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# **Bone Health Assessment in adults with fragility fracture risk factors between 2002-2014: a retrospective cohort study**

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## Abstract

### Background

Lifetime risk of fragility fractures is 50% in post-menopausal women and 20% in men aged over 50 years. Identifying people at high risk facilitates early intervention and reduction of biopsychosocial morbidity associated with these fractures.

### Aim

To explore if bone health assessment (BHA) rates differ between women and men aged 50 years and over with fragility fracture risk factors.

### Design and setting

A primary care-based cohort study

### Method

Patients were identified from the Consultations in Primary Care Archive (CiPCA) database between 2002 and 2014 with one or more fragility fracture risk factors (previous fractures, falls and prolonged steroid use). Evaluation of BHA within twelve months of presentation of the first risk factor was carried out by searching for codes for fracture risk assessment tools (FRAX/QFracture), bone density measurement, specialist service referral or if bone-protection medication was started.

### Results

15,581 patients with risk factors were identified; men represented 40% of the cohort. 1172 (7.5%) had BHA performed within one year of presentation. 8.9% of females and 5.5% of males had BHAs, which was found **with strong statistical evidence** ( $\chi^2 = 59.88$ ,  $p = 1 \times 10^{-14}$ ). This relationship prevailed after adjusting for other covariates such as co-morbidity and number of consultations with an odds ratio of 1.25 (95% Confidence Interval 1.08-1.43).

### Conclusion

This study shows that rates of BHA were generally low and even lower in men. Primary care clinicians should be alert to fragility fracture risk factors in both men and women to enable early assessment and intervention.

## **How this fits in**

Half of all post-menopausal women and a fifth of men over the age of fifty years are expected to sustain a fragility fracture during their lifetime. Identifying high risk patients, to enable early intervention, may lower the number of fragility fractures.

This study has shown that rates of bone health assessment (BHA) were low in both men and women with fragility fracture risk factors. Men had disproportionately lower assessment rates representing an important inequality in management compared to women. It is recommended that primary care clinicians consider BHA in both men and women with fragility fracture risk factors.

## **INTRODUCTION**

Osteoporosis is a common metabolic condition characterised by low bone density with deterioration of the skeletal microarchitecture. This condition, referred to as the 'silent disease'<sup>1</sup> affects 3.5 million people in the UK<sup>2</sup> and is usually detected after fragility fractures are sustained.<sup>3</sup> Common fracture sites include the hip, spine, forearm and humerus; over 500,000 fragility fractures occur annually in the UK,<sup>4</sup> of which 76,000 are hip fractures.<sup>5</sup> Fragility fractures are associated with poor physical, social and psychological impacts including chronic pain and depression, whilst hip fractures increase mortality risk within a year by up to 20%.<sup>6</sup>

Although osteoporosis preferentially affects post-menopausal women, with fragility fractures seen in 50% of women, 20% of men over the age of fifty years are also

expected to sustain a fragility fracture during their lifetime<sup>4</sup> with men carrying a higher mortality rate in the first year following hip fractures compared to women.<sup>7</sup> Identifying men and women with fragility fracture risk factors and conducting an early bone health assessment (BHA) may prevent potentially life-threatening fractures from occurring, as evidence-based treatment to lower fracture risk is available.<sup>8</sup>

BHA includes a fracture risk assessment, measurement of bone density and/or commencement of bone-sparing medication. Early BHA is included in the national guidelines for the identification and management of osteoporosis, which apply to both men and women. Guidance includes a recommendation to calculate fracture risk in adults with risk factors including previous fragility fractures, use of oral corticosteroids, or a history of falls. Absolute fracture risk can be calculated by validated tools including FRAX or QFracture, with advice to perform bone density scanning, or treat with bone-sparing medication where appropriate.<sup>3</sup>

A previous study has shown a reduced rate of fracture risk calculation in populations of men compared to women,<sup>9</sup> though this has yet to be examined in UK primary care. This study will examine rates of BHA in men and women by using routinely collected electronic health record data from UK primary care to test the hypothesis that there is no difference in BHA rates between men and women with risk factors for fragility fractures.

## **METHOD**

A retrospective cohort study over a 12 year period (2002-2014) was conducted using routinely collected electronic primary health care data from the Consultations in Primary Care Archive (CiPCA) database, a resource linking individual patient consultations, investigations and prescriptions from nine GP practices in the Keele GP Research Partnership, North Staffordshire, UK<sup>10, 11</sup> and includes approximately 124,000 registered patients. As the final data entry for the database was in 2016, patients were included till the end of December 2014 to give at least a one year follow-up.

Patients were included in this study if they were aged 50 years and over in the study period with Read codes (Supplementary data 1 and 2) for falls (U10..) or previous fractures in the hip, spine, humerus or forearm or if they had been prescribed 420mg prednisolone or more in a three-month period. Oral steroid use for this study was defined as equivalent to 5mg or more of prednisolone daily for 3 months (84 days) or more. Read codes form a coding system that aids transfer of patient clinical information between practices and for monitoring healthcare delivery as well as for research purposes. As fragility fractures are unlikely to be coded in the CiPCA database, an assumption was made that a previous fracture at one of the above four sites commonly affected by osteoporotic fractures in a patient 50 years or over was a fragility fracture.<sup>12, 13</sup>

Patients were excluded if they were either investigated or treated for fragility fractures with medications including bisphosphonates, raloxifene, denosumab, Hormone Replacement Therapy (HRT) or strontium, in the two years preceding the

study. Patients on HRT (Supplementary data 3) without a history of investigation or treatment for fractures were included. Patients with bony metastases, myeloma and primary bone malignancy at the time when the patient with a risk factor was identified were also excluded as they are likely to develop malignancy-related fractures.<sup>14</sup>

Patients with a cancer diagnosis were included in this study as certain medications for example anti-androgen therapies used in prostate cancer can increase fracture risk.

As national guidance does not specify a timeframe to carry out a BHA, a year was considered by the authors as an adequate period to capture whether assessments were done on at-risk patients, similar to most Quality and Outcomes Framework (QOF) quality indicators in general practice. BHA performed after a year within the study period was recorded, but not classed as an adequate response. In this study, evidence of a BHA was defined by presence of codes for FRAX/QFracture, bone density scan/osteoporosis related codes, prescription of bone-protection medication including HRT and referral codes to the osteoporosis clinic/rheumatology services.

Two covariates used in this study were patient co-morbidity<sup>15</sup> and number of consultations a patient had in a year<sup>16</sup> Patient co-morbidity has been estimated by looking at the drug count of patients.<sup>17</sup> The number of unique British National Formulary (BNF) chapter codes in a patient's prescription data were counted within a year from the patient's inclusion date and divided into three categories; 0-4, 5-9 and  $\geq 10$ .<sup>18</sup> The number of consultations a patient had in a year from presentation of the fracture risk factor was assessed by recording the number of unique dates with

consultation-related codes. Terms related to diagnostic and symptom codes, medication reviews and secondary care specialist investigation codes were included as consultations. The number of consultations a patient had in a year were categorised as; 0-3, 4-6, 7-9 and  $\geq 10$ . The number of prescriptions and consultations were analysed as categorical variables to improve the clinical interpretability of the model estimates derived. Prescription data cutoff points have been successfully used in previous research.<sup>18</sup> The cutoff points for the number of consultations were based on clinical knowledge, but also to ensure that there was no one group that contained only a small number of patients. All patients included in this study were used for the final data analysis even if they died within one year of inclusion.

### **Statistical Methods for Data Analysis**

SPSS Version 27 (2020) was used for data analysis.<sup>19</sup> Chi-squared tests were used to assess for statistically strong associations between BHA and patient sex for the sample overall, and stratified by: age (50-74 years versus  $\geq 75$  years) and risk factor group (fractures only, falls only, use of steroid only or two or more of the risk factors).

Univariate logistic regression analysis was used to look at the strength of the association between BHA and patient sex. A multivariable logistic regression analysis was then used to adjust for other covariates of interest: age, risk factor group, number of consultations, and patient co-morbidity. Age was included as a continuous variable and all other variables were included as categorical variables.



The covariates were all placed in the same model in the multivariable analysis.

Results will be presented as odds ratios with 95% confidence intervals.

## RESULTS

16,954 patients were eligible for study inclusion. 1373 patients were excluded due to various reasons leaving 15,581 patients in the cohort (Figure 1). The mean age was 73.4 years (standard deviation 10.4 years, range 50-106 years). Table 1 shows the descriptive characteristics of patients included in the study.

Table 2 illustrates the proportion of patients included with respect to their risk factors as well as further demographics related to the four groups. Of the 2329 patients who had two or more risk factors, 122 patients had all three risk factors.

1172 (7.5%) patients in this cohort had a BHA carried out within a year of presentation, while 4960 (31.8%) patients had a BHA after a year of inclusion and 9449 (60.6%) patients had no recorded BHA. Table 3 shows the codes documented for those who had a BHA within one year of inclusion (n = 1172).

Women were found more likely to have a BHA compared to men, with 5.5% (n = 349) men and 8.9% (n = 823) women having had a BHA assessment within a year of presentation with a fragility fracture risk factor ( $X^2 = 59.88$ ,  $p = 1 \times 10^{-14}$ ). Table 4 shows differences in BHA rates, by sex stratified by the two age groups (50-74

years,  $\geq 75$  years) and risk factor, the relation between BHA with patient sex was present in both age categories ( $p = 1 \times 10^{-5}$ ,  $p = 6 \times 10^{-11}$  respectively). With respect to the four risk factors; the falls only group showed a statistically strong difference between the two sexes in relation to BHA ( $X^2 = 21.86$ ,  $p = 3 \times 10^{-6}$ ).

Table 5 outlines the univariate followed by multivariate regression analysis of BHA. On univariate analysis, the odds ratio of women having a BHA compared to the men was found to be 1.66 (95% CI 1.46-1.89). Following adjustment for other variables (age, patient co-morbidity, number of consultations and nature of risk factor) the odds ratio for BHA for women compared to men remained statistically strong at 1.25 (95% CI 1.08-1.43).

Of the 940 patients in this cohort who died prior to their one-year follow-up from the inclusion date, 58 patients had a BHA prior to their death.

## **DISCUSSION**

### **Summary**

This retrospective cohort study in North Staffordshire, UK has demonstrated that only 5.5% of men and 8.9% of women had a BHA within a year of recording of at least one of three major risk factors. After adjustment, women were found to be 25% more likely than men to be assessed. The strength of association between patient sex and BHA did not vary with age. However, when stratifying this relation with

respect to reason for BHA, falls was the only statistically strong risk factor showing a difference in rates of BHA with patient sex.

### **Strengths and limitations of study**

This is the first study to our knowledge to examine sex differences with respect to BHA in patients from a UK primary care population who are at risk of osteoporotic fractures. A strength of this study was the large sample size of nearly 16000 patients (60% women and 40% men). Compared to other published papers, this study is unique as it includes three risk factors including fractures originating from four sites: hip, spine, humerus and forearm. Several authors have only looked at patients with previous hip fractures<sup>20-22</sup> while other studies<sup>9,23</sup> have reviewed patients from certain age groups. Incident patients were only included in this study, so the risk of bias from previous investigations and treatments was minimised.

In this study, BHA determination was based on clinical coding. Relying on coding may underestimate BHA as text in some GP consultations may not have been coded, possibly underestimating rates of BHA. FRAX risk assessment was less frequently recorded than DXA and osteoporosis medicines and it is possible this is less likely to be recorded; this could potentially lead to bias in the results as men are likely to be lower fracture risk and less likely to need onward referral for DXA and/or medicine. A further limitation of this study relates to the study period being from 2002 to 2014, while NICE guidance (CG146)<sup>3</sup> on osteoporosis was first published in 2012 and reupdated in 2017.<sup>24</sup> Recent evidence from a single centre in Italy suggests that

sex differences in BHA assessment persist.<sup>25</sup> Although more contemporaneous data from UK are needed, this study represents the best available evidence on this issue.

As only patients with prednisolone use were included, this study cannot assess current BHA practice in patients on other oral steroids such as dexamethasone. However, data from a General Practice Research Database (GPRD) based study<sup>26</sup> has shown prednisolone accounted for over 90% of oral steroid prescriptions, suggesting this study's results are relevant to most patients on oral steroids. We also did not examine the rate of falls risk assessment, which is a further important assessment when considering fracture risk, particularly in those with prior fractures. A further limitation is that the data is generated from North Staffordshire whose population may not be representative of the UK population.

### **Comparison with existing literature**

This study's finding of men having a lower rate of BHA compared to women concurs with other published papers.<sup>9,27</sup> Codes for FRAX/QFracture were used in only 0.5% of the total BHA codes (Table 3), which potentially could be an underestimate. In a Canadian multicentre osteoporosis study looking at men aged 50 years and over, only 2.3% of men with fragility fractures in the cohort were diagnosed with osteoporosis at the start of the study, which increased to 10.3% at five years follow-up.<sup>28</sup> This suggests healthcare providers do not seem to relate fragility fractures in males to the diagnosis of osteoporosis. Underdiagnosis of men with osteoporosis does seem to translate to reduced treatment rates.<sup>29-33</sup> Curtis et al's (2009) study<sup>23</sup> in over 24,000 patients aged 45 years and over demonstrated that the odds ratio of

men receiving osteoporosis treatment compared to women was 0.08 (95% CI 0.06-0.10).

### **Implications for research and/or practice**

This study's findings demonstrate low BHA rates (7.5%) in both women and men with men statistically less likely to have a BHA compared to women. A reduced rate of BHA in both men and women means that opportunities for fracture prevention are lost, potentially leading to fractures which could have been avoided. This study has shown a very low recording or coding of FRAX/QFracture in primary care (0.5%). Identifying high-risk patients with an improved use of these tools could potentially improve clinical management of these patients. A randomised controlled trial<sup>34</sup>, carried out in multiple GP practices in the UK, demonstrated that FRAX-based screening in women aged 70-85 years improved rates of osteoporosis treatment compared to standard care (15% vs 4%) and lowered rates of hip fractures.

Previous qualitative studies have identified barriers to identification and management of osteoporosis in primary care, including perceptions that osteoporosis is low priority, ambivalence about the safety and effectiveness of medication and uncertainty about clinical guidelines.<sup>37,38</sup>

In addition to addressing these barriers, patient campaigns to increase awareness of this clinical problem<sup>35</sup>, primary care incentivisation may help to improve implementation of fracture risk assessments.<sup>36</sup>

Further research in more contemporaneous data sets is needed to establish if BHA rates remain low, and if men remain underrepresented. Furthermore, research is needed to identify other possible characteristics associated with reduced likelihood of receiving bone health assessments in deprived and underserved communities to enable further strategies to target specific high-risk groups.

In conclusion, this study provides evidence that low rates of BHA were carried out in patients with risk factors especially in men. Osteoporosis is a 'silent disease' which has far-reaching social, economic and clinical consequences. Reducing the burden of osteoporosis starts with primary prevention and primary care clinicians are advised to be alert for fragility fracture risk factors in both men and women and proactively engage in early assessment and intervention where appropriate. This may be promoted by financial incentives, support from healthcare commissioners in providing access to relevant services, and policy makers when developing national health strategy.

### **Additional information**

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**Ethical approval:** This study was reviewed by the CiPCA Academic Custodianship Committee, which has its own standard ethical approval granted by the North West (Haydock) Research Ethics Committee.

**Competing interest** No competing interests

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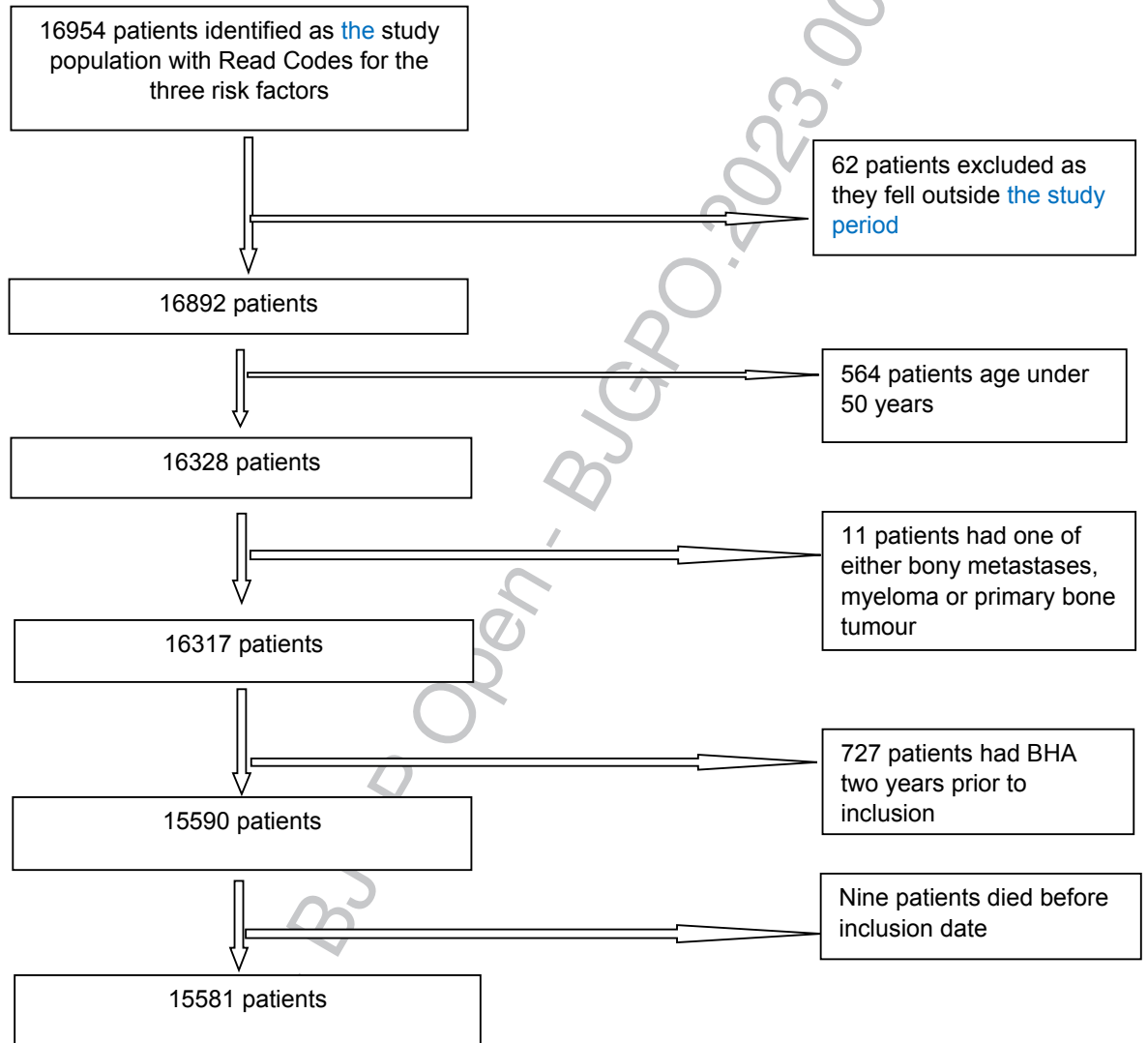
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**Figure 1** Flowchart of patient identification



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**Table 1. Descriptive characteristics of patients in this study**

<b>Demographics</b>		<b>Frequency</b>	<b>Percentage</b>
<b>Age</b>	50-54 years	838	5.4%
	55-59 years	855	5.5%
	60-64 years	1045	6.7%
	65-69 years	2787	17.9%
	70-74 years	2450	15.7%
	≥ 75years	7606	48.8%
	<b>Sex</b>	Male	6302
Female		9279	59.6%
<b>Ethnicity</b>	White British	8626	55.4%
	Mixed	4321	27.7%
	Other White	96	0.6%
	Asian/Asian British	63	0.4%
	Black/African/Black British/Other Black	11	0.07%
	Other Ethnic group	19	0.12%
	Unknown	2445	15.7%

**Table 2. The distribution of risk factors of patients included in this study**

<b>Risk Factor</b>	<b>Number of patients</b>	<b>Percentage of patients</b>	<b>Age mean, standard deviation (range)</b>	<b>Percentage of women</b>
Falls only	9377	60.2%	75.6, 9.1 (50-102)	56.2%
Fracture only	1198	7.7%	69.9, 12.4 (50-106)	77.6%
Use of steroids only	2677	17.2%	67.0, 11.4 (50-102)	55.4%
Two or more risk factors	2329	15.0%	73.7, 9.2 (50-97)	68.7%
Total	15581	100%	73.4, 10.4 (50-106)	59.6%

**Table 3. Type of BHA completed within one year of inclusion in this study**

<b>BHA codes</b>	<b>Number of codes (%)</b>	<b>Number of men (%) of total men's codes</b>	<b>Number of women (%) of total women's codes</b>
FRAX/QFracture	8 (0.5%)	4 (0.9%)	4 (0.4%)
Computerised Bone Densitometry/DXA or Osteoporosis related codes	842 (56.9%)	231 (53.0%)	611 (58.6%)
Referral to specialist	162 (11%)	64 (14.7%)	98 (9.4%)
HRT prescriptions	20 (1.4%)	Not applicable	20 (1.9%)
Bisphosphonates & other Bone Protection prescriptions & related codes (bisphosphonates contraindicated/declined/not indicated)	441 +(6) (30.2%)	135 + (2) (31.4%)	306+(4) (29.7%)
Total codes	1479 (100%)	436	1043



**Table 4. showing Chi squared test done to assess difference with patient sex overall and with stratification of age categories and specific risk factors**

	Observed (%) having a BHA	Expected (%) having a BHA	Chi-square test $\chi^2$ (p-value)
<b>Overall</b>			
Male	349 (5.5%)	474 (7.5%)	59.88 (p = 1 x 10 <sup>-14</sup> )
Female	823 (8.9%)	698 (7.5%)	
<b>Stratified by Age group</b>			
<b>Age category (50-74 years) (N = 7975)</b>			
Male	205 (5.9%)	256.1 (7.4%)	19.45 (p = 1 x 10 <sup>-5</sup> )
Female	384 (8.5%)	332.9 (7.4%)	
<b>Age category (75 or more) (N = 7606)</b>			
Male	144 (5.1%)	217.3 (7.7%)	42.69 (p = 6 x 10 <sup>-11</sup> )
Female	439 (9.2%)	365.7 (7.7%)	
<b>Stratified by risk factor</b>			
<b>Fractures (N = 1198)</b>			
Male	75 (28%)	72.5 (27.1%)	0.16 (p = 0.69)
Female	249 (26.8%)	251.5(27%)	
<b>Falls (N = 9377)</b>			
Male	52 (1.3%)	83.7 (2%)	21.86 (p = 3x10 <sup>-6</sup> )
Female	139 (2.6%)	107.3 (2%)	
<b>Steroids (N = 2677)</b>			
Male	124 (10.4%)	139.3 (11.7%)	3.43 (p = 0.06)
Female	188 (12.7%)	172.7 (11.7%)	
<b>Two or more risk factors (N = 2329)</b>			

Male	98 (13.5%)	107.8 (14.8%)	1.53 (p = 0.22)
Female	247 (15.4%)	237.2 (14.8%)	

*(observed – actual results, expected – number of patients that would fall in each category if no association between the variables exists)*

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**Table 5. Univariate analysis of patient sex on BHA followed by multivariate analysis of various factors affecting BHA including, patient age, co-morbidity, number of consultations and type of risk factor**

Risk Factor	Odds Ratio for BHA	95% Confidence Interval	p-value
Female sex (univariate analysis)	1.66	1.46-1.89	$2 \times 10^{-14}$
Female sex (multivariate analysis)	1.25	1.08-1.43	0.002
Age	1.03	1.02-1.03	$1 \times 10^{-15}$
Consultation category (0-3) Ref			
Consultation category (4-6)	3.20	2.00-5.10	$1 \times 10^{-6}$
Consultation category (7-9)	4.36	2.76-6.88	$3 \times 10^{-10}$
Consultation category ( $\geq 10$ )	8.58	5.57-13.22	$2 \times 10^{-22}$
Co-morbidity (No. BNF Chapters 0-4) Ref			
Co-morbidity (No. BNF Chapters 5-9)	0.97	0.64-1.45	0.864
Co-morbidity (No. BNF Chapters $\geq 10$ )	0.64	0.43-0.96	0.032
Risk factor Fall Ref			
Fracture	21.01	17.16-25.71	$2 \times 10^{-191}$
Steroid Use	7.16	5.89-8.72	$4 \times 10^{-86}$
2 or more risk factors	8.22	6.80-9.95	$8 \times 10^{-104}$