)	**0.003**		
Current Cigarette Smoker	Yes	2.10 (1.39 – 3.18)	**<0.001**	2.56 (1.63 – 4.02)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Nagelkerke's R^2		0.39		0.44	

[a] Missing data on included variables for 29 women.
[b] Missing data on included variables for 9 men.

When "Centre" was added to the models in place of "Destination" there were no substantive changes to the model for women and there were no significant differences between high coffee intake rates at Year 3 between the centres when baseline high coffee intake was taken into account. Likewise, there were no significant differences between the centres when baseline high coffee intake was taken into account for men; a diagnosis of osteopenia was not, however, significantly associated with increased higher coffee intake in men when the analysis was adjusted for Centre (as well as baseline high coffee intake, age group, a recommendation for referral or treatment and smoking status) (OR: 1.41; 95% CI: 0.84 – 2.37). Baseline high coffee

intake and smoking status (at baseline) were the only significant predictors of high coffee intake at Year 3 for men in multivariate analysis adjusted for Centre and the remaining covariates (excluding Destination) on the right side of Table 7.21.

When self reported diagnosis was added to the models in place of feedback diagnosis, a self reported diagnosis of osteopenia, osteoporosis, or a response of "don't know", was not associated with high coffee intake at Year 3 in either women or men. The associations between the remaining variables in the models and high coffee intake at Year 3 were essentially the same as those evident in the models adjusted for feedback diagnosis.

7.8.4 Further Caffeine Analysis: Total Caffeine Intake from Coffee, Tea and Cola

Overall, the mean amount of caffeine intake[52] per day from coffee, tea and colas decreased by Year 3 in women from 311 mg/day to 264 mg/day and in men from 399 mg/day to 356 mg/day. Thus, although there was a statistically significant decrease in caffeine intake since baseline for women (Paired T-test; $t = 10.03$; $p < 0.001$) and men (Paired T-test; $t = 4.70$; $p < 0.001$), the actual mean reduction overall was less than the equivalent of one half cup of caffeinated coffee.

There was a large amount of variance in individual caffeine intake values at Year 3 (as there was at baseline); approximately one quarter of the women and just under one fifth of the men reported no caffeine intake at all and there were a few extremely high values reported, which caused the distributions to be skewed to the right. Because these distributions did not fit with the normality assumptions of linear regression analysis, both the Year 3 and baseline caffeine intakes values were transformed by taking the square root of the total caffeine intake values.[53] By using the square root of caffeine intake there is a de-emphasis of particularly high intake values and a relatively greater emphasis in differences at lower levels of caffeine intake; this is in contrast to the analyses presented above that focused on the high coffee (or caffeine) users.

Multivariable regression analyses of the square root of caffeine intakes at Year 3 were estimated by including the baseline caffeine intake (square root) in the model as a first step, and the other potential explanatory variables of interest; diagnosis, age group, destination of the feedback and recommendation for referral or treatment, together with any other variables that

[52] Responses were missing regarding caffeinated beverage intake at Year 3 for 3 women and 4 men.
[53] The distributions for total caffeine values were first anchored at 1, by adding the constant, 1. The square root was then derived. Transformation of the caffeine intake variables improved the "normality" of the distributions as well as the multivariable residual diagnostics.

were associated with Year 3 caffeine intake in univariate analyses ($p < 0.2$), as a second step. With the exception of diagnosis, destination of the feedback, a recommendation for referral or treatment and age group, all variables that did not contribute significantly to the model were then removed. The results of these multivariable regression analyses are presented in Table 7.22.

Table 7.22: Multivariable Linear Regression Analysis of Factors Associated with Total Caffeine Intake (Square Root) at Year 3 for Women and Men

	WOMEN (N = 1796)		**MEN (N = 846)**	
	B (95% CI)	**p**	**B (95% CI)**	**p**
Intercept	3.92 (2.58; 5.27)	**<0.001**	5.27 (3.95; 6.59)	**<0.001**
Square Root Baseline Caffeine	0.67 (0.64; 0.70)	**<0.001**	0.66 (0.62; 0.71)	**<0.001**
Feedback Diagnosis				
Normal	*Referent*	-----	*Referent*	-----
Osteopenia	0.03 (-0.53 ; 0.59)	0.9	0.73 (-0.14; 1.59)	0.1
Osteoporosis	-0.31 (-1.05; 0.43)	0.4	0.12 (-0.99; 1.22)	0.8
Destination				
To FP only	*Referent*	-----	*Referent*	-----
To participant only	-0.42 (-1.04; 0.21)	0.2	-0.36 (-1.33; 0.60)	0.5
To both	-0.78 (-1.51; -0.05)	**0.04**	-1.06 (-2.22; 0.11)	0.08
Recommendation Yes	0.15 (-0.87; 1.16)	0.8	1.31 (-0.23; 2.83)	0.1
No	*Referent*	-----	*Referent*	-----
Age 40 to 49 years	*Referent*	-----	*Referent*	-----
Group 50 to 60 years	-0.52 (-1.03; 0.01)	0.06	-0.64 (-1.42; 0.15)	0.1
Body Mass Index				
Lowest Quartile	-0.93 (-1.62; -0.24)	**0.008**		
Second Lowest Quartile	-0.92 (-1.59; -0.24)	**0.007**		
Second Highest Quartile	-0.72 (-1.39; -0.05)	**0.03**		
Highest Quartile	*Referent*	-----		
Race/Ethnicity				
"Non-white"	*Referent*	-----		
"White"	1.28 (0.23; 2.32)	**0.02**		
Current Smoker No	*Referent*	-----	*Reference*	-----
Yes	0.78 (0.12; 1.44)	**0.02**	1.37 (0.39; 2.29)	**0.007**
$\mathbf{R^2}$	0.54		0.52	

Baseline caffeine intake explained almost all of the variance (95%) in Year 3 caffeine intake amongst the women; the remaining variables in the model contributed only a further 5% of the explained variance. The second most important predictor of Year 3 caffeine intake was baseline smoking status, which contributed 2% of the explained variance. Likewise for men, baseline caffeine contributed 94% of the explained variance in Year 3 caffeine intake, baseline

smoking status contributed 3% of the explained variance, and the remaining variables combined contributed 3%. Thus, caffeine intake at baseline was by far the most important predictor of caffeine intake at Year 3 and very little change was seen within the subgroups by Year 3.[54]

The models that were derived by linear regression analysis for total caffeine intake at Year 3 were similar to those derived by logistic regression analyses for high coffee intake (as shown in Table 7.21). Significant predictors of high caffeine intake at Year 3 in women, when baseline caffeine intake was taken into account, were being a smoker at baseline and being in the highest quartile for body mass index. The only significant predictor of a higher caffeine intake at Year 3 in men was being a smoker at baseline. Women in the older age group, "non-white" women, and those whose feedback was sent to both the participant and the family physician[55] also reported somewhat lower caffeine intakes at Year 3 than would be predicted by their baseline intakes alone. Most importantly, there was no indication that a test result of osteoporosis was associated with a decreased caffeine intake at Year 3.

There were no substantive changes to the models shown in Table 7.22 when Centre was substituted for Destination as an explanatory variable. Further, there was little variation between the caffeine intakes at the different centres when baseline caffeine was taken into account. There were significantly lower mean caffeine intakes (square root) in one centre; both women and men in Calgary had lower reported caffeine consumption than did women and men in the St. John's centre (the referent).

Substitution of self reported diagnosis for the feedback diagnosis made no difference to the model for women or men; self reported diagnosis was not associated with estimated caffeine intake at Year 3 when baseline caffeine intake was taken into account.

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[54] A Relative Pratt Index (RPI) (379) was computed to partition the variance (R^2) and to determine the relative contribution of each of the explanatory variables to the models. The RPI of baseline caffeine intake (square root) was 0.95 for the model for women and 0.94 for the model for men.

[55] There were 29 women with standardised residuals of greater than 3 standard deviations; when these women were excluded from the analysis the association between the destination variable ("to both") with the square root of caffeine intake became less significant (the *B* coefficient was closer to zero), which indicates that the small association between destination and caffeine seen in the model above was brought about by a few influential values. Removal of these 29 women did not change the associations between the other variables in the model. There were 14 men with standardised residuals greater than 3 SDs; when these men were excluded from the analysis the overall interpretation of the model did not change; there was no association between the diagnosis received in the feedback and caffeine intake at Year 3.

7.9 Sensitivity Analyses: The Effects of Variation in Protocol for Destination of Feedback

To examine the potential effects of a bias in the destination of test results in those centres where the intended protocol deviated for some cases, the above analyses for all behavioural outcomes (information seeking, calcium supplement use, total calcium intake, dietary calcium intake, Vitamin D supplement use, exercise participation, osteoporosis related medication use, cigarette smoking, high alcohol intake, high coffee intake and total caffeine intake) were repeated while excluding those cases where the feedback was not sent according to the established within-centre protocol (see section 5.3).

After exclusion from the analyses of the 90 women and 58 men whose feedback was not distributed according to the established protocol, there were no substantial or meaningful changes to the results or to the interpretation of any of the adjusted regression models. All associations remained essentially the same for the women and men.

7.10 Subgroup Analyses: The Effects of a Report of a Prevalent Spinal Fracture

The potential effect of a report of a significant prevalent spinal fracture from the X-ray, while adjusting for the other factors included in each of the main analyses presented above, was examined by regression analyses of the subgroups of women and men who were aged 50 to 60 years at baseline and attended the X-ray test. Significant vertebral fractures were reported to 92 (8%) of the 1,170 women aged 50-60 years who attended the X-ray and for whom copies of the radiology reports were available,[56] and to 67 (13%) of the 499 men aged 50-60 years who attended the X-ray.

When the analyses of the effects on calcium intake (calcium supplement use, total calcium intake and dietary calcium intake) were repeated in the subgroup of women who underwent the spinal X-ray examination, there were no notable differences in the models to those seen when all women were included: A report of a significant fracture was not significantly associated with Year 3 total calcium, dietary calcium or calcium supplement use in adjusted models. Results of the multivariable logistic regression analyses of calcium supplement use in the subgroup of women who attended the X-ray are shown on the left side of Table 7.23.

[56] Radiography feedback reports were missing for 2 women who attended the X-ray.

Table 7.23: Results of Multiple Logistic Regression Analysis of the Effects of Diagnosis, Destination and Report of a Significant Fracture on Calcium Supplement Use at Year 3 in Women and Men Aged 50 Years and Older

		WOMEN (N = 1159)[a]		MEN (N = 497)[b]	
		OR (95% C.I.)	**p**	**OR (95% C.I)**	**p**
Supplements at Baseline	Yes	12.5 (9.02 - 17.33)	**<0.001**	8.83 (5.31 - 14.68)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis					
	Normal	*Referent*	-----	*Referent*	-----
	Osteopenia	1.69 (1.21 - 2.36)	**0.002**	1.31 (0.79 - 2.17)	0.3
	Osteoporosis	3.75 (2.39 - 5.87)	**<0.001**	2.81 (1.54 - 5.16)	**0.001**
Significant Fracture					
	No	*Referent*	-----	*Referent*	-----
	Yes	1.56 (0.85 - 2.84)	0.1	1.85 (1.00 - 3.43)	**0.02**
Destination	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	1.10 (0.76 - 1.59)	0.7	1.27 (0.73 - 2.21)	0.4
	To both	1.98 (1.30 - 3.01)	**0.001**	1.15 (0.60 - 2.19)	0.7
Recommendation	Yes	2.64 (1.30 - 5.38)	**0.008**	3.51 (1.55 - 7.95)	**0.003**
	No	*Referent*	----	*Referent*	----
BMI	Lowest Quartile	1.27 (0.82 - 1.97)	0.3	0.53 (0.31 - 0.92)	**0.03**
	Second Lowest Quartile	1.53 (1.02 - 2.30)	**0.04**	0.66 (0.36 - 1.22)	0.2
	Second Highest Quartile	1.14 (0.77 - 1.70)	0.5	0.70 (0.43 - 1.15)	0.2
	Highest Quartile	*Referent*	----	*Referent*	----
Race/Ethnicity					
	"Non-white"			*Referent*	**----**
	"White"			3.55 (1.26 - 9.95)	**0.02**
Previous Diagnosis of Osteoporosis	No	*Referent*	----		
	Yes	0.57 (0.29 - 1.12)	0.1		
Current Smoker	No			*Referent*	----
	Yes			0.50 (0.28 - 0.89)	**0.02**
Nagelkerke's R^2		0.43		0.34	

[a] Missing information on included variables for 11 women.
[b] Missing information on included variables for 2 men.

For the equivalent subgroup of men (as shown on the right side of Table 7.23), a report of a significant prevalent spinal fracture was associated with an increased likelihood of calcium supplement use at Year 3 (OR: 1.85; 95% CI: 1.00 – 3.43) in the model adjusted for the feedback diagnosis, a recommendation for referral or treatment, the destination of the feedback, race and smoking status. The association between direct-to-participant feedback and a higher frequency of supplement use at Year 3 was not significant within this older subgroup of men, in contrast to

the association observed in the whole sample of men (see Table 7.5), but the direction of this association was the same in both models.

As seen in the women, there was no association between the estimated amount of total or dietary calcium intake at Year 3 and a report of a significant fracture in men, in either unadjusted or adjusted analysis.

Results of the multivariable logistic regression analyses of Vitamin D supplement use in the subgroups of women and men who attended the X-ray are shown on the left and right side, respectively of Table 7.24.

Table 7.24: Results of Multiple Logistic Regression Analysis of the Effects of Diagnosis, Destination and Report of a Significant Fracture on Vitamin D Supplement Use at Year 3 in Women and Men Aged 50 Years and Older

	WOMEN (N = 1161)[a]		**MEN (N = 497)[b]**	
	OR (95% C.I.)	**p**	**OR (95% C.I.)**	**p**
Baseline Vitamin D Supplement Use Yes	6.61 (4.96 – 8.80)	**<0.001**	9.52 (5.74 – 15.81)	**<0.001**
No	*Referent*	-----	*Referent*	-----
Feedback Diagnosis				
Normal	*Referent*	------	*Referent*	-----
Osteopenia	1.48 (1.09 – 2.00)	**0.01**	1.37 (0.82 – 2.30)	0.2
Osteoporosis	2.52 (1.74 - 3.67)	**<0.001**	1.85 (1.00 – 3.44)	**0.05**
Significant Fracture				
No	*Referent*	-----	*Referent*	----
Yes	1.21 (0.74 – 1.98)	0.5	1.84 (1.00 – 3.39)	**0.05**
Destination To FP only	*Referent*	-----	*Referent*	-----
To participant only	1.33 (0.95 - 1.87)	0.1	0.74 (0.42 – 1.31)	0.3
To both	2.01 (1.37 - 2.94)	**< 0.001**	0.95 (0.50 – 1.78)	0.9
Recommendation Yes	1.69 (0.98 – 2.90)	0.06	3.21 (1.48 – 7.01)	**0.003**
No	*Referent*	-----	*Referent*	-----
Nagelkerke's R^2	0.27		0.30	

[a] Missing data on included variables for 9 women.
[b] Missing data on included variables for 2 men.

A report of a significant fracture was not associated with Vitamin D supplement use in the adjusted model for women aged 50 to 60 years who attended the X-ray; there were no notable differences between the model for this subgroup and the model that included all participants.

Consistent with the observation of an association between report of a significant fracture and calcium supplement use in men; men who received a report of a significant fracture were

more likely to have taken Vitamin D supplements at Year 3 (OR: 1.84; 95% CI: 1.00 – 3.39) when diagnosis (as well as age group, destination of the feedback and a recommendation for referral or treatment) were taken into account. The associations between the other variables in the model for this subgroup were comparable to those in the main model. Results of the multivariable logistic regression analyses of Vitamin D supplement use in the subgroup of men who attended the X-ray are shown on the right side of Table 7.24.

Multivariable logistic regression analysis of the predictors of osteoporosis-related medication use in the subgroup of women aged 50 to 60 years who attended the X-ray examination resulted in comparable regression coefficients for the majority of the variables in the model shown in Table 7.15. In this subgroup of older women however, there was no difference in medication use between the women who had experienced a premenopausal hysterectomy and those who were premenopausal[57] (in contrast to the main model); the association between higher medication use at Year 3 and having had a premenopausal hysterectomy was only observed amongst the younger women, aged 40 to 49 years. A report of a significant fracture had no association however with OHT or osteoporosis medication use at Year 3 in the subgroup of women who attended the X-ray, either in the univariate or adjusted analyses.

Although the number of men who were using osteoporosis-related medications at Year 3 was too small for multivariable analysis, univariate analyses revealed that, amongst the men (all aged 50 years and over) who attended the X-ray examination and who received a diagnosis of either osteopenia or osteoporosis (n = 290), there was greater use of osteoporosis-related medication at Year 3 by those who had received a report of a significant fracture from their X-ray (Chi-Squared = 6.77; df = 1; p = 0.02). Amongst the older subgroup of men who received a diagnosis of osteoporosis (and attended the X-ray), 30% of those who had been informed that they had a significant vertebral fracture were taking medications at Year 3, compared to only 15% of the men with a diagnosis of osteoporosis from DXA but no evidence of a vertebral fracture.

No associations were observed in adjusted models between a report of a significant vertebral fracture and information seeking, exercise participation, cigarette smoking, high alcohol intake and high coffee intake in either women or men and there were no substantial

[57] Note that menopausal status was derived from measures taken at baseline and older women who were premenopausal at baseline were more likely to have reached menopause by Year 3 compared to the younger women.

differences in the direction of the associations that were observed in the models that included all women or men.

Thus, within the older subgroup of men, a report of a significant fracture from the X-ray was found to be associated with somewhat increased calcium supplement and Vitamin D use in adjusted analyses, as well as with osteoporosis related medication use in univariate analysis. A reported significant fracture was not associated with any behavioural outcome in the older subgroup of women. Finally, different influences of reproductive status (a history of hysterectomy) on Year 3 osteoporosis related medication use were observed in the subgroup of older women compared with the full sample of women which included the women aged 40 to 49 years.

7.11 Summary of the Multivariable Models for Correct Awareness, Information seeking and Osteoporosis-Related Behavioural Change

Tables 7.25 (for women) and 7.26 (for men) summarize the significant factors included in the adjusted models[58] presented in this chapter and the previous chapter. Overall, a low BMD test result (osteoporosis or osteopenia) had similar effects on women and men. Although there were variations between the genders in the covariates that were significantly associated with correct awareness of test results, information seeking and changes in health behaviour, those behaviours that were associated with a low BMD diagnosis in women were, for the most part, also associated with a low BMD diagnosis in men.

As can be seen from the tables, for both women and men, a diagnosis of osteoporosis (and of osteopenia, in most cases) was associated with decreased correct awareness of the exact test results, but increased information seeking about osteoporosis, increased calcium supplement use (and hence increased total calcium intake), increased vitamin D supplement use and a greater likelihood of osteoporosis-related medication use (including OHT in women) three years after BMD testing. In addition, an association was evident between a diagnosis of osteoporosis and increased dietary calcium intake in men, but not women. Further analysis of correct awareness (see Chapter 6) revealed that most of the women and men with osteoporosis knew that their results were low, even if they did not know the exact diagnosis; those with a diagnosis of osteopenia were less likely to be aware of a low test result.

There was no association between a low BMD diagnosis and dietary calcium intake in women, or between a low BMD diagnosis and exercise participation, a high alcohol intake, or total caffeine intake in women or men. A low diagnosis was not associated with a change in smoking behaviour in men; however, an *increased* likelihood of smoking, while taking baseline smoking into account, was observed in women who received a diagnosis of osteoporosis compared with those who received a normal diagnosis. No association was found between high coffee intake and a diagnosis of osteoporosis in women or men..

When the feedback was sent to the participant directly, both women and men were more likely to be correctly aware of a normal BMD test result, or a test result of "osteopenia"; however, the destination of the feedback results made no difference to the correct awareness of a diagnosis of "osteoporosis". Direct-to-participant feedback was associated with increased

[58] All models summarized in Tables 6.22 and 6.23 were adjusted for the equivalent baseline behaviours, where applicable, as well as feedback diagnosis, destination, recommendation for referral or treatment, age group and all other significant covariates.

information seeking about osteoporosis and with increased calcium supplementation in women and men, and with increased vitamin D supplementation and exercise participation in women.

When a recommendation (for a referral to an osteoporosis clinic or for treatment) was included in the feedback, a relative increase was seen in some of the health-related behaviours; information seeking, calcium supplementation and Vitamin D supplementation in women and men and total calcium intake, exercise participation, and use of osteoporosis-related medications in women only. Such a recommendation was also associated with a decreased likelihood of a high risk behaviour (smoking) in women at Year 3. As mentioned earlier, associations between a recommendation for referral or treatment and any of these outcomes should be interpreted with caution, however, because all recipients of such a referral were located in two centres and also received a low BMD diagnosis or a report of a prevalent fracture.

Certain factors that are known or believed to be associated with an increased risk of osteoporosis were found to be associated with less likelihood of awareness, information seeking or positive health behaviour change. In particular, women who were current smokers at baseline were less likely to participate in a regular program of exercise, more likely to be high alcohol users and more likely to report high intake of coffee or caffeine at Year 3. Men who were smokers were also more likely to report relatively high coffee and caffeine intake at Year 3, and were less likely to report calcium supplementation. Women who had a history of a "high risk" comorbidity were less likely to report seeking information about osteoporosis or to participate in regular exercise at Year 3.

Other risk factors were associated with more "positive" bone health-related changes. Older women reported increased use of bone related medications and increased exercise participation, and older men were more likely to know that their diagnosis was osteoporosis. Women with a family history of osteoporosis were more likely to know their diagnosis if it was osteopenia and were more likely to be taking osteoporosis-related medication (including OHT) at Year 3; men with a family history had a higher calcium intake compared with men with no family history. Women with a previous diagnosis of osteoporosis were more likely to report information seeking, but were less likely to report calcium supplementation relative to baseline use of supplements. This last observation is likely explained by the high level of baseline calcium supplementation reported by women with a previous diagnosis (i.e., there was little room or need for improvement). A low body mass index was associated with increased information seeking, calcium supplementation, use of osteoporosis-related medications, increased exercise participation and decreased caffeine intake in women.

Women and men in the highest education group (university degree) and women with better self reported health were more likely to participate in regular exercise; women with the highest level of education, however, were the most likely to report high use of alcohol at Year 3. Women with poorer self reported health and men with lower levels of education were less likely to be correct about a borderline (osteopenia) test result, as well as a normal test result. Finally, "non-white" women and men had lower caffeine intakes, but also had lower calcium supplementation and total calcium intake.

Table 7.25: Summary of Significant Associations in Adjusted Analyses with Correct Awareness of Test Results, Information seeking and Osteoporosis-Related Health Behaviour Change in Women

WOMEN	Correct Awareness	Information seeking	Calcium			Vitamin D	Osteoporosis Medications/OHT	Exercise	Smoking	High Alcohol	Caffeine	
			Calcium Supplements	Total Calcium	Dietary Calcium						High Coffee	Total Caffeine
Low BMD Diagnosis[a]	↓[b]	↑	↑	↑[c]		↑	↑	[d]	↑			
Report of Significant Prevalent Fracture												
Feedback Direct to the Participant[e]	↑[f]	↑	↑			↑		↑				↓
Recommendation for Referral or Treatment.		↑	↑	↑		↑	↑	↑	↓			
Family History of Osteoporosis	↑[g]						↑					
High Level of Self Reported Health	↑[h]							↑				
Current Smoker at Baseline	↓[i]							↓		↑	↑	↑

[a] A low BMD diagnosis refers here to a diagnosis of *either* osteoporosis or osteopenia, or both, in comparison with a "normal" diagnosis.
[b] When "closely correct" (see Chapter 5) was supplemented for the outcome, a diagnosis of osteopenia (but not osteoporosis) was associated with being incorrect
[c] This association was seen for the lower 3 quartiles of baseline calcium intake, but not in the highest quartile.
[d] A self reported diagnosis (but not a feedback diagnosis of osteoporosis) was associated with decreased participation in exercise.
[e] Direct-to-participant refers to feedback sent *either* to the participant only or to both the participant and the family physician, or both of these feedback protocols, in comparison with feedback to the family physician only.
[f] Direct-to-participant feedback was associated with correct awareness of "osteopenia" and "normal" test results only.
[g] A family history of osteoporosis was associated with correct awareness of a diagnosis of "osteopenia" only.
[h] A high self reported level of general health was associated with correct awareness of "osteopenia" or "normal" test results only.
[i] Current smokers at baseline were less likely to be correct about their "normal" results only.

WOMEN	Correct Awareness	Information seeking	Calcium			Vitamin D	Osteoporosis Medications/OHT	Exercise	Smoking	High Alcohol	Caffeine	
			Calcium Supplements	Total Calcium	Dietary Calcium						High Coffee	Total Caffeine
Higher Education Level								↑		↑		
History of Relevant Medications												
Low Body Mass Index[a]		↑	↑				↑	↑			↓	↓
Reproductive Status[b]		↓					↑				↓	
Previous Diagnosis of Osteoporosis		↑	↓									
History of Relevant Comorbidity		↓						↓				
Older Age Group							↑	↑				
"Non-white" Race/Ethnicity												↓

↑ Indicates a statistically significant association with a relative increase in the outcome (correct awareness, information seeking or health behaviour).
↓ Indicates a statistically significant association with a relative decrease in the outcome (correct awareness, information seeking or health behaviour).

[a] Refers to a significant association with the 1st, 2nd or 3rd quartile of BMI relative to the highest (4th) quartile.
[b] Relative to the premenopausal women: Women with a history of surgical menopause were less likely to report seeking information about osteoporosis and were less likely to be heavy coffee drinkers at Year 3 compared with baseline. Women with a history of premenopausal hysterectomy were more likely to be taking osteoporosis-related medications (including OHT) at Year 3 and less likely to be heavy coffee drinkers compared with baseline.

Table 7.26: Summary of Significant Associations in Adjusted Analyses with Correct Awareness of Test Results, Information seeking and Osteoporosis-Related Health Behaviour Change in Men

MEN	Correct Awareness	Information seeking	Calcium									Caffeine	
			Calcium Supplements	Total Calcium	Dietary Calcium	Vitamin D	Osteoporosis Medications[a]	Exercise	Smoking	High Alcohol		High Coffee	Total Caffeine
Low BMD Diagnosis[b]	↓[c]	↑	↑	↑	↑	↑	(↑)					↑	
Report of Significant Prevalent Fracture	↑[d]		↑			↑	(↑)						
Feedback Direct to the Participant[e]	↑[f]	↑	↑										
Recommendation for Referral or Treatment.		↑	↑			↑							
Family History of Osteoporosis				↑									
High Level of Self Reported Health													
Current Smoker at Baseline			↓									↑	↑

[a] (↑) Based on univariate analyses only
[b] A low BMD diagnosis refers here to a diagnosis of *either* osteoporosis or osteopenia, in comparison with a "normal" diagnosis.
[c] When "closely correct" was supplemented for the outcome, a diagnosis of osteopenia (but not osteoporosis) was associated with being incorrect
[d] A report of a significant fracture was associated with increased correct awareness of a diagnosis of "osteopenia" and "osteoporosis".
[e] Direct-to-participant refers here to feedback sent *either* to the participant only or to both the participant and the family physician, in comparison with feedback sent to the family physician only.
[f] Direct-to-participant feedback was associated with increased correct awareness of "osteopenia" and "normal" test results only.

MEN	Correct Awareness	Information seeking	Calcium			Vitamin D	Osteoporosis Medications	Exercise	Smoking	High Alcohol	Caffeine	
			Calcium Supplements	Total Calcium	Dietary Calcium						High Coffee	Total Caffeine
Higher Education Level	↑[a]							↑				
History of Relevant Medications	↓[b]											
Low Body Mass Index[c]							(↑)					
History of Relevant Comorbidity												
Older Age Group	↑[d]						(↑)					
"Non-white" Race/Ethnicity			⇓	↓								

↑ Indicates a statistically significant association with a relative increase in the outcome (correct awareness, information seeking or health behaviour).

↓ Indicates a statistically significant association with a relative decrease in the outcome (correct awareness, information

[a] A higher level of education was associated with increased correct awareness of "osteopenia" and "normal" test results only.

[b] History of exposure to relevant medications was associated with decreased correct awareness of a normal diagnosis only.

[c] Refers to a significant association with the 1st, 2nd or 3rd quartile of BMI relative to the highest (4th) quartile.

[d] Older age group was associated with increased correct awareness of a diagnosis of osteoporosis only.

CHAPTER 8: Summary and Discussion

8.1 Introduction

The purpose of this investigation was to explore the effects of low bone mineral density test results in a population-based sample of mid-aged women and men. The study was designed to describe test result awareness and sources sought for information and to determine whether there was an association between receipt of low BMD test results and correct awareness of test results, information seeking about osteoporosis and change in osteoporosis related health behaviour, including the use of bone-specific medications three years after DXA testing. This investigation included a quasi-experimental study of direct-to-participant feedback of test results and its association with correct awareness, information seeking and health behaviour change. Lastly, the effects of demographic factors and risk factors for osteoporosis on awareness, information seeking and health behaviour change following BMD testing were assessed.

The overall design of this research endeavour was an effectiveness study of the provision of BMD test results that incorporated the consideration of multiple factors as independent potential influences on test result awareness and health behaviour. The potential influence that BMD test results, direct-to-participant feedback and other factors have on correct awareness of test results, information seeking or health behaviour was conceptualized using components borrowed from the PRECEDE Model of Health Program Planning and Evaluation (366). Two important considerations underlie the model: both health and the factors that place people at risk result from multiple causes and, because of the multifactorial nature of most health challenges, interventions designed to change behaviour (or the environment) must be multidimensional and participatory. The guiding conceptual framework (as shown in Figure 3.1) assured that potentially important predisposing or enabling influences would be central to the analysis while considering the effectiveness of the main interventions (low *v.* normal BMD test results and direct-to-participant feedback). This study was not designed to test a conceptual model of osteoporosis related health behaviour change; the results will not therefore be discussed in the context of this framework.

This chapter presents a summary and discussion of the results of this research, the strengths and limitations of the study and the implications and conclusions of the findings.

8.2 Summary of the Findings

This study had five specific objectives; a summary of the findings as they relate to each of these objectives follows.

- *To describe the relationship between correct knowledge of test results three years following testing and both a diagnosis of osteoporosis or osteopenia by bone density measurement and the method of test result feedback.*

Women and men were often inaccurate about their diagnosis three years after DXA testing, and those with a diagnosis of osteoporosis or osteopenia were less aware of their precise test results than were those who had received normal test results. Compared with the men, the women were more likely to accurately recall their results. Approximately one third of the women and one quarter of the men who received a diagnosis of osteoporosis were able to recall this precise diagnosis; two thirds of these women and just over one half of these men knew that their results were low however, even if they did not recall a diagnosis of osteoporosis.

When the feedback of test results was sent directly to the participants, rather than only to the family physician, awareness of normal or osteopenia test results was improved. In contrast, direct-to-participant feedback did not improve awareness of a diagnosis of osteoporosis; this indicates that women and men were just as likely to receive, take notice of, or recall their osteoporosis diagnosis whether the results were sent to the participant, to the physician or to both.

- *To describe the information sources accessed by women and by men following DXA testing.*

More than one half of the women and more than one third of the men reported that they had sought further information about osteoporosis during the three years following the DXA test. Literature and the media were the most frequently cited sources of information about osteoporosis and were cited much more frequently than were health-care professionals. Only 19% of the women and 14% of the men reported having sought information about osteoporosis from a physician during the three years since the DXA test; other health care professionals, such as nurses and physiotherapists, were cited by less than 3% of the participants. The internet was also not a major source of information for these women and men; fewer than 3% of the participants sought information on the internet.

- *To examine the association between self reported information seeking about osteoporosis during the three years following testing and both bone density test results and the method of test result feedback.*

More women than men sought information overall, irrespective of their diagnosis, but the relative effect of a diagnosis of osteoporosis on information seeking was similar for women and men: women who were diagnosed with osteoporosis were twice as likely and men who were diagnosed with osteoporosis were two and a half times as likely to have sought information compared with the participants of their respective sex who received a normal diagnosis.

The association between a self reported diagnosis of osteoporosis and information seeking was greater than that found between a feedback diagnosis of osteoporosis and information seeking, particularly for men. Men who recalled a diagnosis of osteoporosis were almost 10 times as likely as those who reported a normal diagnosis to have sought information about osteoporosis; women who recalled a diagnosis of osteoporosis were three and a half times as likely to have sought information compared with women who recalled a normal diagnosis. In contrast to a feedback diagnosis of osteoporosis, there was no difference in the proportion of men and women with a self reported diagnosis of osteoporosis that had sought further information about osteoporosis.

Irrespective of the test result, direct-to-participant feedback led to increased information seeking about osteoporosis by the women (when the results were sent to the participant only) and by the men (whether the results were sent to the participant only or to both the physician and the participant).

- *To explore the associations between changes in osteoporosis related health behaviour three years after DXA testing and both bone density test results and the method of test result feedback.*

Over the three-year period following the DXA testing, the use of calcium or Vitamin D supplements increased overall, as did the average daily intake of calcium. Despite these increases, after their DXA testing, only 55% of the women and 38% of the men consumed the minimum[59] recommended adequate daily intake of calcium of 1000mg/day. The results of this study illustrate however that a diagnosis of osteoporosis or osteopenia from a DXA test had a significant impact on calcium intake and on the use of calcium and Vitamin D supplements. For

[59] 1000 mg/day is recommended as the minimum for men and women aged 19-50 years by both Osteoporosis Canada and Health Canada. For those aged over 50 years, the recommended intake is higher; 1200 mg/day by Health Canada (231) and 1500 mg/day by Osteoporosis Canada (85).

women in particular, the greatest impact on calcium intake was seen amongst those with lower levels of baseline calcium intake.

A diagnosis of osteoporosis (but not osteopenia) by DXA was an important determinant of whether women and men were taking bone-related medications three years later. Nevertheless, the proportion of men with a diagnosis of osteoporosis taking bone-specific medications (bisphosphonates) at Year 3 was only 14%. Women who received a diagnosis of osteoporosis were approximately twice as likely to be taking osteoporosis-related medications (OHT or bisphosphonates) at Year 3 compared with women with a normal diagnosis.

In contrast, a low DXA test result, or even a self reported (or "perceived") low test result had no measurable effect on desirable changes in exercise participation, smoking status, high alcohol use, high coffee intake or total caffeine intake. Rather, women who received a diagnosis of osteoporosis, or self-reported a diagnosis of osteoporosis, were less likely to stop smoking than were women with a normal diagnosis. Although a diagnosis of osteoporosis had no apparent effect on exercise participation, women who recalled a diagnosis of osteoporosis (or who did not know their diagnosis) were less likely to participate in a regular program of exercise three years after DXA than were those who self reported a normal test result.

Thus, although different factors appeared to influence health behaviour change and medication uptake in women and men, the influence of the diagnosis from the DXA was similar: a report of a low BMD test result was associated with bone-related medication uptake, Vitamin D supplement use and increased calcium intake. Report of a low BMD test result was not, however, associated with increased exercise participation, or healthful changes in smoking, alcohol use or caffeine intake.

For men, the association between a self reported diagnosis of osteoporosis and the health behaviours that were apparently more responsive to the provision of a low BMD diagnosis (the use of calcium and Vitamin D supplements and the use of bone-specific medications) was consistently greater than that found between a feedback diagnosis of osteoporosis and changes in these behaviours. Although men who had received a diagnosis of osteoporosis were less likely to be participating in these health behaviours at Year 3 than were comparable women, and men, in general, had a lower awareness of their BMD test results than had women, the men who self-reported (i.e., recalled) a diagnosis of osteoporosis were equally likely as the women to be taking calcium or Vitamin D supplements.

Direct-to-participant feedback led to increased rates of calcium supplement use in both women and men, as well as increased Vitamin D supplement use, and participation in regular

exercise in women only. On the other hand, direct-to-participant feedback had no influence on the uptake of bone-related medications or changes in cigarette smoking, high alcohol intake or high consumption of coffee.

A simple recommendation in the feedback for a referral or treatment also appeared to play a role in information-seeking behaviour, calcium supplement use and Vitamin D supplement use for both women and men. Further, women who received a recommendation had increased rates of bone-related medication use, increased exercise participation, and decreased smoking rates.

- *To assess the influence of other known risk factors on test result awareness, information-seeking and health behaviour change while taking diagnosis by bone density measurement into account.*

Certain factors influenced whether participants were aware of their normal diagnosis (a higher self-reported general health or non-smoking status in women and a higher level of education or no history of exposure to corticosteroids or anticonvulsants in men) or their osteopenia diagnosis (higher self reported general health or a family history of osteoporosis in women and a higher level of education in men). The only factors that were associated with correct awareness of a diagnosis of *osteoporosis* however were observed in men; these were older age and a report of a prevalent spinal fracture. Thus, men who were in the older age group or who received a report that indicated the presence of a prevalent spinal fracture had better awareness of their osteoporosis diagnosis. A report of a significant spinal fracture in men was also associated with a greater likelihood of taking Vitamin D, calcium supplements and bone-specific medications at Year 3. These associations with a report of a prevalent spinal fracture were not seen in women.

Regardless of their diagnosis, certain subgroups of women that may be considered at greater risk for osteoporosis were more likely to be taking bone-related medications (OHT or bisphosphonates): those with a family history of osteoporosis, women in the older age group, women with a lower BMI and, amongst the women aged 40 to 49 years only, those with a premenopausal hysterectomy. Similarly, certain subgroups with risk factors for osteoporosis were more likely to demonstrate positive bone-related health behaviour relative to those at lower risk, irrespective of their diagnosis from the BMD results. This was true for women with a lower BMI who were more likely to have sought information about osteoporosis, to be taking calcium supplements, to take part in regular exercise and to report lower caffeine intake. Also, women in

the older age group had a greater rate of participation in exercise and men who reported a family history of osteoporosis had a higher calcium intake.

Other "at risk" subgroups were less likely to demonstrate positive health behaviours, however. Women with surgically-induced menopause or a history of rheumatoid arthritis or eating disorders were less likely to seek information about osteoporosis, and women with a history of these co-morbidities or with poorer self reported health status and both men and women with lower levels of education were less likely to participate in regular exercise. Tobacco smokers reported a lower level of general health and were more likely to take part in other "high risk" bone-specific behaviour before their DXA testing: at baseline, women and men who smoked were less likely to participate in regular programs of exercise and were more likely to have a high alcohol consumption and consume four or more cups of coffee per day; women who smoked were less likely to have been taking calcium supplements. This subgroup was also the least likely to show a desirable change in their behaviour following DXA testing, irrespective of their DXA test results; women who were smokers at baseline were less likely to take up, or to continue with, exercise participation, less likely to reduce their alcohol intake to two or fewer drinks per day and less likely to reduce their coffee consumption to less than four cups per day. Men who were smokers at baseline were less likely to take calcium supplements at Year 3 and less likely to reduce their coffee consumption to less than four cups per day compared with the non-smokers.

Finally, "non-white" men were less likely to take calcium supplements and had low total calcium intake compared with men who identified themselves as "white", whereas women who were "non-white" consumed less caffeine.

8.3 Population and Generalizability

The CaMOS sample was randomly selected from within nine predominantly urban centres across Canada and is believed to represent approximately 40% of the population of Canada (5;365). The selected centres represent larger urban centres on the whole, but participants were sampled from within a 50-kilometre radius of each CaMOS centre and rural communities were therefore included in the sampling frame, particularly from the areas surrounding the smaller centres, Kingston, St. John's and Saskatoon. Although the participation rates of those who were randomly selected for the CaMOS study were not high (67% of the mid-aged women and 50% of the mid-aged men agreed to complete the full questionnaire), the participation rates are not unusual for a study that requires a significant time commitment and

medical intervention. The participation rate is comparable, for example, to the 64% response rate reported for premenopausal women in Tasmania by the only other published study of the effects of DXA test results on health behaviour in a randomly selected population-based sample (304). Similarly, participation in CaMOS is comparable to that of other population based studies of osteoporosis such as the European Vertebral Osteoporosis Study (EVOS) (380) and the Dubbo Osteoporosis Epidemiology Study (DOES) (381).

A previous comparison between those who agreed to participate in CaMOS and those who refused full participation reported that full CaMOS participants were more likely to have certain risk factors for osteoporosis compared with those who refused full participation but completed a brief questionnaire instead (367). Further assessment of generalizability was addressed in this current study by a comparison of the participants with those who were lost to follow-up or who declined a DXA test and, using the measures that were equivalent, to the mid-aged Canadian population-based sample of the 1996-97 Canadian National Population Health Survey (NPHS).

For the majority of the considered risk factors, the comparisons showed that the study sample did not differ from the women and men who were lost to follow-up, or who did not attend the DXA test. Furthermore, the participants were neither more nor less likely to remain in the study if they received a diagnosis of osteoporosis or osteopenia, or if they received a report of a prevalent fracture. Thus, it appears that the diagnosis from the BMD test was not a reason for loss to follow-up and that the participants represented a fair balance of the diagnostic categories. Bone-specific behaviours measured at baseline were also comparable between the study participants and the women and men who were excluded.

Although the reported rates of use of calcium and Vitamin D supplements at baseline varied among the CaMOS centres, the rates were similar to those reported by other studies conducted in the late 1990s of Canadians' use of supplements (382-384). Similarly, patterns regarding supplement use that were observed in this study have been reported in findings from population surveys; women are more likely than men to take calcium or Vitamin D supplements (382-384), supplement use increases with age (382-384) and smokers are less likely to use supplements (384).

The study participants included a greater proportion of "high alcohol users" but they were less likely to smoke, reported that they were healthier and had a higher level of education compared with the 1996-97 NPHS participants. In addition, the CaMOS women reported a higher frequency of OHT use than did the NPHS women. Others have reported that OHT users

tend to have higher levels of education or socioeconomic status (385-388) and to have healthier lifestyles (389-392); OHT use has been found to be associated with a greater likelihood of alcohol consumption (385;387;391) and less likelihood of smoking (387). The lower prevalence of current smokers in this sample compared with the NPHS sample is congruent with earlier findings, reported at the Epidemiology Congress in 2001, that there were fewer smokers amongst the full CaMOS participants than amongst those who completed the short "Refusal" questionnaire (367). Thus, the mid-aged population sample used for this study may somewhat over-represent healthier and more highly educated Canadian women and men, and somewhat under-represent smokers.

It is possible that a more highly educated, "healthier" sample would be relatively more motivated to take note of their BMD results and to make changes to their lifestyle. Healthier, more educated individuals, and those with higher incomes are typically found to make greater use of screening programs, even in Canada where accessibility based on income should not be an issue (393-398). Although some potential selection bias is possible, it is assumed that those who agreed to participate in the CaMOS study and to undergo a BMD test are representative of those in the community who would choose to attend BMD screening if it were available.

The frequency of reported low BMD diagnoses in this mid-aged sample of men and women is high compared with expected rates of osteoporosis and osteopenia in women and men in this age range (46;47;53). The use of the DXA manufacturers' reference norms to derive the T Scores is believed to have increased the likelihood of a low BMD diagnosis (47;53). In addition, the varying criteria for a diagnosis of osteoporosis or osteopenia, which differed from the WHO criteria at some of the CaMOS centres, favoured a diagnosis of osteoporosis. The rates reported are not therefore reflective of the true prevalence of osteoporosis or osteopenia in this population, but are reflective of the test results and diagnoses that were reported to the participants in the CaMOS study at baseline. The prevalence rates of osteoporosis and osteopenia in the CaMOS population by age group and sex, using standard derivations of BMD values in young CaMOS participants, have been reported elsewhere (47).

This study found that more prevalent spinal fractures were reported for men than for women. The radiologists used subjective criteria to determine whether a fracture was evident. Rather than a reporting bias in favour of fractures in the men, however, this difference appears to reflect a real difference in prevalent spinal fractures between men and women. A previous study that utilised objective comparisons of the spinal radiographs of the men and women in the CaMOS cohort aged 50 years and over, who attended an X-ray, also determined that men aged

50 to 60 years had more spinal fractures than did women of a similar age. This difference between men and women became smaller with advancing age and was reversed in the oldest participants (399). The higher prevalence of spinal fractures in the younger men likely reflects a higher prevalence of non-osteoporotic fractures (those related to trauma). Even still, the association observed in this current study between prevalent spinal fractures and a low BMD in women, and the trend towards a similar association in men, suggests that the spinal fractures that were identified by X-ray were indicative of an increased risk for further fracture.

A low bone density test result was also associated with other known risk factors for osteoporosis: smoking in men, low BMI and older age in women and men, being menopausal and a family history of osteoporosis in women. Further, there was an association in both women and men, between low BMD and being "non-white", which may be related to the lower BMI of the non-white participants. The finding that there were numerous associations and inter-relationships evident between the potential enabling and predisposing influences in this study emphasizes the importance of taking as many of these potential influences as possible into account in the analyses.

8.4 Correct Awareness of BMD Test Results

Although the rate of precise recall or awareness of the diagnosis resulting from a DXA test was not high in this population of Canadian women and men, awareness amongst those with a diagnosis of osteoporosis or osteopenia that their results were low was at least as good as, or better than, that observed in similar studies of women[60] who have been referred to DXA testing centres in the U.S. (300) and Canada (301), even though the intervals between testing and recall were shorter in these earlier studies. The authors of these studies reported that only 50%, or less, of women in referred samples (300;301) that had received a diagnosis of osteoporosis were able to report that their diagnosis was low or below average, whereas 67% of women with osteoporosis in the current study knew that their test results were low (i.e., they were "closely correct"). Amongst participants with osteopenia, only 31% in the U.S. study (300) and 24% in the Canadian study (301) reported that their results were low which contrasts with the 42% of mid-aged women in this sample with the same diagnosis. These randomly selected Canadian women appear therefore to be just as likely as women specifically referred by their physician for BMD testing to be informed, to understand and to recall that they received a low test result.

[60] The study by Pickney and Arnason (300) included 37 men and 977 women, but the results were not reported by sex.

The finding that participants with osteopenia were less likely than those with osteoporosis to report that their test results were low, or below average, is consistent with the results of Pickney and Arnason in their study of women who had been referred for DXA (300); this is not a surprising observation, however, given that osteoporosis is a more serious diagnosis and further away from "normal" than a borderline diagnosis of osteopenia, and therefore less likely to be either presented or perceived as a normal test result.

Overall the men were less aware of their diagnosis from the BMD test than were the women. There have been no previous studies of awareness of BMD test results in men with which to compare these results. The lower rate of awareness of test results in men, even when the results were delivered directly to them suggests that men were less likely than women to take notice of their BMD test results, rather than a gender bias in the reporting of test results by physicians to their patients. This difference may be due to the emphasis on osteoporosis as a woman's disease and the fact that education campaigns about osteoporosis are typically targeted at women. As a result, men may be less likely to see themselves as susceptible to osteoporosis and their test results may seem less relevant, hence they would be less likely to take notice of their diagnosis. Others have found that older men (over 65 years) have poor knowledge of osteoporosis and do not perceive themselves to be susceptible to osteoporosis (400); the results of this study suggest that younger, mid aged men also do not appear to perceive themselves as susceptible to osteoporosis, even when they are informed directly that they are at increased risk of fracture. There is clearly room for improvement in the level of awareness of osteoporosis as a disease of men as well as of women.

A trend in the recall of BMD results, towards a less abnormal result, was evident in these study findings: approximately one third of the men and women with a diagnosis of osteoporosis reported that their diagnosis was "low without osteoporosis" and approximately one third of the men and women with a diagnosis of osteopenia reported that their test results were "normal". In contrast, only a negligible proportion of men and women reported their results as lower than they actually were. This pattern of responses implies an optimistic bias (401;402), or a tendency to believe that one is less at risk than average, in the reporting of BMD test results: Both the women and the men showed a greater tendency to report that their results were average, or close to average, whether or not they were correct. In addition, the pattern of reporting the next less serious diagnosis in the osteopenia and osteoporosis diagnostic subgroups suggests that a significant proportion of the participants that had received and taken notice of their results after testing had "minimized" the seriousness of their own test results by the time of the Year 3

follow-up. A similar minimization of BMD test results was reported by another study in which women with low BMD results tended to minimize their judgment of their own risk compared to others and to minimize the seriousness of osteoporosis over time (334). Although both an optimistic bias and minimization of test results can potentially diminish motivation to adopt recommended preventive behaviours (402), they have been shown to have positive adaptive psychological value, with reduction of stress, better adjustment and active coping (403;404).

In contrast to a previous study of similarly aged randomly selected women, which found that direct-to-participant feedback had a significant impact on the recall of low BMD test results (302), the findings from this study indicated that there was neither an advantage nor a disadvantage associated with relaying osteoporosis results directly to the participants. On the other hand, participants who received direct feedback of their test results were better able to recall their diagnosis if it was osteopenia or normal. This study differed from that of Campbell et al. (302) in the criteria for "low" test results, which could explain the disparity between the two sets of findings. Results that fell in the lowest quartile of the BMD distribution were defined as low in Campbell et al.'s study and the WHO categories were not used, which may have resulted in less frequent communication of the low test results by the physicians. In support of this argument, the rate of correct awareness in the low BMD group when the results were sent only to the physician was only 18% in the study by Campbell et al., while it was 36% of the women with osteoporosis in this study. The current findings that there was no advantage of direct-to-participant feedback in the recall of a diagnosis of osteoporosis suggests that, despite the fact that the overall rates of precise recall of this diagnosis were low, physicians probably relayed the osteoporosis information to their patients, and the specific diagnostic information was not retained by the participants, was poorly understood or was "minimized".

The lower rate of correct awareness of osteopenia or normal results amongst men and women when their results were sent only to the physician indicates that physicians were less likely to communicate these borderline and average test results to their patients. Although it is possible that physicians may have communicated but normalized osteopenia test results given the relatively young age of this sample, the higher rate of incorrect recall of osteopenia by men and women in the "to FP" subgroup was explained by a higher rate of "don't know" responses, rather than responses of "normal". This suggests that the lower rate of correct recall did not occur because physicians were communicating a diagnosis of osteopenia as a normal test result, but rather that the osteopenia test results were not passed on by the physicians.

Thus, direct-to-participant feedback appears to offer the advantage that people are more likely to be aware of their borderline or average test results and are no less aware of their osteoporosis test results than they are when the results are sent only to the family physician. It is arguably preferable that people who have attended a test are made aware of their test results. If their results are normal they may be offered reassurance; if their results are borderline, then an awareness of the associated increased risk offers the opportunity to seek more information and to consider lifestyle modifications that have the potential to lower the risk of becoming osteoporotic and the future risk of fracture.

Several factors that may be considered as indicators of "healthier" individuals (non-smoking status, higher level of education, higher self reported health status and no history of exposure to corticosteroids or anticonvulsants) were found to be associated with awareness of borderline or average results. This may be explained by a greater awareness and monitoring of health in general in these subgroups (393-398).

The findings that men who received a report of a prevalent spinal fracture from the X-ray were more likely to know that they had been diagnosed with osteoporosis suggests that either physicians, or the men themselves, followed up and took more notice of the BMD test results in the presence of this other significant risk factor (212). In addition, men aged 50 years and over were more likely than men aged 40 to 49 years to recall a diagnosis of osteoporosis. This is probably explained by the focus on diagnosis and treatment only for those aged 50 years and over. Canadian guidelines available at the time of baseline testing did not address men and women under the age of 50 years (230), although more recent guidelines specifically recommend that the diagnosis of osteoporosis in men under the age of 50 years should not be made on the basis of densitometry alone (189).

8.5 Information Seeking about Osteoporosis following BMD Testing

The observation that health-care professionals were less frequently sought out for information about osteoporosis than were media and literature sources following DXA testing is similar to previous findings reported in populations of women prior to their BMD testing (333), in young college women (328), and in a large population-based survey in Australian women and men (319). The fact that one third of the women and one fifth of the men in this study cited literature sources and the media as their only sought-out sources of information about osteoporosis, and that health-care professionals were cited far less frequently, is cause for concern given that health-related information in magazines and newspapers is not always

balanced and is often ambiguous (405-407), and that information about medications in the media is reportedly frequently presented with insufficient attention to negative information (408).

Interestingly, only 2-3% of the participants in this study reported accessing the internet to seek information about osteoporosis. This same low rate of internet access for information about osteoporosis was cited by a study of seniors in Alberta, Canada (310) who were surveyed during a similar time period. It is likely that this relatively infrequent use of the internet is attributable to a combination of cohort and age effects: Given that Statistics Canada reported that the number of households seeking health information on the internet increased from 1.1 million to almost 4 million between 1998 and 2002 (409), a younger age group, or a similar aged population sampled today, may well be expected to cite the internet more frequently. As with magazines and other media sources, the internet is not believed to be a reliable source of accurate or unbiased information about osteoporosis (410) or the predictive value of screening tests (411). The findings of this study suggest that there is a need for health-care professionals to play a greater role in providing information to people about osteoporosis, in directing their patients to reliable and tested sources for further information and in assisting with the interpretation of information from other sources.

Men were less likely than women to seek information about osteoporosis from any source, irrespective of their diagnosis by DXA. This gender difference has been observed in the seeking of health information in general (318;319), and is likely to be both a reflection of the proactive attitude toward health that is typically portrayed by women (319) and a consequence of the pervasive presentation of and attention to osteoporosis as a woman's disease by the media and the medical community. Health-care providers should ensure that they use opportunities to provide their men and women patients with relevant and accurate information about osteoporosis risk, preventive options and treatment interventions, so that their patients can make informed decisions about their health-related behaviours and appropriate medications.

The significantly increased rate of information seeking that was reported by both women and men who received a low BMD test result indicates that DXA testing can be effective at initiating information seeking about osteoporosis in high risk individuals. Three quarters of the women and approximately one half of the men in this study diagnosed with osteoporosis reported that they sought further information during the three years since the DXA test; this rate in women is comparable to a very similar rate of information seeking (72%) that was reported in a volunteer sample of women who received below average results from their DXA test (334). As was pointed out by the authors of this latter report, however, there still remained

approximately one quarter of women with low bone density results that did not seek any further information about the disease from any source. Furthermore, in this study nearly one half of the men with a diagnosis of osteoporosis did not seek further information. The reasons why these women and men who were told that they were at high risk did not seek more information were not investigated as part of this research; possible explanations however, include disinterest, adequate existing knowledge about osteoporosis, active avoidance of information because of anxiety or a lack of awareness or understanding of the test results.

As men have typically been found to have relatively poor knowledge about osteoporosis (310;317;400), it seems unlikely that a prior adequate level of knowledge would sufficiently explain why almost one half of the men with osteoporosis did not seek any further information about the disease. Although an active avoidance of information because of anxiety cannot be ruled out as a potential reason for no information seeking, there is evidence that an awareness of an osteoporosis diagnosis did play a role in information seeking, particularly for the men: men and women who *recalled* a diagnosis of osteoporosis were equally likely to have sought information about osteoporosis and the men who reported osteoporosis test results were nearly 10 times as likely to have sought information as the men who reported that their results were normal. These findings suggest that a lack of awareness or understanding of their diagnosis may be responsible for the relatively low rate of information seeking amongst the men with osteoporosis. Further, the results indicate that the time of relaying the BMD test results could be a critical time to engage men and to ensure that they have a clear understanding of the meaning of their diagnosis. It is important to note, however, that because reported information seeking and test results were measured at the same time, a causal relationship cannot be established; men who recalled their low test results may simply have had a greater general interest in osteoporosis or health and would therefore have been more likely to seek information. Further, the information seeking itself may have reinforced awareness of the test results.

Regardless of the underlying reasons why some men and women with low test results did not seek further information, the results show that, while DXA testing itself may have stimulated interest and prompted people to seek out information about osteoporosis, those who received a diagnosis of osteoporosis were at least twice as likely to seek information. This is important because it indicates that individuals who are informed that they are at increased risk are prepared to take more action to learn more about the disease, which ultimately should put them in better positions to make informed decisions. While it may not always be appropriate to change health behaviour (people may already be taking calcium supplements or exercising regularly for

example) seeking further information is a significant positive step in the process towards making informed decisions about recommended bone-related health behaviour and medication options.

Two important risk factors for osteoporosis were found to predict less information seeking in women. The observation that women who had a surgically induced menopause and women with a history of rheumatoid arthritis or an eating disorder were less likely to have sought information indicates that greater attention should be paid to these high-risk women in ensuring that they are informed about the risks of osteoporosis and their available intervention and lifestyle modification options. While it is possible that these subgroups reported less information seeking because they were already better informed at baseline due to their higher risk, the contrasting observation that women with a previous diagnosis of osteoporosis were significantly more likely to report information seeking during the three years following the DXA test suggests that this is not an adequate explanation for the lower rates of information seeking in these women with comorbidity or reproductive risk factors. Women in the lower two quartiles of BMI (≤ 26.1 kg/m^2) were more likely to have sought information than were those in the upper two quartiles; this is likely to be a reflection of the tendency of women who are overweight to pay less attention to positive health promotion or preventive health services compared with those with normal values of BMI (412), rather than a direct result of the relatively higher risk of fracture in those with a lower BMI (161).

8.6 Bone Related Lifestyle Behaviours following BMD Testing

The findings that low DXA test results are effective at influencing the uptake of calcium supplements and Vitamin D supplements support the findings from the single previous investigation by Patel et al. of the impact of low BMD test results on health behaviour in men (a mixed population of patients with prostate cancer and healthy men recruited through advertisements) (340), and those from populations of women who had been referred for DXA testing (3;333;337;338), a random population-based sample of premenopausal women (304), and volunteer or convenience samples of premenopausal, perimenopausal and menopausal women (305;306;334). The influence of low BMD results from DXA on supplement use has therefore been a consistent observation across different populations; this study demonstrates that low DXA results are effective at increasing calcium and Vitamin D intake in mid-aged men and women who have been randomly selected from the population.

In agreement with the results of previous studies that have assessed the effects of low BMD test results on uptake or adherence to bone-specific medication use in women

(3;332;333;337;338;340;342;344;345) the use of bone-specific medications was significantly higher among women who received a diagnosis of osteoporosis from the DXA test. This was evident, regardless of whether women were already taking such medications at baseline. Likewise, a diagnosis of osteoporosis by DXA was associated with the use of bone-specific medications in men. Although this is the first study to demonstrate that low BMD test results from DXA are effective at initiating the use of bone-specific medication in a randomly selected population-based sample of mid-aged men and the only study that has assessed the use of bone-specific medications in men as much as three years after BMD testing, these results are in agreement with the reported findings in a non-equivalent sample of men by Patel et al. (340) and a population-based sample of men (and women) aged 65 years and over (352).

These findings add to the existing literature by demonstrating that the influence on the use of supplements and bone-specific medications is observable as much as three years after testing. Health behaviours that are measured this long after DXA testing may be expected to be more established and persistent than those measured only a short time following testing; this is longer than the average follow-up periods reported in previous studies of bone-related health behaviour change following DXA. It is also of note that the majority of clinical trials that have been cited as evidence for the protective effect on fracture risk of commonly prescribed bone-specific medications have involved exposure time periods of at least three years (284-286;288;413;414) and the positive effect of calcium supplementation on bone density has been observed after at least two years of treatment (220;221).

This study also found that women with the lowest baseline calcium intakes who were diagnosed with osteoporosis demonstrated the greatest relative increases in total calcium intake indicating that the test results were most effective in women who were most in need of a modification of calcium intake and most likely to benefit from calcium supplementation, that is those with low BMD and low baseline calcium intakes (215;221;415).

Dietary intake of calcium may have been influenced by a diagnosis of osteoporosis for the men in this study, but this was not evident for the women. The results of other studies of women pertaining to dietary calcium intake after DXA have been inconsistent; some have demonstrated a relative increase in dietary calcium following receipt of low BMD results (3;305;337;338), others have not (304;306;332;333;339) and, in contrast to the current findings, Patel et al. (340) found no change in dietary calcium following low BMD test results in men. Such variation between studies may be explained by differences between the study populations and the measurement methods. Although simple self-report of a change in diet, which several

previous studies have relied upon (3;332;337;338;340), is subject to recall bias, the use of food frequency questionnaires (FFQs) for calculating calcium intake is also open to considerable error in measurement (although arguably less potential bias) because variation between individuals in estimations of portion size and in specific food choices means that they are not quantitatively precise.

Given that the results show an association between a diagnosis of osteoporosis and increased dietary calcium in men, the finding that there was no relationship between a *recalled* diagnosis of osteoporosis in men and increased dietary calcium intake is surprising, particularly because the relationship between recalled diagnosis and the other behaviours that responded to a report of low BMD results was very strong in men. This paradoxical finding suggests that the increased dietary calcium observed in men could be a chance association brought about by changes in diet for other reasons rather than an intentional change brought about by their bone-related diagnosis.

Regardless of the calcium source however, low BMD test results led to a relative increase in total calcium brought about by the uptake or maintenance of calcium supplement use in women and a combination of supplement use and possibly increased dietary calcium in men. Thus, there was a significant improvement between baseline and Year 3 in the proportions of women and men diagnosed with osteoporosis that were estimated to be consuming the lowest minimum adequate intake of 1,000 mg/day of calcium: from 48% to 71% of the women and from 27% to 51% of the men. These estimates[61] of calcium intake at Year 3 also indicate however that more than one quarter of the women and nearly one half of the men with a diagnosis of osteoporosis were still consuming less than the recommended adequate intake of daily calcium for adults aged 19 to 49 years of age, and even more were consuming less than the recommended intake for women and men over 50 years of age. These observations indicate that there is still room for improvement in the achievement of sufficient calcium intakes for mid-aged women and men regardless of BMD test results.

The observed effects of low DXA test results on Vitamin D supplement use are encouraging given that the authors of the BC Nutrition Survey reported that few women and men aged 50 to 71 years were taking Vitamin D supplements and that most people over the age of 50 years would not meet adequate intake levels for Vitamin D without taking a supplement (383). Other authors also have drawn attention to the high prevalence of Vitamin D deficiency in

[61] These quantitative estimates of calcium are very approximate: FFQs are not a reliable means of assessing the adequacy of intakes of nutrients and are intended instead to rank or compare nutrient intakes amongst individuals.

Canadians and recommended that dietary supplementation be considered (235). Three years following DXA, 67% of women with a diagnosis of osteoporosis were taking Vitamin D supplements compared with 38% of those who received a normal diagnosis and 41% of men with osteoporosis were taking Vitamin D compared with 25% of men with a normal diagnosis.

As seen with information seeking, a perceived diagnosis of osteoporosis was even more strongly associated with calcium and Vitamin D supplement uptake after DXA testing than a feedback diagnosis of osteoporosis, particularly in the men. This suggests that the men's lower awareness that they were diagnosed with osteoporosis, as well as their lower baseline use of supplements, may at least partially explain the lower rate of supplement use by men, compared with women, following a diagnosis of osteoporosis. It is to be expected that people need to understand their diagnosis or risk before they will consider lifestyle modification or treatment, and previous studies have found that women who understand their BMD test results were more likely to be treated with bone-specific medications (300;301;331).

Sixty three per cent of the women and 14% of the men who received a diagnosis of osteoporosis were taking bone-related medications three years after their DXA tests. Even though one third of the women were already taking OHT or bisphosphonates before the DXA test, the uptake of bone-specific medications in women who were diagnosed with osteoporosis was clearly much greater than that seen in the men with the same diagnosis. At the time of this study, OHT was the most commonly prescribed preventive medical therapy for osteoporosis in menopausal women and was also commonly prescribed for symptoms associated with perimenopause and menopause, thus at least part of this difference may be explained by the influence of the low test results on menopausal women who were already considering OHT for hot flushes and night sweats; the low BMD diagnosis may have tipped the balance of the decision in favour of starting OHT. Other likely explanations for the much lower rate of medical therapy in men are the higher relative risk of osteoporotic fracture in women (i.e., potentially greater justification for treatment), the general emphasis on and attention to osteoporosis as a woman's disease, and the lack of guidelines and criteria for treatment of osteoporosis in men. The rate of bisphosphonate use by men in this study was, however, much lower than the 41% treatment rate reported by Patel et al. (340) for men diagnosed with osteoporosis by DXA. Their combined sample of men with prostate cancer and volunteers from the community were older on average than the CaMOS mid-aged men and a shorter time period was used (initiation of therapy within six months of DXA) to define medication use. Differences in population characteristics, differences in prescribing practices and insurance coverage between the U.S. and Canada, and

reduced adherence to medication over time are likely to explain the discrepancy in the estimated magnitude of the effect of low BMD results on bone-specific medication therapy in men.

Because this study did not address whether medications or supplements were initiated, but then stopped prior to the Year 3 follow-up, it is not possible to determine the extent to which bone-specific medications were prescribed or initiated and then discontinued. Non-adherence is a significant issue for OHT (347-350) and for bisphosphonates (347;351;416) (but also for calcium and Vitamin D supplements (417)). Although it is very unlikely that all of the women and men with a diagnosis of osteoporosis were prescribed medications, non-adherence to recommended therapy is likely to explain why some of the 37% of women and 86% of the men with a diagnosis of osteoporosis were not taking bone-specific medications at Year 3.

Interestingly, a report of a significant prevalent vertebral fracture from the spinal X-ray had an influence on calcium supplement use, Vitamin D supplement use and the use of bone-specific medications by men with a low BMD diagnosis. Thus, amongst the group who had an X-ray, men with osteoporosis were twice as likely to be taking bone-specific therapy and almost twice as likely to be taking calcium and Vitamin D supplements if they also received a report of a vertebral fracture. Thirty percent of the men aged between 50 and 60 years who were informed that they had a prevalent fracture and who received a diagnosis of osteoporosis from the DXA were taking bisphosphonates three years after testing. This treatment rate falls within the range reported by other authors for men with a fragility fracture who were then followed up with a DXA test (357). Reportedly few men, as well as women, are followed up appropriately with diagnostic testing after fracture; rates of treatment with bone-specific medications are low following a fragility fracture, but even lower in the absence of follow-up testing (333;356;357). These results, and the observation that no men with a reported prevalent vertebral fracture were taking bisphosphonates if they had a normal BMD test result, provide further evidence that low DXA test results have the potential to be influential in decisions relating to the treatment of men who present with a fracture, and that treatment rates are still low in these men, even in the presence of these two significant risk factors.

The influence of a report of a prevalent fracture was not seen in bone-specific medication or supplement use by women, even though the existence of a prevalent fracture is associated with a doubling of the fracture risk associated with a low BMD in both women and men (212). It is possible that a low BMD was seen as a serious enough diagnosis by itself to warrant treatment and lifestyle considerations, and hence the report of a prevalent vertebral

fracture did not have a significant influence on these decisions by the women and their physicians.

As expected, and as reported in a similar study of mid-aged women (345) the use of bone-related osteoporosis medications was significantly more prevalent in the women and men aged 50 years and over than it was in the 40- to 49-year olds. Younger men and women may have taken a "watchful waiting" approach; treatment is not generally recommended for women or men under the age of 50 years. In addition, many of the younger women in this study were pre- or perimenopausal and OHT would not have been appropriate or indicated. Irrespective of their diagnosis, women with a family history of osteoporosis were more likely to be taking osteoporosis-related medications, which indicates that those at higher risk were the most likely to be treated. Women in the highest quartile of BMI were less likely to be taking bone-related medications; less frequent OHT use is typically found amongst women who are heavier or overweight (385;386); this common association is likely to explain the observed relationship between BMI and bone-specific medication use in this study.

Regardless of the diagnosis from DXA, men who identified themselves as "non-white" (who were predominantly, but not exclusively, of Chinese or South Asian origin in this study population) were less likely to take calcium supplements and less likely to demonstrate an increased calcium intake after the DXA test. Furthermore, this subgroup also reported lower intakes of calcium at baseline. As there is evidence that low dietary calcium is a risk factor for hip fracture in Asian men (418) and it is known that calcium intake levels, or the consumption of dairy products, in Asian populations are usually lower than comparable "white" populations (419-422), it may be important to focus attention on strategies to educate Asian men, as well as the physicians who counsel them, about the importance of calcium intake.

The findings of this study that indicate that low BMD results were ineffective at bringing about reductions in the frequency of current smoking behaviour, or in the frequency of high alcohol use, have been consistently reported by previous authors who have evaluated the impact of low BMD test results on one or both of these health behaviours (3;304-306;336;340); only a single study has been able to demonstrate an effect on smoking behaviour (338) while there have been no reports of changes in alcohol use following receipt of low BMD test results. Although some previous researchers have reported results in agreement with these findings, that low BMD test results have no impact on exercise behaviour or caffeine intake (306;332-334;339;340), others have reported positive effects on these behaviours (3;304;305;336-338). The differences in findings between these studies may be explained by different measurement methods,

populations, or intervals between DXA and follow-up. The indication is that, in relationship to low BMD results, positive changes in exercise and caffeine intake are less amenable than supplement use and that smoking and high use of alcohol are particularly resistant to change.

One possible reason for the lack of effectiveness of DXA test results on these other health behaviours is a relatively low level of perceived benefit by both patients and physicians of making proposed changes to these lifestyle behaviours. Although lack of exercise, smoking, heavy alcohol use and high caffeine intake are all considered to be risk factors for osteoporosis and fracture risk, and the results of observational studies have suggested that smoking cessation may reduce fracture risk (264;267;269;270), only increased exercise has been found to be an effective intervention for increasing BMD in controlled trials (261). Guidelines and recommendations have not been consistent about the role of all risk factors and interventions. As noted by Diez (171), in his review of selected guidelines for osteoporosis diagnosis, whereas published guidelines have not varied with regards to the influence of certain risk factors, such as low estrogen, age, low body mass index, limited calcium intake and exercise, there are discrepancies in the emphasis placed on particular lifestyle factors, including smoking, excessive caffeine or heavy alcohol use. Some published guidelines emphasize these as important risk factors for osteoporosis, while others either do not mention them at all or list them as having only marginal impact on bone (171). It may therefore be expected that these health behaviours would be addressed by physicians less frequently when counselling their patients with low BMD test results about their health behaviour and lifestyle options. Furthermore, although people are aware of the association between low calcium intake and osteoporosis, they may be less likely to know that lack of exercise, smoking or excessive alcohol intake are risk factors, as demonstrated by a recent study that compared knowledge in men with osteoporosis and age-matched controls: both cases and controls were less likely to know that high alcohol intake and smoking were risk factors for osteoporosis, and that high impact exercise improved bone, than they were to know that low calcium and vitamin D were risk factors for osteoporosis (317).

Of the two behaviours that have been most consistently associated with the risk of osteoporosis, calcium intake and exercise participation, it is not altogether surprising that exercise appears to present the greater challenge in terms of behavioural change. Blalock et al. observed this same disparity following an educational intervention about osteoporosis (322) and suggested that it is likely that there are greater barriers to engaging in exercise. It is certainly plausible that it is more difficult to initiate and commit to a program of exercise than it is to increase calcium intake, particularly if this intake can be increased by the taking of supplements.

Some potential predisposing influences were found to be associated with increased exercise. The presence of socioeconomic disparities in healthful behaviours (397;423;424), independent of the BMD test results, was suggested by the observations that women and men with the highest level of education were more likely to participate in exercise and that women and men in the highest income quintile were more likely to have exercised at baseline. Furthermore, women in the lowest quartile of BMI, who reported that they were healthier, who were non-smokers and who did not have a history of a significant comorbidity for osteoporosis risk were more likely to be exercising at Year 3. It appears that significant subgroups of the population that are at greater risk of osteoporosis will require targeted interventions and effective methods to support exercise initiation and maintenance.

Even though a report of osteoporosis was not associated with a change in exercise participation, the finding that the women who recalled their diagnosis as osteoporosis were less likely to be participating in regular exercise than were women who recalled a normal diagnosis is a concern. A previous study of the effects of low BMD test results in a population of women referred for DXA found that some women who received low results worried more about fractures and limited their activities because of a fear of falling (3); this same phenomenon may explain the relative reduction in exercise amongst some of the women in this study. Fear of falling as a potential reason for a decrease in exercise participation was not assessed as part of this study, but the findings suggest that physicians should be aware of such potential negative influences of BMD testing; patients with low BMD results should be counselled about the importance of staying active and the potential benefits of exercise participation. In general, undesirable effects of either low or normal BMD test results on bone specific health behaviours have rarely been noted by previous studies, although the frequently used method of simply asking subjects if they have improved their health behaviour since the BMD test would not have detected negative changes in these behaviours.

The finding that women smokers who were diagnosed with osteoporosis were less likely to have stopped smoking by Year 3 than were women with a normal DXA result was also an unexpected result. The explanation for this finding is not obvious, although the possibility that the receipt of an osteoporosis diagnosis caused sufficient anxiety to reduce the likelihood of smoking cessation cannot be ruled out. Previous authors have found that anxiety may be increased in women who receive below average BMD test results relative to those who receive normal results (334). Smokers emerged as a particularly high risk behavioural group in this study and the findings emphasize the importance of paying particular attention to them. Not

only were "unhealthy" bone related behaviours more frequent in smokers at baseline, but these behaviours were also more resistant to change. Specific interventions that are tailored to smokers to support all recommended health behaviour changes, and that treat high risk behaviours as a group rather than individually, may be necessary before DXA testing is likely to be effective at promoting positive behaviour change in smokers.

Participants in this study may have shown little or no change in high alcohol intake because, for most of them, no change was required; baseline levels of this health related behaviour were particularly low in women. In addition, the literature concerning the association of alcohol intake with osteoporosis is not straight forward; positive associations between moderate alcohol consumption and bone mass have been reported (162;163) and a U-shaped relationship likely exists between alcohol intake and fracture risk (277). Thus, another potential explanation for the lack of influence of low BMD test results on this health behaviour is that individuals or their physicians may have found it difficult to assess whether their alcohol intake was moderate ("good") or high ("bad") and if a change was warranted. The added awareness of the potential protective effects of moderate alcohol consumption on other diseases, such as heart disease, stroke, rheumatoid arthritis and Alzheimer's disease (425) may further impede the potential of low BMD test results to influence the modification of high, or excessive, intakes of alcohol that are detrimental to bone and health.

Other potential predisposing influences were associated with reductions in high alcohol or high caffeine intake even though low BMD test results failed to influence these behaviours. Women with certain risk factors for osteoporosis (lower BMI, surgical menopause or premenopausal hysterectomy and lower levels of education) were more likely to make positive changes to their high risk alcohol or caffeine behaviours, even though it is not possible to tell whether these behavioural changes were a result of participation in the CaMOS study and DXA testing.

8.7 Direct-to-Participant Feedback and Bone-Related Health Behaviour

The results of this study indicate that direct-to-participant feedback of the test results had a significant influence on some, but not all, health behaviours, and that this influence was independent of the DXA results. Women and men who received their feedback directly were more likely to have sought further information about osteoporosis and to take calcium supplements, and women were also more likely to take Vitamin D supplements and to participate in a regular exercise program. These findings suggest that engaging participants in the care of

their own health by delivering their results directly to them has the potential to prompt them to learn more about the disease and its associated risks and treatments, which in turn may lead to some positive changes in their bone-specific behaviours.

Other health behaviours that were assessed were not associated with direct-to-participant feedback, including Vitamin D supplement use and exercise participation in men and dietary calcium intake, high use of alcohol, high caffeine intake and smoking in women and men. In addition, direct-to-participant feedback did not have any apparent effect on bone-specific medication use in either women or men. These results agree with most of the findings reported by the two previous studies that addressed the influence of direct-to-participant feedback on bone-related health behaviour. As seen in this study, Campbell et al. (302) reported that their sample of randomly selected mid-aged women in Scotland were no more likely to take OHT and no less likely to smoke cigarettes two years after their results were sent to both the women directly and to their physicians when compared with women whose results were sent to their physicians only. Similarly, Wallace et al. (339) reported that women aged 65 years or younger, who were recruited from amongst women who had been referred for DXA testing, were no more likely to report a high dietary calcium intake if they received feedback directly from a consultant. On the other hand, the observation in this study that exercise participation in women was influenced by direct feedback of results contrasts with the negative findings regarding this behaviour by these previous authors (302;339). High rates of baseline exercise, short term follow-up and high attrition (339), as well as different means of measuring and defining exercise participation (302;339) may explain the discrepant findings. To my knowledge, the current study is the first study to assess the effects of direct-to-participant feedback of BMD test results on calcium supplement use, Vitamin D supplement use and high caffeine intake in women and the first to assess its effect on any bone-related health behaviour in men.

Potential negative effects of direct-to-participant feedback were not addressed by this study, but there was no evidence of a reduction in activity (as defined by participation in regular activity) amongst women or men who received their low BMD test results directly. Previous studies have reported that levels of anxiety (302;339) and depression (339) have not been found to differ in women who have received direct feedback of DXA results.

The relationships that were found between direct-to-participant feedback and positive changes in health behaviour (calcium supplements in men and women, Vitamin D supplements, exercise and caffeine intake in women) were evident in each case when the BMD results were sent to both the participant and to the physician. This suggests that the provision of test results

to the participant as well as to the physician has the most potential to lead to better awareness and knowledge about osteoporosis (through information seeking) as well as positive changes in health-related behaviour. The provision of test results directly to participants further provides a "back up" method of ensuring that the results reach the patient. It is known that even when patients have been referred for a DXA test, physicians do not always review and act on low test results (426); the results of this present study suggest that physicians are less likely to review borderline or normal test results.

The means by which direct-to-participant feedback may lead to positive health behavioural changes were not measured as part of this research. One possible explanation however is that the combined effect of empowerment or "activation" (358;360) of the participant and the direct involvement of the family physician as a potentially important source of information and potential reinforcing factor for positive behavioural change (see Figure 3.1) resulted in the positive changes that were observed in some bone-related behaviours. Previous literature suggests that patients who have been primed with information about their health, and encouraged to formulate questions, prior to consultations with their physicians, are more effective at eliciting information from their physicians (361;427): It is feasible that direct provision of test results similarly served to prime the participants to seek and gain information, and to make informed decisions about appropriate changes to their health behaviour. Thus, these findings provide evidence that involving patients in their health care by delivering bone density test results directly to them may activate or empower both women and men to seek out more information about osteoporosis and may have some impact on the initiation or maintenance of healthful bone-related behaviour.

8.8 Recommendation for Follow-up or Treatment

A relatively simple intervention by two of the testing centres may have had a significant positive effect on information seeking about osteoporosis for both women and men; a recommendation included in the feedback report for a referral to an osteoporosis program (or for treatment in a few cases) was associated with a nine-fold increase in reported information seeking by the women and almost a three-fold increase in information seeking by the men. Likewise, the inclusion of such a recommendation was associated with an increased likelihood of bone-specific medication use, exercise participation and smoking cessation in women and with an increased likelihood of calcium and Vitamin D supplement use in both women and men.

Most often, the recommendation was to refer the participant to a local osteoporosis clinic, but in a few other cases (<10%) there was a specific recommendation for treatment by medication. A previous study of the effect of long clinical bone densitometry reports compared with short technical reports showed that more detailed reports had a significant impact on the understanding of BMD results and patient management by physicians, and also that physicians preferred to receive reports with treatment and follow-up recommendations (428). The findings of this current study suggest that a simple recommendation for a referral to an osteoporosis clinic program, or for treatment, was effective at improving the treatment as well as the bone-specific health behaviours of high-risk women and men.

Although the effects of this intervention must be interpreted cautiously because it was localized to only two centres where differential resources may have facilitated information seeking and was included at the discretion of the physicians at these centres (and therefore subject to potential bias), it does indicate that the effects of a simple, low cost intervention such as a recommendation by the physician who interprets the BMD scan has the potential to be an effective intervention. This warrants further investigation.

8.9 Strengths and Limitations

This study has several strengths. Firstly, this was a prospective study of a large randomly selected population-based sample of men and women; it is the first study to investigate the effects of BMD testing in a population-based sample of men and one of only two studies to assess men's behavioural change following DXA testing. The follow-up period for this study was likely to have been long enough to allow for the establishment of health behaviours and medication use. Additionally, several potential predisposing factors have been considered that may either serve to identify specific subgroups that are more or less amenable to the effects of DXA test results, or to confound the influences of low DXA test results. Baseline measures of all behavioural variables were taken into account rather than relying on self-reports of behavioural change with its associated potential recall bias. Finally, all analyses were subject to further sensitivity or alternative analyses in an attempt to control for or identify potential biases and systematic errors that are typically inherent in observational data.

The results of this study are expected to be generalizeable to community-dwelling mid-aged women and men who live in or near major urban centres of Canada and who are willing to attend BMD testing. The results may not however be generalizeable to populations that were not represented by the study sample: Women and men under the age of 40 years or over the age of

60 years, Aboriginal populations of Northern Canada and people dwelling in rural areas or living in institutions may be expected to respond differently to DXA test results and to direct-to-participant feedback. In addition, women and men who are not English-, French-, or Cantonese-speaking were not represented; minority cultural or ethnic groups who converse in less commonly used languages in Canada may be expected to respond differently to BMD test results as well as to direct-to-participant feedback. Further, it is acknowledged that the sample may be somewhat over-representative of non-smokers, and of healthier, more highly educated women and men; adjustment was included for these and other potential confounders. The 14% of participants who declined the BMD test or were lost to follow up did not differ from the women and men who were included in the study in terms of BMI, race, menopausal status, neighbourhood income quintile, family history of osteoporosis, history of exposure to a significant "high risk" comorbidity or medication, and baseline levels of all health behaviours other than smoking; furthermore diagnosis was not associated with loss to follow up.

Many of the variables used for this study were based on self-report. Recall bias is a potential problem with this method of data collection and occurs when individuals in the affected group report their exposures differently from those who are not affected. Individuals with low BMD results, for example, might have minimized their reported intake of alcohol or maximized their reported intake of calcium to appear more acceptable to the interviewer. The CaMOS study design may have limited the potential for recall bias to some extent, however, by using trained interviewers rather than self-administered questionnaires, and by incorporating detailed, closed-ended questions such as food frequency questionnaires listing individual food items and amounts. Furthermore, neither the participants nor the interviewers were aware of the hypotheses of this particular study, with health behaviour as an outcome of interest, and the participants were not specifically asked about health behaviour change. This may have resulted in less pressure to report improved behaviour or differential reporting of behaviours than that present in previous studies that specifically asked about behaviour change as a result of DXA testing. Instead, the study was presented to the interviewers and participants as an investigation of the incidence and prevalence of osteoporosis and a description of the influence of potential risk factors on bone density and fracture risk.

Recall of historical events, such as a history of exposure to corticosteroids or anticonvulsants or a family history of osteoporosis, may have been subject to errors in recall. This is not a significant limitation, however, because an "awareness" of these potential risk factors or exposures was the factor of interest rather than the actual exposure. Measurements of

the main explanatory variables (the diagnosis received, the destination of the feedback and whether a recommendation for treatment or follow-up was included in the feedback) did not rely on self-report and were collected by objective methods, as were height and weight (and hence BMI). In addition, because the participants were requested to bring all their current medications to their baseline and Year 3 interviews current medications and supplements were verified by the interviewers.

Although parts of the CaMOS questionnaire that were used to derive variables for this study have been extensively tested for validity and reliability, such as those items taken directly from the NPHS and the SF-36, and other components of the questionnaire, such as the reproductive history questions, have been shown to have high reliability (429), other questions that were generated specifically for the CaMOS study have not yet undergone reliability or validity testing. In particular, this may limit the interpretation of findings involving the continuous measures of calcium intake and caffeine intake. Calculations of calcium and caffeine intake were however calculated with reference to listings in the Canadian Nutrient File (375). There is some possibility that dietary calcium intake at Year 3 was underestimated because fortified beverages that became available in Canada between baseline and the Year 3 follow-up were not included on the Year 3 questionnaire. If there was differential uptake of fortified beverages by those diagnosed with osteoporosis, for example, then a relative increase in dietary calcium intake in the lower BMD groups may have been missed or underestimated. It should be noted however that, according to marketing data,[62] the sales of fortified soy and rice beverages in the Canadian market made up only 0.2% of the total fluid dairy sales during the years 2003-2005. This suggests that the exclusion of these particular beverages from the calculations of dietary and total calcium intake is unlikely to have had a significant effect on the estimates of dietary or total calcium intake.

Many of the explanatory and outcome variables were measured as, or collapsed into, dichotomous categories, which may have resulted in the oversight of existing subtle differences between subgroups. Although no associations were found between the results of the DXA testing and participation in a regular exercise program, for example, there may have been differences between different diagnostic subgroups and amongst those who participated in regular exercise, in the amount of time spent exercising or the intensity of the exercise. On the other hand, the results of the analyses of the two health behaviour outcomes that were measured

[62] Source: A.C.Nielsen; Canada Retail Sales Data (2003-2005). Personal Communication, Dr. Susan Barr 2007.

as continuous variables (calcium and caffeine intake) and as dichotomous measures (calcium supplement use and high coffee intake) led to comparable interpretations.

Race, which is likely to represent a conflation of different language abilities, ethnic and cultural backgrounds, immigration status, and genetic variants, was dichotomized due to the small numbers in the "non-white" groups. The majority of participants who were categorized for the purpose of this study as "non-white" described themselves as Chinese (49%) or South Asian (22%); other racial or ethnic groups were not as well represented. Because this variable was collapsed into two broad categories, the interpretation of the association with the race/ethnicity variable cannot be assumed to apply to any one specific "non-white" group.

Neighbourhood income quintile was used as a contextual estimate of socioeconomic status for this study, but was derived from only the first three digits, or the Forward Sortation Area (FSA), rather than the full six digits of the postal code and is therefore only a crude estimation of neighbourhood income. A previous study of Canadians with rheumatoid arthritis reported that even when neighbourhood income quintile was derived from all six digits it correlated poorly with self reported measures of SES (individual income and education) in people aged 50 years and over (430). On the other hand, neighbourhood income has been found to correlate well with these self reported measures in younger (asthmatic) Canadian patients (431). The finding that a lower neighbourhood income quintile was associated with lower levels of education in both women and men, suggest that there is some validity in the contextual estimate of SES in this population. It is unlikely, however, that neighbourhood income quintile, based on only the FSA, is a highly sensitive predictor of individual SES in this mid-aged population, thus real associations between SES and the outcomes in this study may have been missed.

It is not possible to accurately estimate any variation resulting from differences associated with the CaMOS centres, rather than from the method of feedback of test results because the feedback method was almost completely nested within the centres. Unmeasured potential enabling factors that may have been associated with the centre, such as the availability of community resources and local health promotion campaigns, as well as the sociocultural environment, could account for some or all of the differences in awareness of test results, information seeking and health behaviour that were found to be associated with direct-to-participant feedback. While adjustment for individual level variables measured at baseline may have countered some of the limitations brought about by this nesting, interpretation of the effects

of this intervention on awareness, information seeking and health behaviour change is limited due to this aspect of the study design.

This study assessed multiple outcomes; the statistical likelihood of finding a chance association was therefore increased.

A control group of men and women who did not undergo DXA testing and did not attend an extensive interview about the risk factors for osteoporosis was not included in this study. It is possible that these interventions may have resulted in information seeking and positive bone-specific health behaviour changes, irrespective of the test result; these potential influences could not be assessed by this study. It is known that simply being part of a study and being observed can be sufficient to instigate behavioural changes and this is a common problem with clinical trials of preventive interventions with behavioural outcomes (432); people who are being observed tend to perform or behave in more positive ways than they would otherwise. Still, the results of two published studies that have investigated the effects of randomization to DXA (both in mid-aged women) suggest that women who receive average or normal DXA test results are no more likely than are women who are randomized to no DXA to demonstrate increased bone-specific behaviour and medical therapy (332) or OHT use (345).

Although the potential roles of many different individual-level factors were taken into account in this study, there are other unmeasured factors that may have influenced whether the participants were aware of their test results, whether they sought information and whether they adopted health behaviour changes. The way in which information is communicated by physicians, for example, can have a significant impact on how patients interpret an "at risk" diagnosis, whether they attend to the information or whether they decide to adhere to recommended interventions (359). Family physicians were not contacted and participants were not asked whether they had discussed their results with their physician. Similarly, the role played by systemic conditions such as programs and resources was not addressed; participants were not asked whether they had attended community osteoporosis clinics or participated in osteoporosis education programs, for example.

The questionnaires were administered in the latter half of the 1990s; OHT is no longer recommended as a preventive intervention for osteoporosis in menopausal women due to adverse findings from the primary prevention trials of estrogen and progestin (81) and estrogen-alone (82) by the Women's Health Initiative. Many other preventive bone-specific medications, including the selective estrogen receptor modulator (SERM) raloxifene and several bisphosphonates, are available and have been used increasingly as the prescriptions of OHT for

osteoporosis have declined (433); women, however, appear to be just as likely to discontinue raloxifene or a bisphosphonate as they are to discontinue OHT (299;416). Thus, there is no reason to expect that these results regarding the use of OHT and the bisphosphonates that were available at the time of this study would not be just as applicable to alternative therapies available today. Furthermore, the guidelines and recommendations regarding bone-specific health behaviours have not changed significantly since the CaMOS cohort was recruited.

It is possible that the level of awareness about osteoporosis amongst consumers and physicians has increased since the CaMOS study was initiated. With the aim of facilitating physicians' understanding of an individual's risk of fracture and their decision making for therapy interventions, attempts are now being made to change from the simple reporting of BMD test results and WHO diagnostic categories in Canada to a categorization of an individual's 10-year risk of fracture as low, medium or high based on other risk factors, such as age and sex, as well as their DXA test results (434). While the effectiveness of these reporting changes is not yet known, the results from studies that have been conducted since the CaMOS baseline have indicated that the level of awareness of osteoporosis and the likelihood of intervention in high risk cases, particularly among men, remains low (333;435;436) and that physicians are unclear about the diagnosis of and interventions for osteoporosis and report that they do not use clinical practice guidelines for osteoporosis (95). It therefore seems reasonable to assume that the findings from this study are a reliable indication of the potential effectiveness of BMD screening in a mid-aged population of Canadians today.

8.10 Implications and Future Directions

The use of BMD testing by DXA as a screening tool, while controversial, is not recommended for women or men under the age of 65 years. Nevertheless there is evidence that guidelines for referral to DXA are not always followed and that mid-aged women in particular, are frequently "screened" for osteoporosis (4;44;95;96). The 40–60 year old CaMOS cohort provided a model for the assessment of the potential effectiveness of a DXA screening program for mid-aged women and men in Canada on awareness of osteoporosis-related risk, information seeking and bone-specific health behaviours, including medication use. Non-selective DXA testing in this population of mid-aged women and men appears to be effective at promoting information seeking about osteoporosis, the initiation or continuation of calcium and Vitamin D supplements and the use of bone-specific medications in women and men who are found to be at a relatively higher risk of future fracture because of low bone density.

DXA testing should not be expected to influence exercise participation or high risk bone-specific health behaviours (smoking, high alcohol use and high caffeine intake). Specific health behaviour interventions to support those with osteoporosis would need to be implemented and evaluated for effectiveness before DXA test results are likely to have a significant impact on these challenging behaviours; low test results alone and standard care are not sufficient to have any impact on them.

Although the potential impact of DXA testing on osteoporotic fractures is greater in mid-aged women than in mid-aged men because of the higher relative risk of fracture in women and the greater impact of test results on medication uptake, there was still room for considerable improvement in calcium intake levels, Vitamin D supplement use and exercise participation, as well as "high risk" bone-related health behaviours, amongst women diagnosed with osteoporosis. The findings that low BMD test results have only a moderate influence on the proportion of women and men meeting the minimum recommended intake levels of calcium, and on the use of both bone specific medication and Vitamin D supplements, implies that the potential impact of a general DXA screening program for mid-aged women and men would be limited. Given other limitations of BMD testing in this age group such as the significant cost, the uncertainty of the long term benefits of available medications or supplementation and the poor predictive value of BMD for fracture (which means that only a proportion of those who are destined to fracture would be identified as "at risk"), the results of this study do not provide sufficient evidence to support a policy for general population BMD screening in this age group. Only a small proportion of those who are destined to experience osteoporotic fracture would be expected to benefit from such a program.

The findings from this study underline the importance of considering a DXA test only if the results are expected to influence treatment or lifestyle decisions; there is no value in using DXA as a resource for women (or for men) if there are no plans to add medication or to change health behaviours in the event of a low DXA test result. Osteoporosis-related health behaviours should be evaluated before referral for testing to determine whether changes would be recommended and the likelihood of acceptance of recommended health behaviours and medical therapies in the event of a low test result should be discussed.

In contrast to women, DXA testing in this age group of men is not common. Even though BMD test results were found to be effective at increasing calcium and Vitamin D intake in men with low bone density, screening for low BMD in this age group of men is unlikely to be a valuable intervention for the reduction of the burden of osteoporotic fractures in men: Firstly,

there is a low absolute risk for fracture for men of this age in the absence of other risk factors, and secondly the results of this study indicate that in the event that men are diagnosed with osteoporosis or osteopenia, they are unlikely to increase their exercise participation or reduce high risk behaviours, they are only moderately likely to take calcium or Vitamin D supplements and few men with osteoporosis would maintain a bone-specific medical therapy. There was some indication from this study on the other hand, that treatment decisions for men with prevalent vertebral fractures may be influenced by DXA test results, and referral for diagnostic BMD testing of men who present with fragility fractures should be encouraged.

The findings that very few men with a low BMD were aware that they were diagnosed with osteoporosis, even when informed of their results directly, emphasizes the need to pay greater attention to the portrayal of osteoporosis as a disease of men as well as women and to education campaigns that are relevant to men. Overall, women were more likely to be aware of their diagnosis, more likely to seek information about osteoporosis and more likely to participate in healthy bone-related behaviours. The results of this study suggest, however, that men who are aware of their low bone density results are just as likely to seek information and to take supplements as are women when they are aware of their low test results; behavioural change in those men who are at increased risk should first be targeted by ensuring that test results, and the message that osteoporosis is relevant to men, are effectively communicated to them.

Because these results indicate that men are prepared to increase their calcium and Vitamin D intake when they understand that they may be at risk for osteoporosis-related fracture and when osteoporosis is made relevant to them, educational interventions that target adequate intakes of these nutrients, which are typically below recommended levels, may be successful. In addition, physicians should pay extra attention to calcium intake levels of "non-white" men because there is evidence that their intake of calcium is low, in general, and is not as responsive to the influence of DXA testing, or to the report of a relative increased risk of fracture. Low calcium intake is likely to be a risk factor in many men in this subgroup; further research would be required however to determine which particular "non-white" men are at risk.

Smokers stand out as a high risk group because they demonstrate a combination of behaviours that jeopardize their bone health and they are particularly resistant to change even when they are informed of their increased risk. It is possible that high risk behaviours in women and men who smoke may be more effectively addressed as a group of behaviours and it seems very unlikely that low DXA results alone would provide sufficient motivation for smokers to stop smoking.

Even though correct recall of a diagnosis of osteoporosis or osteopenia was low in men, it was not particularly high in women; neither women nor men can be relied upon to accurately report the results of their DXA tests. Although this has implications for questioning whether osteoporosis has relevance to this age group of women and men, it also has implications for clinical practice and research situations where self report of medical history is commonly used to acquire data. It is possible that some people "minimize" their diagnosis of osteoporosis or osteopenia, in which case it is not known whether a more focused effort to effectively communicate DXA test results would change their awareness of risk, or even if an improvement in the awareness of risk would offer an advantage; this would certainly merit further investigation.

When communicating the risk information from DXA test results, it is essential that psychological distress is minimized; women and men who receive a DXA result should be made aware of the limitations of the test and the uncertainties that accompany a diagnosis of osteoporosis by BMD as well as the importance of remaining active and exercising.

The results of this study imply that physicians do not always relay to their patients the normal or borderline results of DXA tests. Ideally, physicians should communicate the results of DXA testing to their patients, irrespective of the result, and use this as an opportunity to counsel their patients about the meaning of the results as well as about lifestyle interventions that have the potential to lower their risk of developing osteoporosis as they get older. The findings here have demonstrated that receipt of a borderline diagnosis (osteopenia) is sufficient to increase the intake of calcium and Vitamin D in women and men; people cannot however be expected to initiate behavioural changes in response to a low DXA result if they are not informed of their diagnosis. Women and men are interested in seeking further information about osteoporosis after a DXA test, particularly if the results are low; consultations to discuss test results should be used by health-care providers not only as an opportunity to provide patients with information about osteoporosis, its risk factors and options for lifestyle modification or therapy, but also to direct patients to reliable and trusted sources for further information.

Direct-to-participant feedback, together with feedback to their physician, should be considered as a potential method for informing women and men of their DXA results. Not only does it hold the potential to lead to greater awareness of test results, or risk status, amongst those who receive borderline as well as average results, it may also lead to increased information seeking about osteoporosis and positive changes in specific bone-related health behaviours

regardless of the diagnosis. At the very least, direct-to-participant feedback provides a back up to ensure that patients receive their test results in the event that physicians do not pass them on.

Regarding reports of low BMD results, the inclusion of a simple recommendation for a referral to an osteoporosis program in the community, or for treatment, may be effective at increasing information seeking about osteoporosis and the participation in certain bone-specific health behaviours, particularly in women. This intervention merits further research in a controlled study. Future research could include an assessment of the effects of direct-to-participant feedback of test results and the inclusion of a recommendation for referral to an osteoporosis clinic in reports of osteoporosis, in a randomized controlled design. These two simple interventions demonstrated potential effectiveness in this study but the replication of these effects in the absence of the potential biases that were intrinsic to this quasi-experiment should be addressed. Future assessments of DXA interventions, and direct-to-participant feedback, should incorporate the measurement of potential negative consequences of the receipt of low DXA test results such as fear, anxiety or worry, as well as inappropriate limiting of activities.

Although the design of this study was limited to a follow-up period of three years, the CaMOS study is still underway and the cohort is now in its 11th year of follow-up. One potential direction of research would be to investigate the effects of serial bone density tests (conducted at 3, 5 and 10 years in mid-aged women and men) on awareness of test results and the persistence of the behavioural changes and medications that were reported at Year 3. Furthermore, the impact of the uptake of calcium and Vitamin D supplements as well as the use of bone-specific medications amongst those with low BMD results could be investigated.

Other substantive work that could follow from this study is an economic evaluation of the potential impact of screening for low bone density in women or men within this age range, who have or do not have risk factors for osteoporosis. The estimates provided by this research of the impact of DXA testing on the use of supplements and bone-specific medications within sex, age and specific risk factor subgroups provide a foundation for such an economic analysis. Other requirements for such an analysis would include (but are not limited to) estimates of the prevalence of osteoporosis or osteopenia in this age group, estimates of the efficacy of these interventions for fracture prevention in mid-aged men and women with osteoporosis or osteopenia, estimates of the risk of fracture associated with these diagnoses in mid-age, and estimates of the various costs associated with screening, preventive treatment and the treatment and care of those with osteoporosis-related fracture. Finally, this study should be replicated in a

population-based sample of older women and men to determine if the same factors are influential in awareness of DXA test results, information seeking and bone-related health behaviours in those aged 65 years and over, the age group for whom DXA screening is currently recommended.

8.11 Conclusion

Osteoporosis is a significant public health problem for both women and men with devastating associated personal and economic costs. Prevention and early intervention offer the greatest potential to change the course of this disease and to minimize the related morbidity, mortality, quality of life and economic burden. BMD testing as a means of identifying those at increased risk for fracture offers the potential for intervening, through lifestyle modification and medical therapy, with the aim of reducing bone loss or increasing bone density in those who are at greatest risk of future fracture. If BMD testing is to have this potential, however, test results must be effectively communicated to women and men so that they are made aware of their risk; people also need to be knowledgeable about the lifestyle modifications and medical therapy options that are available to them. Finally, those tested must be willing to initiate and maintain recommended behavioural changes and therapies. Population-based screening for osteoporosis is controversial; although it is not currently recommended for those under the age of 65 years in the absence of other risk factors, there is evidence that guidelines for referral to DXA are only loosely followed, particularly for perimenopausal women, and the question of whether non-selective screening by DXA would be worthwhile is regularly discussed in the literature.

The findings from this study show that BMD testing in women and men aged 40 to 60 years is associated with information seeking about osteoporosis and with a relative increase in calcium and Vitamin D intakes as well as medical therapy in those at greatest risk for future fracture compared with those who are deemed at average risk. However, awareness of low test results was poor, and the absolute impact of a low BMD test result on the uptake, or continuation, of calcium and Vitamin D supplementation was only moderate; there remained a substantial proportion of women and men with a diagnosis of osteoporosis that still had an insufficient intake of calcium and were not taking Vitamin D supplements. Furthermore, the impact of a diagnosis of osteoporosis on medical therapy for men in particular, was small. Finally, there was no evidence that low DXA test results increased exercise participation or reduced "high risk" health behaviours in those with low BMD test results. Among smokers, a

group known to be at particular high risk for osteoporosis, the influence of BMD testing on positive health behaviours was even less evident than among non-smokers.

In conclusion, there is insufficient support, based on these findings, for population-based screening for men and women aged 40 to 60 years. Rather, these results support the general consensus that DXA screening in this age group should not be recommended; not only are there low positive and negative predictive values for fracture (as shown by other studies, not the subject of this work), but the provision of a low BMD test result appears to have only a moderate impact on changes in calcium and Vitamin D intake and medication uptake in women and men who are found to be at risk of future fracture, and no apparent influence over other bone-related health behaviours. The conclusions from this study are specific to the age group of the study participants; the potential influence of low BMD test results and direct-to-participant feedback may be different for older aged women and men who are screened by DXA. For situations where DXA testing is justified, certain subgroups were identified (smokers, women with a history of rheumatoid arthritis or eating disorders, women with a lower level of general health and "non-white" men) that are likely to require more intensive support and interventions if BMD testing is to have any influence over their health behaviours and ultimately their fracture risk. Finally, a relatively simple intervention, direct-to-participant feedback of test results, demonstrated the potential to have a positive influence over certain bone-specific health behaviours.

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Appendix A

Relevant Questions from the Baseline CaMOS Questionnaire

Q. 1.7 How do you best describe your race or colour?
(Interviewer does not read list. Marks all that apply)

____ White
____ Chinese
____ South Asian
____ Black
____ Native/Aboriginal Peoples of N. America
____ Arab/West Asian
____ Filipino
____ South East Asian
____ Latin American
____ Japanese
____ Korean
____ Other (specify) _____

Q. 1.8 How many years of school have you finished? *(Mark the highest grade completed)*

____ Less than Grade 9
____ Grade 9-13, without certificate or diploma
____ High School certificate or diploma
____ Trades or professional certificate or diploma (CEGEP in Quebec)
____ Some university without certificate or diploma
____ University degree

Q. 2.1 MEDICAL HISTORY

Has a doctor ever told you that you have any of the following conditions?

Osteoporosis _____ Y / N / DK

Rheumatoid Arthritis _____ Y / N / DK

Eating Disorder _____ Y / N / DK

Q. 3.1 DRUGS AND MEDICATION

Have you ever taken any of the following medications daily for more than one month?

Dilantin (seizure pills) / Phenobarbital ____ Y / N

Cortisone / Prednisone
- Oral ____ Y / N
- Inhaled ____ Y / N
- Injection a) Intravenous ____ Y / N
  b) Intramuscular, Subcutaneous ____ Y / N

Q. 3.2

Current Medications and/or self administered supplements taken on a regular basis:

Medication and supplements from contents of medicine cabinet

Name: Dose: Frequency:

Medications were brought to the interview by the participant and recorded in detail by the interviewer.

Q. 5.2 Have your menstrual periods stopped for more than one year?
(No period one year or more after menstruation)

Yes _____ At what age?_____
No _____

Q. 5.3 Have you had your uterus removed *(hysterectomy)*?

Yes _____ At what age? _____
No _____

Q. 5.4 Have you ever had one or both ovaries removed?

Yes, one ovary removed _____ At what age? ____
Yes, both ovaries removed _____ At what age? ____
(if ovaries were removed in separate occasions, write the age that the second ovary was removed)
Yes, do not know how many ____ At what age? ____
No ____

Q. 5.5 Do you or did you ever take estrogen for menopause or for any other reason?

- Yes Currently
- Yes, but not now
- No

Q. 5.6. Do you or did you ever take Provera for menopause or for any other reason?

- Yes, currently
- Yes, but not now
- No

Q. 9.1 Have you ever used any of the following tobacco products daily for at least 6 months?

Cigarettes Yes ____ No ____
If yes, go to question9.2

Q. 9.2 Are you currently smoking cigarettes? Yes ____ No ____

Q. 10.1 Food Intake: How often *(on the average)* have you eaten the following items during the last 12 months?

Food	Never	Serving per month	week	day	Serving Size
Milk to drink inc.choc milk and hot cocoa w/milk					__ 125ml (0.5 cup) __ 250 ml (1.0 cup) __ 375 ml (1.5 cup)
Milk on cereal					__ 60 ml (0.25 cup) __ 125 ml (0.5 cup) __ 375 ml (1.0 cup)
Milk/cream in tea/coffee					__ 15 ml (1 tablesp.) __ 30 ml. (2 tablesp.) __ 60 ml (4 tablesp.)
Milk desserts *(tapioca, rice pudding)*					__ 125 ml (0.5 cup) __ 375 ml (1.0 cup)
Hard Cheese *(to eat, in sandwich or mixed dish)*					__ 15 g (0.5 oz..) __ 30 g. (1 oz..) __ 60 g (2 oz.)
Yogurt					__ 125ml (0.5 cup) __ 250 ml (1.0 cup) __ 375 ml (1.5 cup)
Ice-cream, ice milk or frozen yogurt					__ 125ml (0.5 cup) __ 250 ml (1.0 cup) __ 375 ml (1.5 cup)
Cream soups made with milk					__ 125ml (0.5 cup) __ 250 ml (1.0 cup) __ 375 ml (1.5 cup)
Canned salmon or sardines with bones					__ 30 g. (1 oz.) __ 60 g (2 oz.) __ 90g (3 oz)
Broccoli					__ 60 ml (0.25 cup) __ 125 ml (0.5 cup) __ 375 ml (1.0 cup)
Dark leafy greens (bok choy, kale, gailan orChinese broccoli, collards, dandelion greens)					__ 60 ml (0.25 cup) __ 125 ml (0.5 cup) __ 375 ml (1.0 cup)
Dried peas or beans (navy, pinto, kidney)					__ 60 ml (0.25 cup) __ 125 ml (0.5 cup) __ 375 ml (1.0 cup)
Whole wheat bread, buns, rolls, bagels, etc.					1 serving = 1 slice, ½ bagel, ½ pita
Tofu					__ 60 ml (0.25 cup) __ 125 ml (0.5 cup) __ 375 ml (1.0 cup)

Q. 10.2 How many of the following drinks did you consume, in the past 12 months?

In these questions, one serving of alcoholic beverage is:

- *1 bottle or can of beer or a glass of draft (12 oz.)*
- *1 glass of wine or a wine cooler (4-5oz)*
- *1 straight or mixed drink with (1 – 1 ½ oz.) hard liquor*
- *the reference measure for 1 serving of tea or coffee is 6oz (tea cup size)*
- *the reference measure for 1 serving of cola is 12oz – 1 can (355ml)*

Beverages	None	serving/month	serving/week	serving/day
Coffee: Caffeinated Decaffeinated				
Tea: Caffeinated Decaffeinated				
Colas Caffeinated Decaffeinated				
Alcoholic Beverages				

Q.. 11.3. Do you currently participate in any regular activity or programme (*either in your own or in a formal class):*

- Yes
- No

Q. 15.1 (*From the SF-36)*

In general, would you say your health is:

- Excellent
- Very Good
- Good
- Fair
- Poor

Appendix B

Relevant Questions from the Year 3 CaMOS Questionnaire

Q. 1.5. What were the results of your bone density test, 3 years ago?

- Don't know, I am unsure
- High or normal bone density
- Low without osteoporosis (borderline "osteopenia")
- Low or "osteoporosis"
- N/A (No DXA test at baseline)

.

Q. 1.6 In the past 3 years, have you sought information on osteoporosis:

from the Osteoporosis Society of Canada?.....Y / N

from a local pubic health resource? (*eg. Women's health centre)*.....Y / N

from a health care professional?: Nutritionist.....Y / N

Physiotherapist or exercise specialist....Y / N

Nurse.....Y / N

Physician.....Y / N

Other.....Y / N

Specify _____

From another source?.....Y / N

Specify _____

Q. 3.2

Current Medications and/or self administered supplements taken on a regular basis: Medication and supplements from Contents of medicine Cabinet

Name: Dose: Frequency:

Medications were brought to the interview by the participant and recorded in detail by the interviewer.

Q. 5.10. In the past 3 years have you taken estrogen for menopause or for any other reason?

- Yes Currently
- Yes, but not now
- No

Q. 5.11. In the past 3 years have you taken Provera (*medroxyprogesterone acetate)* for menopause or for any other reason?

- Yes, currently
- Yes, but not now
- No

Q. 5.12 Have you ever taken Prometrium for menopause or for any other reason?

- Yes, currently
- Yes, but not now
- No

Q. 9.1 In the past 3 years, have you smoked cigarettes daily for at least 6 months?

- Yes
- No (go to Q. 9.6)

Q. 9.2 In the past 3 years, did you start smoking for the first time?

- Yes
- No

Q. 9.3 Are you currently smoking?

-Yes
- No

Q. 10.1 *See question 10.1 in Appendix A: The food question was identically worded on both the Baseline and Year 3 questionnaires.*

Q. 10.2 *See question 10.2 in Appendix A: The beverage question was identically worded on both the Baseline and Year 3 questionnaires.*

Q. 11.3 Do you currently participate in any regular activity or programme (*either on your own or in a formal class)?*

Yes ____

No ____

Appendix C

CALCIUM CONTENT OF VARIOUS GROUPS OF FOOD USED TO DERIVE CALCIUM INTAKE BY CaMOS

FOOD (100G)	MG CALCIUM (Average of foods in group)
Milk to drink Whole, partly skimmed 2%, 1%, chocolate, skim	124 mg
Milk on cereal Whole, 20%, 1%. Skim	127 mg
Milk/cream in tea or coffee	119 mg
Milk Desserts Tapioca, rice pudding made with milk	101 mg
Hard cheese Cheddar, Provolone, Gouda, Colby, Edam, Gryère, Swiss, Brick	780 mg
Yogourt	163 mg
Ice cream, Frozen yogurt, Ice Milk	136 mg
Cream Soups made with milk	74 mg
Salon/Sardines with bones	315 mg
Broccoli	49 mg
Dark leafy greens Bok Choy, collards, dandelion greens	128 mg
Legumes Navy Beans, pinto beans, kidney beans	46 mg
Bread – White - Whole wheat	68 mg 106 mg
Newfoundland bread – white - Whole wheat	135 mg 174 mg
Tofu average for caSo2 and MgCl precipitate	337 mg

Appendix D

CAFFEINE CONTENT OF BEVERAGES USED TO DERIVE CAFFEINE INTAKE BY CaMOS

One serving = 6oz.	Amount of caffeine
Coffee caffeinated:	131.04mg
Coffee decaffeinated:	3.6mg
Tea caffeinated:	42.0mg
Tea decaffeinated:	1.2mg
Cola caffeinated:	19.3mg
Cola decaffeinated:	0.0mg.

Appendix E

Table E.1 Destination of Feedback and its Association with the Other Explanatory Variables in Women

Destination of Feedback (Total N = 1832)[a]		**Direct to FP** N = 382 (21%)	**Direct to Pt** N = 935 (51%)	**Direct to Both** N = 515 (28%)
		N (%)	N (%)	N (%)
[b]Significant Prevalent Fracture* **		7 (2.7)	31 (5.6)	54 (15.1)
Age Group	40 to 49 years	111 (29.1)	309 (33.0)	142 (27.6)
	50 to 60 years	271 (70.9)	626 (67.0)	373 (72.4)
Body Mass Index (BMI)*				
	Lowest Quartile	70 (18.3)	246 (26.4)	142 (27.6)
	Second Lowest Quartile	95 (24.9)	243 (26.1)	120 (23.3)
	Second Highest Quartile	106 (27.7)	220 (23.6)	130 (25.3)
	Highest Quartile	111 (29.1)	223 (23.9)	122 (23.7)
"Non-white" Race * **		7 (1.8)	24 (2.6)	76 (14.8)
Reproductive Status* **				
	Premenopausal	118 (30.9)	341 (36.5)	179 (34.8)
	Naturally Menopausal	134 (35.1)	348 (37.3)	216 (42.0)
	Surgically Menopausal	24 (6.3)	84 (9.0)	32 (6.2)
	Premenopausal Hysterectomy	106 (27.7)	161 (17.2)	87 (16.9)
Education* **				
	Incomplete High School	78 (20.4)	269 (28.8)	110 (21.4)
	Complete High School	48 (12.6)	185 (19.8)	103 (20.0)
	Postsecondary Education	176 (46.1)	335 (35.8)	196 (38.1)
	University Degree	80 (20.9)	146 (15.6)	106 (20.6)

Destination of Feedback (Total N = 1832)[a]	Direct to FP N = 382 (21%)	Direct to Pt N = 935 (51%)	Direct to Both N = 515 (28%)
Estimated Neighbourhood Income*			
Lowest	72 (19.3)	155 (16.9)	75 (14.8)
Second Lowest	79 (21.2)	171 (18.6)	80 (15.8)
Middle	57 (15.3)	180 (19.6)	85 (16.8)
Second Highest	77 (20.6)	202 (22.0)	109 (21.5)
Highest	88 (23.6)	210 (22.9)	157 (31.0)
Awareness of Family History	61 (16.2)	170 (18.2)	81 (15.7)
Previous Diagnosis of Osteoporosis	15 (3.9)	48 (5.1)	19 (3.7)
History of Comorbidity	25 (6.6)	45 (4.8)	25 (4.9)
History of medication exposure	64 (16.8)	109 (11.7)	53 (10.3)
General Health			
Poor/Fair/Good	123 (32.2)	339 (36.3)	173 (33.6)
Very Good/Excellent	259 (67.8)	595 (63.7)	342 (66.4)
Current Cigarette Smoker**	64 (16.8)	177 (18.9)	63 (12.2)
Current Calcium Supplement Use***	85 (22.3)	421 (45.0)	263 (51.1)
Current Vitamin D Supplement Use***	86 (22.5)	318 (34.0)	189 (36.7)
Current Regular Exercise***	241 (63.1)	474 (50.7)	296 (57.5)
High Alcohol Intake	9 (2.4)	44 (4.7)	29 (5.6)
High Coffee Intake**	56 (14.7)	179 (19.1)	62 (12.0)
Current OHT*	129 (33.8)	347 (37.1)	159 (30.1)
Current Osteoporosis Medication	0 (0.0)	4 (<1.0)	4 (<1.0)
	Mean (SD)	**Mean (SD)**	**Mean (SD)**
Total Calcium (mg/day)	1002 (647)	1035 (596)	1019 (591)
Dietary Calcium (mg/day)***	866 (566)	784 (448)	730 (448)
Total Caffeine (mg/day)**	306 (263)	334 (330)	275 (233)

* $p \leq 0.05$. ** $p \leq 0.01$ ***$p \leq 0.001$. Tests of significance were made across the three groups using the Chi Square Test or Anova as appropriate

[a] Missing information on destination of feedback for 5 women

[b] Only relevant to the women aged 50 to 60 years who attended the X-ray test and for whom data was available (N = 1170).

Table E.2 Destination of Feedback and its Association with the Other Explanatory Variables in Men

Destination of Feedback (Total N = 865)[a]	**Direct to FP** N = 188 (22%)	**Direct to Pt** N = 456 (52%)	**Direct to both** N = 221 (26%)
	N (%)	N (%)	N (%)
[b]Significant Prevalent Fracture**	8 (6.9)	28 (11.7)	31 (21.5)
Age Group			
40 to 49 years	70 (37.2)	173 (37.9)	68 (30.8)
50 to 60 years	118 (62.8)	283 (62.1)	153 (69.2)
"Non-white" Race ***	6 (3.2)	25 (5.5)	34 (15.4)
Body Mass Index (BMI)			
Lowest Quartile	44 (23.4)	108 (23.7)	63 (28.6)
Second Lowest Quartile	47 (25.0)	123 (27.0)	47 (21.4)
Second Highest Quartile	54 (28.7)	105 (23.0)	57 (25.9)
Highest Quartile	43 (22.9)	120 (26.3)	53 (24.1)
Education			
Incomplete High School	30 (16.0)	103 (22.6)	46 (20.8)
Complete High School	30 (16.0)	70 (15.4)	32 (14.5)
Postsecondary Education	65 (34.6)	159 (34.9)	69 (31.2)
University Degree	63 (33.5)	124 (27.2)	74 (33.5)
Estimated Neighbourhood Income			
Lowest	33 (17.9)	84 (18.8)	41 (18.8)
Second Lowest	35 (19.0)	78 (17.5)	42 (19.3)
Middle	29 (15.8)	92 (20.6)	48 (22.0)
Second Highest	36 (19.6)	88 (19.7)	39 (17.9)
Highest	51 (27.7)	104 (23.3)	48 (22.0)
Awareness of Family History	17 (9.2)	49 (10.7)	10 (4.5)
Previous diagnosis of Osteoporosis	3 (1.6)	2 (0.4)	2 (0.9)
History of Comorbidity	2 (1.1)	9 (2.0)	10 (4.5)
History of medication exposure	20 (10.7)	35 (7.7)	13 (5.9)
General Health			
Poor/Fair/Good	59 (31.4)	152 (33.3)	75 (33.9)
Very Good/Excellent	129 (68.6)	304 (66.7)	146 (66.1)
Current Cigarette Smoker**	43 (23.0)	110 (24.1)	32 (14.5)
Current Calcium Supplement Use*	27 (14.4)	97 (21.3)	57 (25.8)
Current Vitamin D Supplement Use**	20 (10.6)	93 (20.4)	54 (24.4)

Destination of Feedback (Total N = 865)[a]	Direct to FP N = 188 (22%)	Direct to Pt N = 456 (52%)	Direct to both N = 221 (26%)
Current Regular Exercise	110 (58.5)	236 (51.8)	116 (52.7)
High Alcohol Intake	37 (19.9)	70 (15.4)	29 (13.1)
High Coffee Intake	49 (26.1)	136 (29.8)	55 (24.9)
Current Osteoporosis Medication	0 (0.0)	1 (<1.0)	0 (0.0)
	Mean (SD)	**Mean (SD)**	**Mean (SD)**
Total Calcium (mg/day)	915 (682)	872 (566)	892 (616)
Dietary Calcium (mg/day)	851 (609)	805 (527)	809 (500)
Total Caffeine (mg/day)	402 (300)	415 (356)	365 (319)

* $p \leq 0.05$ **$p \leq 0.01$ *** $p \leq 0.001$. Tests of significance were made across the three groups using the Chi Square Test or Anova as appropriate

[a] Missing information on destination of feedback for 4 men.
[b] Only relevant to the men aged 50 to 60 years who attended the X-ray test (N = 499).

Table E.3 CaMOS Centre and its Association with the Other Explanatory Variables in Women

CENTRE[a] (Total N = 1837)	**VR** n = 219	**CA** n = 212	**SK** n = 205	**HA** n = 190	**TO** n = 194	**KN** n = 190	**QC** n = 239	**HX** n = 192	**ST** n = 196
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
[b]Significant Prevalent Fracture* **	13 (9.8)	37 (23.0)	7 (4.8)	14 (10.9)	8 (6.6)	1 (1.4)	5 (3.5)	5 (3.7)	2 (1.6)
Age Group									
40 to 49 years	77 (35.2)	51 (24.1)	59 (28.8)	53 (27.9)	58 (29.9)	63 (33.2)	87 (36.4)	56 (29.2)	58 (29.6)
50 to 60 years	142 (64.8)	161 (75.9)	146 (71.2)	137 (72.1)	136 (70.4)	127 (66.8)	152 (63.6)	136 (70.8)	138 (70.4)
BMI* **									
Lowest Quartile	68 (31.1)	48 (22.6)	64 (31.4)	33 (17.5)	48 (24.9)	36 (18.9)	89 (37.4)	33 (17.2)	39 (19.9)
Second Lowest	50 (22.8)	56 (26.4)	46 (22.5)	52 (27.5)	46 (23.8)	49 (25.8)	64 (26.9)	52 (27.1)	43 (21.9)
Second Highest	51 (23.3)	56 (26.4)	45 (22.1)	49 (25.9)	53 (27.5)	54 (28.4)	44 (18.5)	52 (27.1)	55 (28.1)
Highest Quartile	50 (22.8)	52 (24.5)	49 (24.0)	55 (29.1)	46 (23.8)	51 (26.8)	41 (17.2)	55 (28.6)	59 (30.1)
"Non-white" Race/Ethnicity * **	42 (19.2)	10 (4.7)	6 (2.9)	5 (2.6)	37 (19.1)	0 (0.0)	1 (0.4)	6 (3.1)	0 (0.0)
Reproductive Status* **									
Premenopausal	89 (40.6)	78 (36.8)	71 (34.6)	55 (28.9)	66 (34.2)	62 (32.6)	95 (39.7)	62 (32.3)	60 (30.6)
Natural.menopause	82 (37.4)	81 (38.2)	84 (41)	69 (36.3)	90 (46.6)	84 (44.2)	79 (33.1)	67 (34.9)	68 (34.7)
Surgical menopause	11 (5.0)	12 (5.7)	13 (6.3)	27 (14.2)	16 (8.3)	21 (11.1)	16 (6.7)	9 (4.7)	15 (7.7)
Pre. hysterectomy	37 (16.9)	41 (19.3)	37 (18)	39 (20.5)	21 (10.9)	23 (12.1)	49 (20.5)	54 (28.1)	53 (27.0)

[a] CA = Calgary, HA = Hamilton, HX = Halifax, KN = Kingston, QC = Quebec City, SK = Saskatoon, ST = Saint John's, TO = Toronto, VR = Vancouver.
[b] Relevant only to the women aged 50 to 60 years who attended the X-ray and for whom data was available (n = 1170).

CENTRE (Total N = 1837)	VR n = 219	CA n = 212	SK n = 205	HA n = 190	TO n = 194	KN n = 190	QC n = 239	HX n = 192	ST n = 196
[a]**Education***									
Incomp. HS	43 (19.6)	44 (20.8)	56 (27.3)	68 (35.8)	36 (18.6)	38 (20.0)	95 (39.7)	31 (16.1)	47 (24.0)
Comp. HS	51 (23.3)	39 (18.4)	25 (12.2)	51 (26.8)	35 (18.0)	33 (17.4)	56 (23.4)	25 (13.0)	23 (11.7)
Postsec. Ed.	81 (37.0)	96 (45.3)	72 (35.1)	57 (30.0)	72 (37.1)	75 (39.5)	77 (32.2)	89 (46.4)	89 (45.4)
Univ. Degree	44 (20.1)	33 (15.6)	52 (25.4)	14 (7.4)	51 (26.3)	44 (23.2)	11 (4.6)	47 (24.5)	37 (18.9)
Neighbourhood Income Quintile									
Lowest	28 (13.2)	31 (14.8)	38 (18.8)	31 (16.5)	26 (13.6)	34 (18.4)	39 (16.6)	38 (20.5)	36 (20.3)
Second Lowest	35 (16.5)	30 (14.3)	38 (18.8)	37 (19.7)	34 (17.8)	31 (16.8)	47 (20.0)	37 (20.0)	39 (22.0)
Middle	40 (18.9)	29 (13.8)	31 (15.3)	41 (21.8)	34 (17.8)	44 (23.8)	46 (19.6)	30 (16.2)	21 (11.9)
Second Highest	49 (23.1)	50 (23.8)	49 (24.3)	35 (18.6)	37 (19.4)	43 (23.2)	48 (20.4)	40 (21.6)	36 (20.3)
Highest	60 (28.3)	70 (33.3)	46 (22.8)	44 (23.4)	60 (31.4)	33 (17.8)	55 (23.4)	40 (21.6)	45 (25.4)
Awareness of Family History* **	42 (19.2)	26 (12.3)	57 (27.8)	36 (18.9)	26 (13.5)	35 (18.4)	27 (11.3)	32 (16.7)	31 (16.2)
Previous Diagnosis	8 (3.7)	10 (4.7)	15 (7.3)	11 (5.8)	9 (4.6)	8 (4.2)	8 (3.3)	5 (2.6)	9 (4.6)
History of Comorbidity	12 (5.5)	12 (5.7)	12 (5.9)	10 (5.3)	13 (6.7)	7 (3.7)	5 (2.1)	11 (5.7)	13 (6.7)
History of Med. Exposure**	20 (9.1)	19 (9.0)	20 (9.8)	24 (12.6)	26 (13.4)	28 (14.7)	26 (10.9)	40 (20.8)	24 (12.2)
General Health									
Poor/Fair/Good	81 (37.0)	63 (29.7)	83 (40.5)	65 (34.2)	75 (38.7)	59 (31.2)	91 (38.1)	64 (33.3)	58 (29.6)
V. Good/Excellent	138 (63.0)	149 (70.3)	122 (59.5)	125 (65.8)	119 (61.3)	130 (68.8)	148 (61.9)	128 (66.7)	138 (70.4)
Current Smoker*	26 (11.9)	33 (15.6)	47 (22.9)	31 (16.3)	21 (10.8)	36 (18.9)	44 (18.4)	32 (16.7)	34 (17.3)
Calcium Supp. Use***	123 (56.2)	113 (53.3)	124 (60.5)	81 (42.6)	84 (43.3)	89 (46.8)	72 (30.1)	51 (26.6)	35 (17.9)

[a] Incomp. HS = Some high school, Comp. HS = Completed high school, Postsec. Ed = Postsecondary education, Univ. Degree = University degree.

CENTRE (Total N = 1837)	VR n = 219	CA n = 212	SK n = 205	HA n = 190	TO n = 194	KN n = 190	QC n = 239	HX n = 192	ST n = 196
Vitamin D Supp. Use* **	91 (41.6)	84 (39.6)	90 (43.9)	61 (29.2)	60 (30.9)	64 (33.7)	57 (23.8)	56 (29.2)	31 (15.8)
Regular Exercise* **	135 (61.6)	126 (59.4)	108 (39.3)	91 (47.9)	99 (51.0)	115 (60.5)	94 (39.3)	119 (62.0)	126 (64.3)
High Alcohol Intake	12 (5.5)	12 (5.7)	5 (2.4)	10 (5.3)	14 (7.2)	9 (4.7)	10 (4.2)	6 (3.1)	4 (2.1)
High Coffee Intake* **	24 (11.0)	38 (17.9)	57 (27.8)	31 (16.3)	18 (9.3)	40 (21.1)	30 (12.6)	22 (11.5)	37 (18.9)
Current OHT**	59 (26.9)	64 (30.2)	68 (33.2)	76 (40.0)	63 (32.5)	71 (37.4)	106 (44.4)	70 (36.5)	60 (30.6)
Current Osteoporosis Med.	1 (0.5)	2 (0.9)	2 (1.0)	0 (0.0)	2 (1.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	Mean (SD)	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***
Total Calcium (mg/day) * **	990 (579)	1123 (633)	1225 (644)	1012 (604)	970 (583)	974 (526)	912 (526)	990 (693)	1023 (597)
Dietary Calcium (mg/day) * **	678 (405)	803 (479)	812 (486)	771 (481)	728 (416)	793 (408)	766 (444)	846 (627)	894 (490)
Total Caffeine (mg/day) * **	267 (258)	308 (258)	382 (368)	312 (280)	268 (189)	334 (256)	313 (396)	275 (198)	345 (318)

* $p \leq 0.05$ **$p \leq 0.01$ *** $p \leq 0.001$. Tests of significance were made across the groups using the Chi Square Test or Anova as appropriate

Table E.4 CaMOS Centre and its Association with the Other Explanatory Variables in Men

CENTRE[a] (Total N = 865)	VR n = 107	CA n = 92	SK n = 104	HA n = 99	TO n = 97	KN n = 81	QC n = 101	HX n = 90	ST n = 98
	N (%)	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*	*N (%)*
[b]Significant Prevalent Fracture**	11 (17.2)	15 (25.9)	4 (6.5)	15 (23.4)	9 (15.8)	1 (3.7)	4 (8.2)	5 (8.5)	3 (5.1)
Age Group									
40 to 49 years	39 (36.4)	34 (37.0)	40 (38.5)	34 (34.3)	29 (29.9)	26 (32.1)	43 (42.6)	31 (34.4)	37 (37.8)
50 to 60 years	68 (63.6)	58 (63.0)	64 (61.5)	65 (65.7)	68 (70.1)	55 (67.9)	58 (57.4)	59 (65.6)	61 (62.2)
Body Mass Index***									
Lowest Quartile	35 (33.0)	22 (23.9)	28 (26.9)	12 (12.1)	32 (33.0)	15 (18.5)	29 (28.7)	17 (18.9)	27 (27.6)
Second Lowest Quartile	25 (23.6)	21 (22.8)	42 (40.4)	22 (22.2)	15 (15.5)	13 (16.0)	31 (30.7)	24 (26.7)	24 (24.5)
Second Highest Quartile	27 (25.5)	24 (26.1)	14 (13.5)	25 (25.3)	23 (23.7)	29 (35.8)	21 (20.8)	25 (27.8)	29 (29.6)
Highest Quartile	19 (17.9)	25 (27.2)	20 (19.2)	40 (40.4)	27 (27.8)	24 (29.6)	20 (19.8)	24 (26.7)	18 (18.4)
"Non-white" Race/Ethnicity***	21 (19.6)	5 (5.4)	5 (4.8)	4 (4.0)	22 (22.7)	2 (2.5)	1 (1.0)	4 (4.4)	1 (1.0)
[c]Education**									
Incomp. HS	19 (17.8)	18 (19.6)	26 (25.0)	25 (25.3)	12 (12.4)	16 (19.8)	33 (32.7)	15 (16.7)	15 (15.3)
Comp. HS	15 (14.0)	14 (15.2)	7 (6.7)	18 (18.2)	14 (14.4)	14 (17.3)	18 (17.8)	10 (11.1)	22 (22.4)
Postsec. Ed.	35 (32.7)	28 (30.4)	40 (38.5)	31 (31.3)	32 (33.0)	25 (30.9)	41 (40.6)	34 (37.8)	30 (30.6)
Univ. Degree	38 (35.5)	32 (34.8)	31 (29.8)	25 (25.3)	39 (40.2)	26 (32.1)	9 (8.9)	31 (34.4)	31 (31.6)
Neighbourhood Income Quintile Lowest	22 (20.6)	18 (19.8)	18 (17.8)	18 (18.4)	16 (17.0)	18 (23.4)	14 (14.1)	16 (18.0)	18 (18.8)
Second Lowest	19 (17.8)	17 (18.7)	12 (11.9)	18 (18.4)	17 (18.1)	14 (18.2)	24 (24.2)	21 (23.6)	13 (13.5)
Middle	24 (22.4)	19 (20.9)	19 (18.8)	20 (20.4)	18 (19.1)	15 (19.5)	24 (24.2)	14 (15.7)	16 (16.7)
Second Highest	20 (18.7)	21 (23.1)	24 (23.8)	19 (19.4)	16 (17.0)	12 (15.6)	17 (17.2)	16 (18.0)	21 (21.9)
Highest	22 (20.6)	16 (17.6)	28 (27.7)	23 (23.5)	27 (28.7)	18 (23.4)	20 (20.2)	22 (24.7)	28 (29.2)

[a] CA = Calgary, HA = Hamilton, HX = Halifax, KN = Kingston, QC = Quebec City, SK = Saskatoon, ST = Saint John's, TO = Toronto, VR = Vancouver

[b] Relevant only to the men aged 50 to 60 years who attended the X-ray (N = 499).

[c] Incomp. HS = Some high school, Comp. HS = Completed high school, Postsec. Ed = Postsecondary education, Univ. Degree = University degree.

CENTRE (Total N = 865)	VR n = 107	CA n = 92	SK n = 104	HA n = 99	TO n = 97	KN n = 81	QC n = 101	HX n = 90	ST n = 98
Awareness of Family History	8 (7.5)	5 (5.4)	16 (15.4)	6 (6.1)	10 (10.3)	12 (14.8)	4 (4.0)	8 (9.1)	8 (8.2)
Previous Diagnosis	1 (0.9)	1 (1.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.1)	2 (2.0)
History of Comorbidity	7 (6.5)	3 (3.3)	4 (3.8)	2 (2.0)	2 (2.1)	1 (1.2)	0 (0.0)	0 (0.0)	2 (2.1)
History of Medication exposure**	5 (4.7)	3 (3.3)	6 (5.8)	10 (10.1)	10 (10.3)	9 (11.1)	7 (6.9)	17 (19.1)	2 (2.0)
General Health									
Poor/Fair/Good	39 (36.4)	25 (27.2)	29 (27.9)	39 (39.4)	33 (34.0)	31 (38.3)	31 (30.7)	32 (35.6)	27 (27.6)
Very Good/Excellent	68 (63.6)	67 (72.8)	75 (72.1)	60 (60.6)	64 (66.0)	50 (61.7)	70 (69.3)	58 (64.4)	71 (72.4)
Current Smoker	21 (19.6)	13 (14.1)	23 (22.1)	23 (23.2)	12 (12.4)	21 (25.9)	28 (27.7)	22 (24.7)	22 (22.4)
Calcium Supplement Use***	37 (34.6)	19 (20.7)	34 32.7)	18 (18.2)	18 (18.6)	20 (24.7)	8 (7.9)	13 (14.4)	14 (14.3)
Vitamin D Supplement Use***	35 (32.7)	22 (23.9)	31 (29.8)	17 (17.2)	17 (17.5)	18 (22.2)	7 (6.9)	7 (7.8)	13 (13.3)
Regular Exercise*	56 (57.1)	55 (60.4)	60 (57.7)	48 (48.5)	56 (57.7)	45 (55.6)	38 (37.6)	53 (58.9)	56 (57.1)
High Alcohol Intake*	17 (15.9)	13 (14.1)	3 (2.9)	22 (22.2)	10 (10.3)	20 (24.7)	14 (13.9)	18 (20.0)	20 (20.8)

CENTRE (Total N = 865)	VR n = 107	CA n = 92	SK n = 104	HA n = 99	TO n = 97	KN n = 81	QC n = 101	HX n = 90	ST n = 98
High Coffee Intake	23 (21.5)	25 (27.2)	40 (38.5)	25 (25.3)	23 (23.7)	31 (38.3)	27 (26.7)	23 (25.6)	24 (24.5)
Current Osteoporosis Medication(s)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mean (SD)	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***	***Mean (SD)***
Total Calcium (mg/day) ***	765 (577)	1063 (644)	1043 (662)	856 (570)	743 (453)	981 (672)	742 (391)	946 (690)	879 (665)
Dietary Calcium (mg/day) ***	674 (404)	995 (561)	919 (652)	797 (528)	700 (422)	895 (591)	710 (366)	871 (616)	828 (593)
Total Caffeine (mg/day) *	390 (303)	357 (315)	464 (392)	399 (297)	398 (369)	498 (442)	356 (304)	396 (271)	390 (303)

* $p \leq 0.05$ **$p \leq 0.01$ *** $p \leq 0.001$. Tests of significance were made across the groups using the Chi Square Test or Anova as appropriate

Appendix F

Table F.1: Relationships between Information seeking from at Least One Source (in the past 3 years) and Potential Explanatory Variables

	Women[a] Sought information from at least one source			Men[b] Sought information from at least one source		
	N	(%)	p*	N	(%)	p*
Feedback Diagnosis						
Normal	454	(48%)	**<0.001**	100	(26%)	**<0.001**
Osteopenia	324	(58%)		127	(42%)	
Osteoporosis	234	(75%)		94	(54%)	
Self Reported Diagnosis						
Normal	442	(49%)	**<0.001**	103	(29%)	**<0.001**
Osteopenia	267	(73%)		105	(65%)	
Osteoporosis	120	(83%)		43	(78%)	
"Don't Know"	188	(43%)		69	(24%)	
Significant Prevalent Fracture[c] Yes	61	(66%)	**0.05**	26	(39%)	1.0
No	594	(55%)		166	(38%)	
Destination						
To GP only	176	(46%)	**<0.001**	46	(25%)	**<0.001**
To participant only	546	(58%)		177	(39%)	
To both	294	(57%)		98	(44%)	
Recommendation Yes	125	(93%)	**<0.001**	50	(69%)	**<0.001**
No	893	(53%)		272	(34%)	
Age group						
40 to 49 years	309	(55%)	0.9	114	(36%)	0.8
50 to 60 years	709	(56%)		208	(37%)	
Body Mass Index						
Lowest Quartile	293	(64%)	**<0.001**	93	(42%)	**0.007**
Second Lowest Quartile	276	(60%)		90	(41%)	
Second Highest Quartile	224	(49%)		76	(35%)	
Highest Quartile	224	(49%)		62	(29%)	
Race "White"	951	(55%)	0.2	290	(36%)	**0.05**
"Non-white"	67	(63%)		32	(49%)	
Reproductive Status						
Premenopausal	351	(55%)	**0.01**			
Naturally Menopausal	403	(57%)				
Surgically Menopausal	59	(42%)				
Premen.Hysterectomy	205	(57%)				
Education						
Incomplete. High School	242	(53%)	0.6	69	(39%)	0.9
Complete High School	189	(56%)		50	(38%)	
Postsecondary Education	396	(56%)		105	(36%)	
University Degree	191	(57%)		98	(37%)	

		Women[a] Sought information from at least one source		Men[b] Sought information from at least one source	
		N (%)	p*	N (%)	p*
Neighbourhood Income Quintile	Lowest	168 (55%)	0.4	59 (37%)	1.0
	Second lowest	176 (53%)		57 (37%)	
	Middle	187 (58%)		65 (39%)	
	Second highest	226 (58%)		62 (37%)	
	Highest	239 (53%)		75 (37%)	
Centre	Vancouver	186 (85%)	**<0.001**	81 (76%)	**<0.001**
	Calgary	84 (40%)		19 (21%)	
	Saskatoon	136 (66%)		51 (49%)	
	Hamilton	110 (58%)		41 (41%)	
	Toronto	79 (41%)		29 (30%)	
	Kingston	75 (40%)		14 (17%)	
	Quebec City	169 (71%)		40 (40%)	
	Halifax	69 (37%)		11 (12%)	
	Saint John's	109 (56%)		36 (37%)	
Family History of Osteoporosis	Yes	193 (62%)	**0.02**	34 (44%)	0.2
	No or DK	822 (54%)		288 (37%)	
Previous diagnosis of osteoporosis or osteopenia	Yes	62 (75%)	**<0.001**	4 (57%)	------
	No or DK	956 (55%)		318 (37%)	
History of Comorbidity	Yes	45 (47%)	0.1	11 (52%)	0.2
	No	973 (56%)		311 (37%)	
Medication Exposure	Yes	118 (52%)	0.3	26 (38%)	1.0
	No	900 (56%)		295 (37%)	
General Health	Poor/Fair/Good	341 (53%)	0.2	110 (39%)	0.6
	Very Good/Excellent	677 (57%)		212 (36%)	
Current Smoker	Yes	156 (51%)	0.1	64 (35%)	0.5
	No	862 (56%)		258 (38%)	

* Tests of significance were made across the groups using the Chi Square Test.

[a] N = 1836 or less in some cells due to missing data on certain variables. Information seeking response missing for one woman.

[b] N = 869 or less in some cells due to missing data on certain variables. No missing responses for Information seeking.

[c] Relevant only to the women (n = 1170) and men (n = 499) aged 50 to 60 years, who attended the X-ray and for whom data was available.

Appendix G

Table G.1: Multiple Logistic Regression Analysis of Self Reported Diagnosis and Other Factors Associated with Information seeking about Osteoporosis for Women and Men

		WOMEN (N = 1824)[a]		**MEN** (N = 860)[b]	
		OR (95% C.I.)	**p**	**OR (95% C.I)**	**p**
Self Reported Diagnosis	Normal	*Referent*	-------	*Referent*	-----
	Osteopenia	2.07 (1.56 - 2.75)	**<0.001**	3.80 (2.51 - 5.76)	**<0.001**
	Osteoporosis	3.37 (2.08 - 5.45)	**<0.001**	9.75 (4.62 - 20.57)	**<0.001**
	Don't Know	0.73 (0.57 - 0.93)	**0.01**	0.74 (0.52 - 1.07)	0.1
Destination					
	To FP only	*Referent*	-----	*Referent*	-----
	To participant only	1.59 (1.23 - 2.06)	**<0.001**	1.93 (1.27 - 2.94)	**0.002**
	To both	1.02 (0.76 - 1.37)	0.9	1.71 (1.05 - 2.78)	**0.03**
Recommendation					
	Yes	9.46 (4.78 - 18.70)	**<0.001**	2.90 (1.61 - 5.24)	**<0.001**
	No	*Referent*	-----	*Referent*	-----
Age Group	40 to 49 years	0.97 (0.75 - 1.25)	0.8	0.94 (0.68 - 1.29)	0.7
	50 to 60 years	*Referent*	-----	*Referent*	-----
Body Mass Index					
	Lowest quartile	1.41 (1.06 - 1.87)	**0.02**		
	Second lowest quartile	1.29 (0.97 - 1.70)	0.08		
	Second highest quartile	0.87 (0.66 - 1.14)	0.3		
	Highest quartile	*Referent*	-----		
Reproductive Status					
	Premenopausal	*Referent*	-----		
	Naturally Menopausal	1.00 (0.77 - 1.31)	1.0		
	Surgically Menopausal	0.61 (0.40 - 0.93)	**0.02**		
	Premen.Hysterectomy	1.23 (0.91 - 1.67)	0.2		
Self-reported previous diagnosis	Yes	1.99 (1.15 - 3.44)	**0.01**		
	No or DK	*Referent*	-----		
History of Comorbidity	Yes	0.66 (0.29 - 1.04)	0.07		
	No or DK	*Referent*	-----		
Nagerkele's R^2		0.17		0.22	

[a] Missing information on included variables for 14 women
[b] Missing information on included variables for 9 men