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Fracture prevention: a population-based intervention delivered in primary care

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Summary

Background: Osteoporosis is common, increasing as the population ages and has significant consequences including fracture. Effective treatments are available.
Aim: To support proactive fracture risk assessment (FRAX) and optimizing treatment for high-risk patients in primary care.
Design: Clinical cohort
Setting: November 2017 to November 2018, support was provided to 71 practices comprising 69 of 90 practices within two National Health Service Clinical Commissioning Groups areas. Total population 579 508 (207 263 aged over 50 years).
Participants: FRAX (National Institute for Care and Clinical Excellence, NICE CG146) in (i) males aged 75 years and over, (ii) females aged 65 years and over, (iii) females aged under 65 years and males aged under 75 years with risk factors and (iv) under 50 years with major risk factors.
Results: A total of 158 946 met NICE CG146, 11 961 were coded with an osteoporosis diagnosis (7.5%), of those, 42% were prescribed treatment with a bone sparing agent (BSA). In total, 6942 were assessed to initiate BSA. Thirty percent of untreated osteoporosis diagnosis patients had never been prescribed BSA. Even when prescribed, 1700 people (35%) were for less than minimum recommended duration. Of the total 9784 patients within the FRAX recommended to treat threshold, 3197 (33%) were currently treated with BSA and 3684 (37%) had no history of ever receiving BSA. From untreated patients, expected incidence of 875 fractures over a 3-year period (approximately £3.4 million). Treatment would prevent 274 fractures (cost reduction: £1 274 045, with prescribing costs: saving £805 145 after 3 years of treatment).
Conclusion: Underdiagnosis and suboptimal treatment of osteoporosis was identified. Results suggest that implementing NICE guidance and optimizing treatment options in practice is possible and could prevent significant fractures.

Introduction

Annually, osteoporosis results in over 200 000 fractures in the UK[1] and nearly 9 million fractures worldwide.[2] The social and economic burden of fragility fractures is largely hidden, and osteoporosis remains hugely underdiagnosed in the UK. Fragility fractures alone are expected to increase by 26% from 2017 figure of 520 000–660 000 by 2030. Estimates suggest that the National Health Service (NHS) faces an annual burden of £4.5 billion in healthcare costs associated with fragility fractures, increasing to £5.9 billion by 2030.[3]

The UK's ageing population is set to continually rise, with an estimated 24% aged over 65 years in 2047,[4] meaning the prevalence of chronic conditions, such as osteoporosis, will further increase, leading to an exponential rise in the incidence of fragility fractures as a result of osteoporosis.[3] The burden of fragility fractures in the UK already exceeds that for chronic obstructive pulmonary disease and ischaemic stroke[5] and is reported to be the fourth most burdensome chronic disease in the UK. Hip fractures alone (22% of fragility fractures[3]) are almost as common and costly as stroke and the incidence is rising.

Osteoporotic fragility fractures can cause substantial pain and severe disability to patients, often leading to reduced quality of life. Approximately 50% of patients suffering a hip fracture can no longer live independently.[1] Studies also suggest that both hip and vertebral fractures are associated with a significant mortality.[6,7]

Aside from the stated increases, there remains an identified treatment gap. In part due to the underdiagnosis of osteoporosis but there are also opportunities to improve care following a fracture. The report, 'Broken bones, broken lives: A roadmap to solve the fragility fracture crisis in the United Kingdom', provides evidence that despite the availability of effective preventative therapies and management approaches for fragility fractures, 49% of women over 50 years of age in the UK are not receiving treatment following a hip fracture.[3] After a fragility fracture, women are five times more likely to experience a second fracture within the next year,[3,8] yet less than half the women who sustain a hip fracture at or after the age of 50 years within the UK go on to receive treatment for osteoporosis in the following year.[9]

National Institute for Health and Care Excellence (NICE) recommend that adults assessed as high or intermediate risk of fragility fracture and diagnosed with osteoporosis should be offered bone-sparing drug treatment.[10] National Institute for Care and Clinical Excellence (NICE) also recommend that adults prescribed bone-sparing drug treatment are reviewed 4 months after starting treatment and annually thereafter.[8] Medication reviews should assess how a person is managing their treatment and patients should be asked about adverse effects and treatment adherence.[10]

Bisphosphonates have been widely used in the treatment of osteoporosis and have been shown to prevent bone loss and reduce the incidence of fractures in patients with osteoporosis.[11] They bind strongly to bone mineral and inhibit bone resorption and this effect lasts for many months after treatment has stopped raising concerns regarding the[12] potential of increased bone fragility due to suppression of normal bone remodelling. It is recommended that adults taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment.[10]

The 2016/17 hospital episodes statistics suggests that the North East region has a significantly higher incidence of hip fracture than the England average (643 per 100 000 vs. 575 per 100 000).[13]

This programme set out to support the prevention of fragility fractures and improve the management of osteoporosis by assisting in the implementation of key recommendations and standards.

Materials and methods

The project undertook a fracture risk assessment (FRAX) of patients meeting NICE CG146 criteria[14] in (i) males aged 75 years and over, (ii) females aged 65 years and over, (iii) females aged under 65 years and males aged under 75 years in the presence of risk factors and (iv) people aged under 50 years with major risk factors.

Oversight of the project

Delivery of this service improvement project was through a Joint Working agreement between Amgen Ltd and the Academic Health Science Network for the North East and North Cumbria (AHSN NENC). The first phase of the programme involved engagement with Clinical Commissioning Groups (CCGs) and key opinion leaders from across the footprint. The project was delivered by Interface Clinical Services Ltd. The AHSN NENC approached CCGs in the first instance to understand local pathways and explore the challenges faced across the region.

Process

Following initial engagement across bone health services in the North East, a programme for primary care delivery was developed to allow patient identification. A period of service design took place, and through collaborative working with local stakeholders a protocol was agreed ensuring a consistent and holistic direction for clinical pharmacists to follow in practice working with clinical teams. The project was pragmatic in its approach, recognizing that practices required different priorities and approaches.

Interface developed a technology platform which enabled a FRAX to be completed on every patient in every participating practice that was within scope of NICE CG146.[14] Risk scores were calculated for each patient using the FRAX algorithm.[15] The FRAX calculation is derived from the clinical record and is therefore is only as accurate as the coding within the clinical system. For example, parenteral hip fracture is generally not coded but contributes to a FRAX calculation but cannot be identified from the clinical system unless coded. Some calculations will therefore be an underestimation of risk. Initial practice level screening using FRAX therefore identified those at risk which required subsequent more detailed note review.

Interface provided a team of experienced clinical pharmacists whose role it was to review those considered high risk via FRAX and to complete a data analysis process within the practices and to then to make recommendations and agree an implementation plan. The practice team and individual clinicians remained in control of implementing any recommendations. The pharmacists used FRAX values in keeping with National Osteoporosis Guideline Group (NOGG) thresholds.[1] Below is a summary of the approach adopted at practice level:

Phase 1 Stratification—analysis of electronic clinical systems to identify patients as per agreed cohorts. Patients of greatest risk could be highlighted by referencing FRAX score, presence of

osteoporosis diagnosis, duration of current therapy, clinical issues [e.g. GFR (glomerular filtrate rate) compliance, side effects].

Phase 2 Presentation of findings—Interface pharmacists presented patient cohorts to the lead GP within each participating practice in dashboard format to allow immediate comparison and understanding of scale.

Identified patients were segmented into four priority groups for review defined according to current guidelines:

- Coded with osteoporosis diagnosis but no evidence of current bone sparing agent (BSA). 'Bone sparing therapy is recommended for treatment and prevention of osteoporosis—NOGG20171, NICE TA46414 and NICE QS1498'.
- Not coded with osteoporosis diagnosis but deemed high risk as per FRAX and no evidence of current BSA. 'Bone sparing therapy may be considered for patients in whom a fracture risk assessment is completed and results indicate high 10-year risk of significant fracture—NOGG20171, NICE TA46414 and NICE QS1498'.
- Prescribed BSA for consideration for treatment holiday. 'NICE QS 149 recommends adults having long-term bisphosphonate therapy have a review of the need for continuing treatment'.
- Cohort 4—prescribed BSA but Electronic Health Records (EHR) data suggests clinical factors may affect optimal treatment (e.g. reduced GFR, potential side effects, treatment failure or poor compliance) 'NICE QS 149 recommends review of patient compliance and specific considerations on prescribing in renal insufficiency'.

Results

Between November 2017 to November 2018, support was provided to 71 practices, which comprised 69 of the 90 practices within two NHS CCG areas. Practice list size ranged from 2060 to 35 700 (average 8264, which is similar to the UK National average of 8420).[14] The total population of the 71 practices was 579 508 patients including 207 263 over the age of 50 years.

Stratification of those undergoing FRAX

Across the 71 practices participating in the programme 158 946 patients were identified as meeting NICE CG146 criteria and a subsequent FRAX assessment was completed in 153 206 of those patients, the results of which are shown in Figure 1a. It was not possible to complete a FRAX calculation in 5740

patients due to missing data points within the clinical system, e.g. body mass index. Additional clinical markers were also collated to inform further prioritization of patients for intervention and illustration of the level of risk within these patient groups. This additional information included osteoporosis diagnosis and hip fracture prevalence. Figure 1a confirms that in those with a FRAX score of 45% or more, approximately one in three patients had already suffered at least one hip fracture and more than half already had an osteoporosis diagnosis.

Presentation of findings and determining the patient cohorts

The FRAX assessment led to 28 657 individuals who were subsequently prioritized for further assessment and allocated to cohorts for assessment and review (Figure 2a).

A total of 12 200 did not meet the cohort criteria above so were perhaps osteoporotic and on bone sparing treatment had not yet reached the review period for a treatment holiday, no clinical issues had been noted in the patients record to affect ongoing therapy or FRAX score did not suggest high risk.

Patients coded with osteoporosis diagnosis but no evidence of current BSA

In total, 11 961 patients were coded with an osteoporosis diagnosis (7.5%) of those, 42% were prescribed current treatment with BSA leaving 6942 patients for assessment to initiate BSA. Thirty percent of those currently untreated osteoporosis diagnosis patients have never been prescribed BSA (Figure 2b). Twenty-five percent of untreated osteoporosis diagnosed patients had tried two or more BSA in the past.

Figure 2c suggests that the absence of treatment in patients with an osteoporosis diagnosis is sometimes but not always explained by appropriate treatment holiday. Even where multiple BSA have been tried, 1700 patients (35%) did not receive treatment for the minimum recommended duration suggesting poor adherence and endorses NICE recommendation to regularly complete medication reviews with patients prescribed BSA.[8]

Patients not coded with osteoporosis diagnosis but deemed high risk as per FRAX and no evidence of current BSA

Of the total 9784 patients within the FRAX recommended to treat threshold, only 3197 (33%) were currently treated with a BSA and 3684 (37%) had no history of ever receiving a BSA.
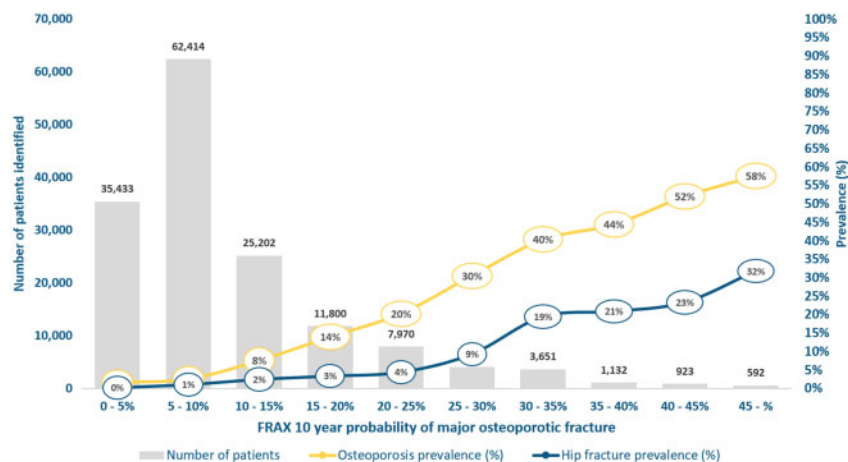

Figure 1. FRAX assessment of area population mapped with osteoporosis and hip fracture prevalence.

(a)

579,508
total local population

158,946
patients meeting NICE CG146

153,206
patient FRAX assessments

28,657
patients meeting project criteria

16,457
patients allocated to review cohorts

2,367	3,139	4,009	6,942		3,285	766
Cohort 4: Review current BSA prescription for possible clinical issues with treatment	Cohort 3: Review current BSA prescription for treatment holiday	Cohort 2: Treat as per FRAX assessment and no BSA prescription	Cohort 1: Osteoporosis diagnosis and no BSA prescription		H/O fragility fracture but no current BSA	facilitated interventions or referrals back to GP for bone health assessment

1,229 Referrals to GP	27 Referrals to GP	22 Referrals to GP	760 Referrals to GP	420 Referrals to GP
4,502 Interventions	848 Interventions	927 Interventions	682 Interventions	2,045 Interventions

1,891
H/O fragility fracture and no history of BSA

265
facilitated interventions or referrals back to GP for bone health assessment

(b)

6,942

478   1,258   2,067   3,139

■ Never prescribed BSA ■ History of 1 BSA ■ History of 2 BSA ■ History of ≥ 3 BSA

(c)

997, 379, 335, 335, 439, 498, 334, 283, 223, 193, 206, 151, 127, 97, 69, 53, 49, 27, 28, 20, 32

< 1 year, 1 years, 2 years, 3 years, 4 years, 5 years, 6 years, 7 years, 8 years, 9 years, 10 years, 11 years, 12 years, 13 years, 14 years, 15 years, 16 years, 17 years, 18 years, 19 years, ≥ 20 years

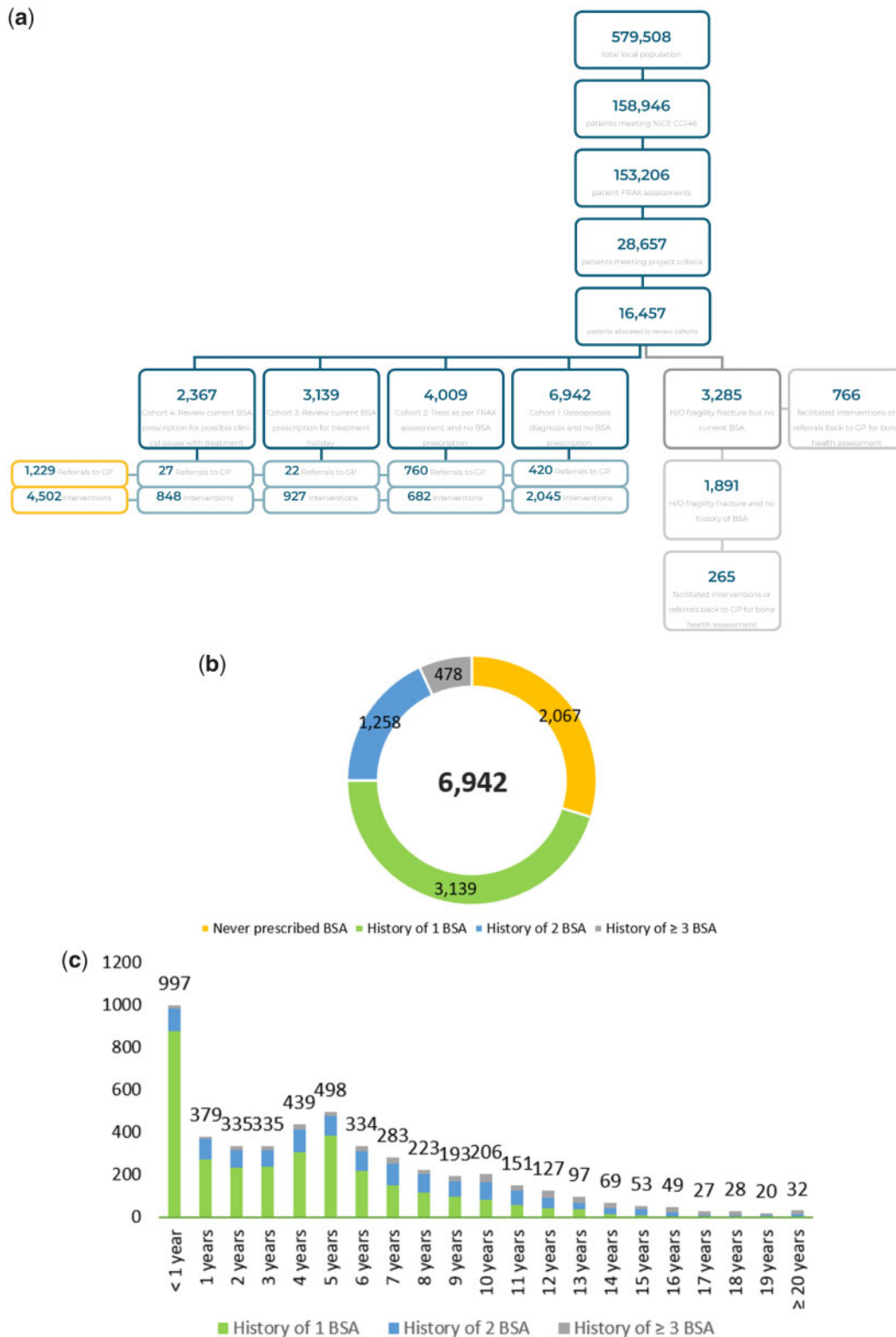■ History of 1 BSA   ■ History of 2 BSA   ■ History of ≥ 3 BSA

Figure 2. (a) Consort diagram of total population in blue boxes with interventions delivered in yellow boxes and fragility fractures in grey boxes. (b) Previous bone sparing agent usage in currently untreated osteoporosis diagnosed patients. (c) Combined duration of treatment of all previously tried bone sparing agent treatments in patients with osteoporosis but no current therapy.

There was a treatment gap potential of 6587 patients not currently receiving BSA that are considered high risk (i.e. treat as per FRAX) of fracture. A further 10 812 were highlighted for consideration of bone health assessment that were not currently receiving treatment. Four hundred and eighty-seven patients were currently prescribed treatment with a BSA but did not
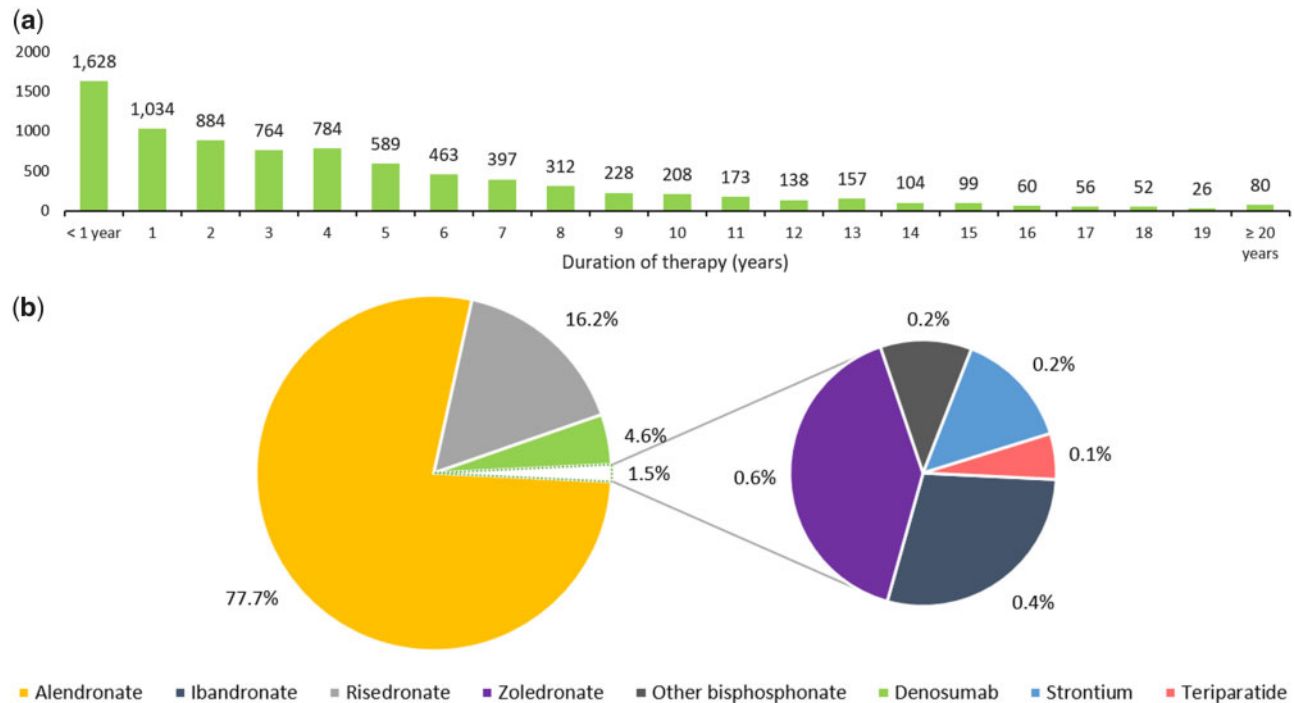
(a)

(b)

Figure 3. (**a**) Duration of treatment with current bone sparing agent therapy. (**b**) Bone sparing agent prescribing across all reviewed practices.

appear to have an osteoporosis diagnosis and are below the treatment threshold according to their FRAX assessment. It is possible that these patients were simply not coded as osteoporotic but have a DEXA or fracture history that indicates treatment.

In total, 8236 patients were prescribed current BSA, average duration of treatment was 5 years. Figure 3a, however, shows that despite NICE recommending that adults who have been taking bisphosphonates for at least 3 years have a review of the risks and benefits of continuing treatment[8] this did not appear to be occurring in practice. It is important to note that some patients in this group may be eligible for ongoing treatment due to their individual risks of further fracture, but 1153 patients had been prescribed their current therapy for 10 years or more (14%).

It is clear in Figure 3b that the majority of patients (78%), where treated, are being prescribed the preferred first line agent alendronate.

Fragility fractures

A number of patients identified with osteoporosis or a history of a major osteoporotic fracture were found to have no history of BSA (Figure 4).

It was also possible to predict the potential number of fractures prevented calculated based on NICE data model[15,16] using age/sex and the costs for these calculated. From the untreated patients in the project population, there would be an expected incidence of 875 fractures over a 3-year period (223 hip, 208 vertebral, 126 humerus and 318 wrist fractures), the cost of which would equate to approximately £3.4 million. If treatment is adopted amongst these patients and complied with, this would prevent 274 fractures (74 hip, 114 vertebral, 26 humerus and 60 wrist fractures prevented). The associated costs of these fractures would be £2 116 839 and treatment with alendronate would be £468 900, totalling £2 585 739 (figures have been

rounded during the calculations). This suggests that should a locality adopt this project on a wider scale and referrals for treatment be encouraged, although there should be an expected uplift in prescribing, the savings in fracture prevention outweigh such costs. For the practices engaged with this project there would be fracture cost reduction of £1 274 045 and therefore with prescribing costs incorporated, an overall total area saving of £805 145 after 3 years of treatment.

Discussion

Our study represents a large scale review of fracture risk and osteoporosis management in the North East of England. This has shown that risk is high and that osteoporosis is prevalent. Despite this, and the associated evidence for the benefits of BSAs, the use of these agents is limited. We have also shown that a structured approach to identifying those at high risk of osteoporosis is possible and effective.

Furthermore, we were able to calculate the potential cost savings for this approach which were considerable. This is not forgetting the improvement in quality of life for those patients who would otherwise have been affected by a significant fracture.

It is important to acknowledge some limitations. FRAX is a risk score and calculated using clinical data. It was frequently found that some parameters were not routinely collected in the primary care record, e.g. family history. Arguably this would underestimate the risk and therefore would suggest that the potential clinical and cost savings of this approach would be increased if a comprehensive data set were available. Our project was delivered in a pragmatic way. We did not define the clinical pathways but were clear that once identified the management of patients was via established clinical guidelines. In some instances, these were locally determined and therefore there were some minor differences between management of patients between practices.
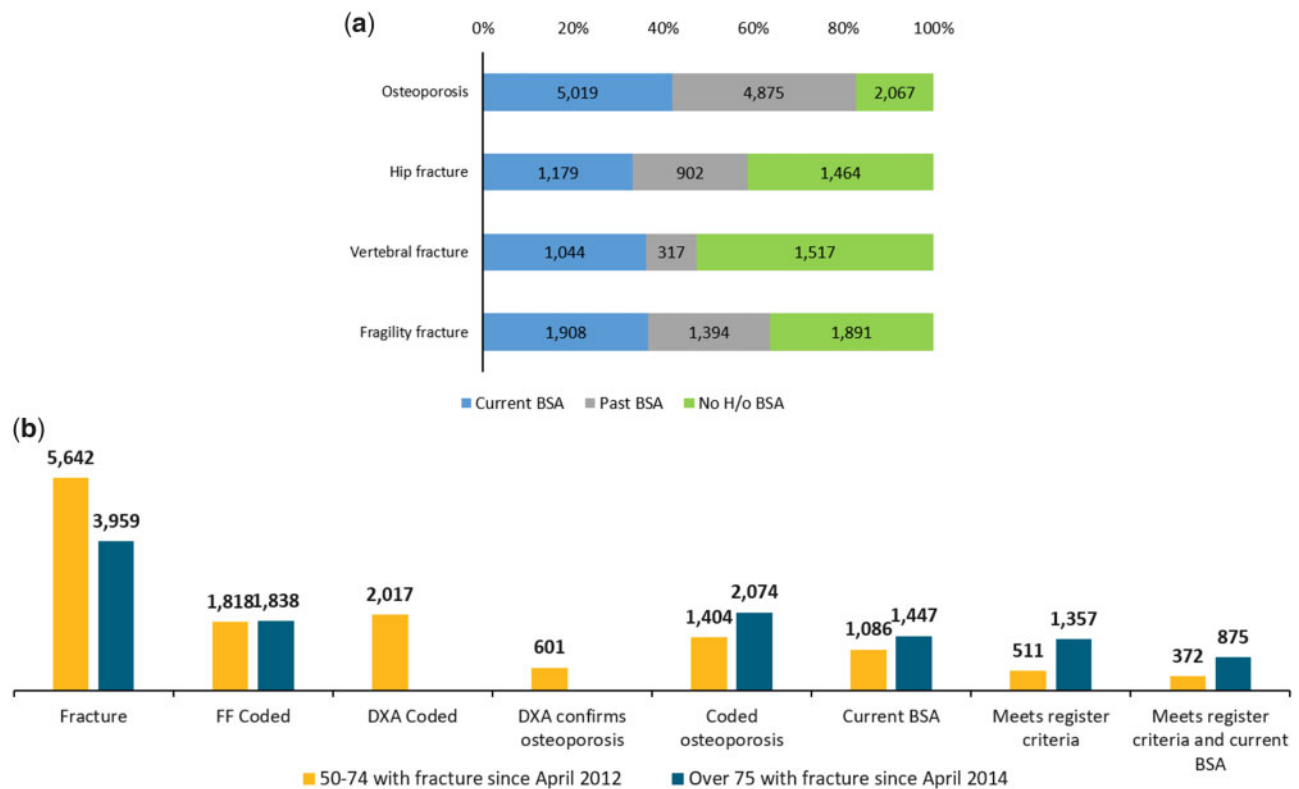
Figure 4. (a) Analysis of bone sparing agent treatment in patients with osteoporosis diagnosis or history of major osteoporotic fracture. (b) Proportion of patients aged over 50 sustaining a fragility type fracture since April 2012 with a coded fragility fracture.

Overall interface pharmacists reviewed the notes of 28 657/ 15 127 (52% identified within the review criteria) patients and helped facilitate 5731 patient interventions through this project and without this those patients would remain unidentified, unmanaged, suboptimally controlled and at higher risk of future fracture. Through the stratified approach, identifying these patients means the screening burden of the 15 127 patients has been taken away from the practice.

The project confirmed underdiagnosis of osteoporosis as well as suboptimal management of patients and fracture prevention within this population. The results suggest that if NICE guidance[10] is fully adopted and patients prescribed bone sparing therapy attend for an annual bone health review, alternative treatment options could be provided at an earlier opportunity in low adherence patients and thus prevent significant fractures.

Funding

Data availability

Data is available anonymously via Interface Clinical Services on request.

Conflict of interest. None declared.

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