

# Prevalence and treatment of osteoporosis in older Australian men: findings from the CHAMP study

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Since 1996, Australian men and women have been entitled to subsidised osteoporosis treatments through the Pharmaceutical Benefits Scheme (PBS) if they have had a minimal trauma fracture or have radiological evidence of one or more vertebral deformities. In 2007, this subsidy was extended to include patients aged 70 years or older with bone mineral density (BMD) T-scores  $\leq -3$  at either the femoral neck or lumbar spine, even in the absence of a minimal trauma fracture or vertebral deformity. Previous studies, mainly involving women, suggest that many people with osteoporosis remain untreated, even after a minimal trauma fracture.<sup>1</sup> Men are even less likely to receive treatment for osteoporosis, although osteoporotic fractures in elderly men are associated with increased morbidity, greater functional decline, higher mortality and increased health costs compared with osteoporotic fractures in women.<sup>2,3</sup>

The aims of our study were to determine the proportion of community-living older men who met the PBS criteria for osteoporosis-specific treatments (mainly bisphosphonates), and to determine the proportion of men meeting these criteria who were actually receiving treatment for osteoporosis.

## METHODS

### Sample

The Concord Health and Ageing in Men Project (CHAMP) is a longitudinal study of health and ageing in men. Between 2005 and 2007, all community-dwelling men aged 70 years or over living in three local government areas surrounding Concord Hospital, Sydney, were invited to participate. The New South Wales electoral roll was used as the sampling frame. Invitation letters were sent to 3627 men, and contact was made with 3005. One hundred and ninety of the contacted men were not eligible for the study because they were no longer living in the local community. Of the 2815 eligible men with whom contact was made, 1511 participated in the study (54%). An additional 194 men aged 70 years or over who were living in the study area heard

## ABSTRACT

**Objective:** To determine the proportion of older Australian men who meet the Pharmaceutical Benefits Scheme (PBS) criteria for osteoporosis treatment and are receiving effective treatment.

**Design and setting:** A population-based, cross-sectional analysis of the baseline phase of the Concord Health and Ageing in Men Project (CHAMP), a large epidemiological study focusing on the health of older men. Data were collected through questionnaires and clinical assessments. Bone mineral density (BMD) of the hip and spine was measured by dual x-ray absorptiometry (DXA). Vertebral deformities were identified from DXA lateral vertebral fracture assessment images. The study was conducted at Concord Hospital, Sydney, between January 2005 and May 2007.

**Participants:** 1705 community-dwelling men aged 70 years or over from a defined geographical region around Concord Hospital.

**Main outcome measures:** Prevalence of vertebral deformities; previous minimal trauma fractures; BMD T-scores  $\leq -3$ ; falls in the previous 12 months; use of bisphosphonates and calcium and vitamin D supplements.

**Results:** Of the 1705 men seen at baseline, 1626 completed all DXA scans and 401 (25%) met one or more of the PBS criteria for osteoporosis treatment. Ninety per cent of the men who met the PBS criteria were unaware they had osteoporosis. Of the men eligible for PBS-subsidised treatment, 39 (10%) reported use of a bisphosphonate, 56 (14%) had taken calcium supplements, and 28 (7%) had taken vitamin D supplements. Only three men had taken calcium, vitamin D and bisphosphonates in combination.

**Conclusions:** Despite a high prevalence of osteoporosis in elderly Australian men, awareness, diagnosis and treatment of the condition remain very low.

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about the study from friends or in local media and volunteered to take part before receiving an invitation letter.

### Bone mineral density measurements

Areal BMD ( $\text{g}/\text{cm}^2$ ) of the lumbar spine (L1–L4) and right hip was measured by dual x-ray absorptiometry (DXA) using a Discovery W scanner (Hologic Inc, Bedford, Mass, USA). Coefficients of variation for scans duplicated on 30 men were 2.1% for the femoral neck and 1.6% for the lumbar spine. Anteroposterior measurements were taken of the lumbar spine for vertebrae L1–L4. T-scores of individual vertebrae as well as the total area were calculated using the United States male reference range for the lumbar spine and US National Health and Nutrition Examination Survey reference range for the hip. All participants for whom the combined area of L1–L4 or at least two lumbar vertebrae had T-scores  $\leq -3$ <sup>4</sup> were deemed to meet the PBS BMD criteria for

subsidised osteoporosis treatment. PBS criteria differ from World Health Organization definitions of osteoporosis (T-score  $< -2.5$ ), osteopenia (T-score between  $-2.5$  and  $-1$ ) and normal BMD (T-score  $> -1$ ).

### Vertebral deformities

Vertebral deformities were ascertained from lateral spinal scans of the area between thoracic 4–5 and lumbar 4–5 vertebrae, using the instant vertebral fracture assessment (VFA) function of the DXA scanner. Two scientists who were experienced in diagnosing vertebral deformities assessed the scans visually and semi-quantitatively. A vertebral deformity was defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a minimum 20% reduction in any of these heights compared with the vertebral body above or below the affected vertebral body.<sup>5</sup>

## History and medication use

A fracture history was obtained at the baseline interview for each patient. Only fractures that had occurred in the 10 years before baseline were used in our analyses. Ten years was chosen as the cut-off time because the association between prevalent fractures and subsequent fractures wanes with time.<sup>6</sup> Three observers (KB, VN and RGC) independently rated fractures using the description of the mechanism of injury. Fractures were classified as minimal trauma fractures if the mechanism of injury was described as a fall from standing height or less; a fall on steps or curbs (but not down steps); or a minimal trauma incident other than a fall (eg, turning over in bed or coughing). There was a high level of agreement between observers, with all kappa ( $\kappa$ ) values being >0.84.

Medication use was ascertained by interview, and participants were asked to bring all prescription and non-prescription medication to the clinic for verification. Use of bisphosphonates and calcium and vitamin D supplements was coded as positive if participants brought them to the clinic or reported they had ever taken them.

Awareness of osteoporosis was determined from answers to the question, "Has a doctor or health care provider ever told you that you have osteoporosis (sometimes called 'brittle bones')?" Falls in the previous 12 months were established at the baseline interview.

## Statistical analysis

Analyses were restricted to the 1626 men who completed all DXA scans. The most common reasons for incomplete scans were bilateral hip replacements ( $n=25$ ) (because of the metal in the hips) and being unable to lie on the side for VFA scans ( $n=53$ ). SAS software, version 9.1 (SAS Institute Inc, Cary, NC, USA) was used for all data analyses. Bivariate associations between variables were assessed using  $\chi^2$  tests, and trend was assessed using the Mantel-Haenszel test.

## Ethics approval

The CHAMP study was approved by the Concord Hospital Human Research Ethics Committee.

## RESULTS

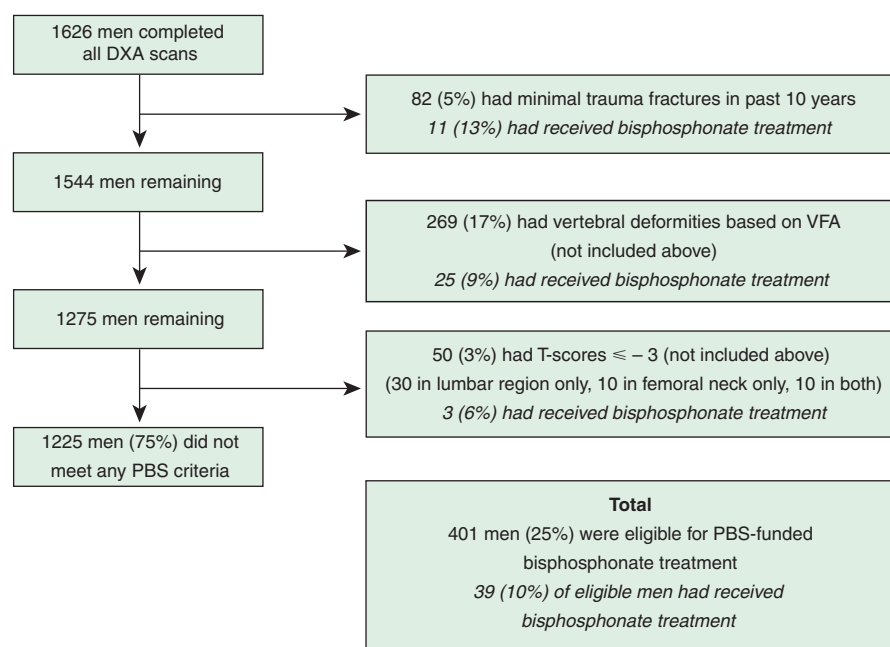
The prevalences of minimal trauma fractures, vertebral deformities and T-scores  $\leq -3$  are shown in Box 1. Four hundred and one men (25%) were eligible for PBS-subsidised treat-

### 1 Number (%) of participants who met PBS 2007 criteria for subsidised osteoporosis treatment, by age group\*

Age group (years)	Minimal trauma fracture	Vertebral deformity	T-score $\leq -3$	At least one PBS criterion met	Total in age group
70–74	32 (5%)	90 (14%)	31 (5%)	136 (21%)	654
75–79	23 (4%)	103 (20%)	22 (4%)	130 (25%)	515
80–84	14 (5%)	55 (19%)	15 (5%)	75 (25%)	296
85–89	9 (7%)	31 (25%)	6 (5%)	43 (35%)	124
$\geq 90$	4 (11%)	9 (24%)	5 (14%)	17 (46%)	37
Total	82 (5%)	288 (18%)	79 (5%)	401 (25%)	1626

PBS = Pharmaceutical Benefits Scheme. \* Categories are not mutually exclusive (eg, 29 men with T-score  $\leq -3$  and 15 men with vertebral deformity also had fractures).

### 2 Flowchart for diagnosing men aged $\geq 70$ years with osteoporosis\*



DXA = dual x-ray absorptiometry. PBS = Pharmaceutical Benefits Scheme. VFA = vertebral fracture assessment. \* The flowchart shows the number of men meeting PBS criteria for subsidised osteoporosis treatment and, in italics, the number of men who had received bisphosphonate treatment. At each level, men in the category above were excluded to determine the number of men who met the next criterion.

ment, mainly due to the presence of vertebral deformities. Five per cent of men qualified on the basis of minimal trauma fracture, independent of BMD, and 3% qualified on the basis of low BMD in the absence of a minimal trauma fracture (Box 2). The proportion of men meeting the PBS criteria increased with age, from 21% in the 70–74-years age group to 46% in the  $\geq 90$ -years age group ( $P$  for trend <0.001) (Box 1). There was no significant difference in prevalence of past fractures ( $P=0.4$ ), vertebral deformities ( $P=0.1$ ) or T-scores  $\leq -3$  ( $P=$

0.2) between men recruited by invitation letter ( $n=1436$ ) and men who volunteered to be in the study before receiving a letter ( $n=190$ ).

One hundred and fifty-three men (9%) reported having at least one fracture in the previous 10 years; 82 of these fractures (76 non-vertebral and 6 vertebral) were classified as minimal trauma fractures, of which 61 (74%) occurred in the 5 years before baseline.

Two hundred and eighty-eight men (18%) had prevalent vertebral deformities, 1195

(74%) had no deformity and 143 (9%) had scans that were indeterminable.

Seventy-nine men (5%) had T-scores  $\leq -3$  at one or more sites. The prevalence of T-scores  $\leq -3$  varied by the site measured: 1% at the total hip, 2% at the femoral neck and 4% at the spine (3% in the combined L1–L4 area and another 1% in either two or three individual lumbar vertebrae). The large increase in the prevalence of T-scores  $\leq -3$  only occurred from the age of 90 years onwards: 14% of these oldest men had a T-score  $\leq -3$ , compared with 5% of men aged under 90 years.

According to the WHO osteoporosis criteria, of the 82 men with a history of minimal trauma fracture, 18 (22%) had BMD in the normal range (T-score  $> -1$ ), 45 (55%) had osteopenia (T-score between  $-2.5$  and  $-1$ ), and 19 (23%) had osteoporosis (T-score  $< -2.5$ ). Of the 288 men with vertebral deformities, 74 (26%) had BMD in the normal range, 162 (56%) had osteopenia and 52 (18%) had osteoporosis.

As some men met multiple criteria, a diagnostic flowchart was created to determine the numbers of men who met the PBS criteria and the proportional contribution of each criterion (Box 2). The flowchart shows how the men in the CHAMP study would have been identified as meeting the PBS criteria for osteoporosis treatment if they had been “screened” by first taking a history of minimal trauma fracture, then, if they did not meet this criterion, looking for evidence of a vertebral deformity and, finally, in the remaining men, measuring BMD. Two men met all three PBS criteria for osteoporosis treatment, 41 met two criteria and 358 met one criterion.

Of the 401 men who met the PBS criteria for treatment, 351 (88%) did so on the basis of one or more vertebral deformities or a history of minimal trauma fracture. Fifty men (13%) met the criteria on the basis of DXA alone, with 40 of these men having T-scores  $\leq -3$  in the lumbar spine.

A significantly higher proportion of men who met PBS criteria for osteoporosis treatment reported falling at least twice in the previous 12 months (11% of men who met PBS criteria had experienced falls compared with 7% of men who had not;  $P = 0.004$ ).

### Treatment

Of the 401 men eligible for subsidised treatment under the PBS, 10% had taken, or were taking, a bisphosphonate, 14% a calcium supplement, and 7% a vitamin D supplement. Less than 1% had taken both vitamin D and calcium in conjunction with a bisphosphonate (Box 3).

Men were most likely to have taken bisphosphonates following a minimal trauma fracture (13%) and least likely if they had T-scores of  $\leq -3$  with no fracture history (6%) (Box 2). Of the men who had had two or more falls and met PBS criteria, 16% had received bisphosphonate treatment, 9% had taken calcium, 7% had taken vitamin D, and none had taken the combination of bisphosphonate, calcium and vitamin D. An analysis of men who met the PBS criteria and had low BMD (T-scores  $< -1$ ) revealed similar low levels of treatment (data not shown).

Only 10% of men who met the PBS criteria reported knowing they had “osteoporosis”.

A further 45 men had taken bisphosphonates but did not meet the PBS criteria for subsidised osteoporosis treatment. Eight of these men self-reported Paget's disease and six additional men were receiving glucocorticoid therapy. It was unclear why the remaining men were taking bisphosphonates.

### DISCUSSION

Almost a quarter of the men in the CHAMP study met the PBS criteria for subsidised osteoporosis-specific treatment with bisphosphonates, but few of these men had received treatment or were aware they had osteoporosis. This lack of awareness may have resulted in substantial underestimation of osteoporosis prevalence in men in a recent report by the Australian Institute of Health and Welfare that relied on self-report of osteoporosis.<sup>7</sup>

Most men met the PBS criteria on the basis of PBS-defined vertebral deformities. Estimates of the prevalence of vertebral deformities reported in previous studies have varied widely, owing to different definitions of vertebral deformity. Out of a group of 555 men aged  $\geq 60$  years in the Geelong Osteoporosis Study, 10% of men aged 70–79 years and 15% of those aged 80 years or over had prevalent vertebral deformities, defined as at least 25% vertebral height reduction.<sup>8</sup> The Dubbo Osteoporosis Epidemiology Study reported a vertebral deformity prevalence of 31% among 114 men of mean age 68.2 years.<sup>9</sup> Other large epidemiological studies outside Australia have reported vertebral deformity prevalence rates of 13%–39% in men aged over 70 years.<sup>8,10</sup>

### 3 Proportion of men who met PBS 2007 criteria for subsidised osteoporosis treatment and were receiving medication

Medication	At least one PBS criterion met	Minimal trauma fracture*†	Prevalent vertebral deformities*†	T-score $\leq -3$ †	Total number receiving medication
Bisphosphonates	39 (10%)	11 (13%)	31 (11%)	8 (10%)	84
Bisphosphonates only	26 (7%)	8 (10%)	20 (7%)	7 (9%)	53
Bisphosphonates + calcium	8 (2%)	1 (1%)	7 (2%)	1 (1%)	28
Bisphosphonates + vitamin D	2 (1%)	0	2 (1%)	0	11
Bisphosphonates + calcium + vitamin D	3 (1%)	2 (2%)	2 (1%)	0	8
Calcium‡	56 (14%)	15 (18%)	41 (14%)	10 (13%)	160
Calcium only	38 (10%)	8 (10%)	29 (10%)	8 (10%)	105
Calcium + vitamin D	10 (3%)	6 (7%)	5 (2%)	1 (1%)	35
Vitamin D§	28 (7%)	9 (11%)	17 (6%)	4 (5%)	100
Vitamin D only	16 (4%)	3 (4%)	10 (4%)	3 (4%)	62
Total in category	401	82	288	79	

PBS = Pharmaceutical Benefits Scheme. \* Individual PBS criteria. † These categories are not mutually exclusive. ‡ Includes bisphosphonates + calcium. § Includes bisphosphonates + vitamin D, and calcium + vitamin D.

Identifying men with vertebral deformities is very important, as the presence of asymptomatic vertebral deformities is a strong predictor of future fracture risk,<sup>8</sup> associated with a 19-fold increased risk of future vertebral fractures and 2.3-fold increased risk of hip fractures.<sup>11</sup> In light of the high prevalence of vertebral deformities, our study raises the question of whether VFA scans may have a role to play in assessing osteoporosis risk. However, vertebral deformities identified by VFA scan alone do not meet the current PBS criterion for osteoporosis treatment, because the cost-effectiveness of basing treatment on the results of VFA has not been evaluated.

Despite the presence of lumbar osteoarthritis in many older men in our study, lumbar scans were informative, as they identified 30 men who would not otherwise have been identified as meeting the PBS criteria.

Very few men who met the PBS criteria for osteoporosis treatment were being treated with a bisphosphonate, calcium or vitamin D. This is consistent with other studies showing low rates of treatment for osteoporosis, even in people who are seen in hospital after minimal trauma fractures.<sup>1,12,13</sup> Low treatment levels persist, despite evidence that treatment with bisphosphonates reduces vertebral and non-vertebral fractures in men.<sup>14</sup> It should be noted that all bisphosphonate trials include calcium and vitamin D supplements as part of the treatment, yet few men in the CHAMP study had taken these supplements in conjunction with a bisphosphonate.

Identifying men who will benefit from osteoporosis treatment and increasing the proportion of eligible men receiving appropriate treatment is a public health issue. Both non-pharmacological treatments (falls prevention, physical activity, calcium and vitamin D supplementation) and pharmacological treatments need to be implemented to reduce fracture rates. Currently it is projected that, because of the ageing population, hip fractures may double by 2026 and increase fourfold by 2051.<sup>15</sup> After a hip fracture, men are less likely than women to return to their homes or mobilise independently.<sup>16</sup> Additionally, they have markedly higher mortality rates than women after all major fractures.<sup>17</sup>

The CHAMP study is one of the largest studies of osteoporosis in elderly men ever conducted in Australia. The participation rate of about 50% is similar to other studies of the very elderly requiring detailed physi-

cal assessments. Men in the CHAMP study are representative of men in the study area in terms of age and ethnicity<sup>18</sup> and have similar health characteristics to older men in the nationally representative MAtES study.<sup>19</sup> Nevertheless, it is likely that frailer men in poor health would have been less likely to have participated in our study, resulting in an underestimation of the prevalence of fractures and of low BMD.

The PBS requires vertebral deformities to be determined by radiographs, rather than VFA, as used in this study. VFA scans agree well with lateral spinal radiographs (96.3% agreement;  $\kappa = 0.79$ ), and the sensitivity and specificity of VFA are both greater than 90%.<sup>20</sup> However, VFA is better at detecting fractures with more than 25% height reduction, and may miss milder deformities or deformities in the upper thoracic spine, resulting in under-reporting of vertebral deformities.<sup>21</sup>

A weakness of our study was that minimal trauma fractures were self-reported rather than validated with radiological evidence, as is required to obtain PBS funding. In a European study of men aged over 70 years, self-reported fractures had a false positive rate of 11% and an under-reporting rate of 14%.<sup>22</sup>

In conclusion, our study confirms and quantifies the scope of underdiagnosis and undertreatment of older men with osteoporosis as defined by PBS guidelines. An important step forward is to build public and general medical awareness that osteoporosis is common in older men and that minimal trauma fractures and vertebral deformities are indicators of increased risk of future fractures. Obtaining information about previous fractures, identifying vertebral deformities and testing BMD, where appropriate, can identify men at higher risk of fracture who may benefit from interventions.

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## COMPETING INTERESTS

Markus Seibel is a member of advisory boards for Merck Sharp and Dohme, Novartis, Amgen and Sanofi-Aventis, and has received funding from these companies for institutional research. Philip Sambrook is a member of advisory boards for

Merck Sharp and Dohme, Novartis, Amgen, Sanofi-Aventis and Servier, and has received speaker fees from these companies.

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