Primary Care Medicines Optimisation Project for Improving Anti-Osteoporosis Medication Adherence

Project Outcome Report

March 2023

Contents

1. Executive summary

Osteoporosis is the most common chronic bone disease; it results in weakening of bones and can lead to fragility fractures, a broken bone after a fall from standing height or less. Fragility fractures affect one in two women and one in five men over the age of 50 and can have a devastating, permanent impact on patients' lives. They can cause substantial pain and disability, increased mortality, significantly impacting on quality of life and an individual's confidence to remain independent.

Anti-osteoporosis medications (AOM) are highly effective in reducing the risk of fracture, yet it is well documented that adherence to the medication regime is a major issue, with approximately 50% of patients stopping taking their medication within the first year. Patients with osteoporosis are usually monitored by their GP within primary care, and as such providing an easy and effective way to regularly monitor the adherence to treatment is crucial to improving patient outcomes and preventing fragility fractures.

The GRASP-Osteoporosis project was a collaboration between the University of Oxford, PRIMIS (part of the School of Medicine, University of Nottingham) and the Oxford Academic Health Science Network. The project was run as a pilot within eight GP practices in Oxfordshire, in order to test proof of concept. The primary aim was to improve adherence to medication by identifying patients at high risk of fragility fracture and supporting these patients through medication review with a focus on appropriate medication initiation and duration of therapy.

Participating practices ran five reports during the project period, following which the results were analysed and feedback sought on the tools. The outputs enabled the project tools to be changed and improved during the pilot. To support local improvement, practices were able to access online resources as well as online support calls with the local secondary care lead.

At baseline, there was significant variability in AOM use and adherence. Despite a 1.35% increase in the eligible population over the course of the pilot, QOF coding for fractures increased substantially by 20.8%. Even with the greater number of patients coded, adherence rates were sustained. A total of 283 patients were reviewed, 89 patients (31.4%) had their treatment restarted or switched and 45 (15.9%) had their treatment stopped or paused. Reviews took the form of desktop reviews in 60% of patients, while 40% required a phone call or face to face appointment. Results varied between the eight practices with two practices improving the adherence to Denosumab from 76% and 80% to 91%. An additional 252 patients were on AOM at the end of the pilot, and assuming this increase was largely due to GRASP-Osteoporosis given the negligible change in the patient population, the impact of this would result in 13 fewer fractures within the next two years, with a hospital cost saving of £97,294.

The outputs from the pilot demonstrate significant increases in coding, appropriate AOM prescribing and adherence in these pioneer practices and justify extending the programme across a broader range of practices.

2. Rationale for project

2.1 Osteoporosis and fragility fractures – background information

Osteoporosis affects over 3.7 million people in the UK. It is the most common chronic bone disease affecting both men and women, and is more common in older people. Osteoporosis, meaning 'porous bone', develops when the creation of new bone is slower than the loss of old bone. The disease is characterised by low bone density, making bones more fragile and more likely to break.

Osteoporosis is sometimes referred to as the 'silent' disease as people cannot feel their bones weakening, and often it remains undiagnosed until a fragility fracture occurs. A fragility fracture is a fracture following a fall from standing height or less. Fragility fractures are common with one in two women and one in five men suffering a fragility fracture after the age of 50. People who sustain one fracture are at double the risk of sustaining a subsequent fracture in the next two years, with re-fractures leading to worse health outcomes, higher mortality, and higher care home admissions.

Fragility fractures can have a devastating impact on people. They can cause substantial pain and severe disability, having a significant impact on quality of life and an individual's ability and confidence to remain independent:

- 1 in 3 people with long-term pain after a fragility fracture describe it as unbearable[i]
- 80% of people are unable to climb stairs, shop, or garden after a hip fracture[ii]
- Hip fractures are associated with decreased life expectancy, with 20% of cases being fatal and 50% resulting in permanent disability

As well as the huge impact on an individual, fragility fractures are extremely costly to the health and social care economy. Over 500,000 fragility fractures present to hospital in the UK each year[iii], costing an estimated £4.4bn (excluding social care costs)[iv]. As the UK population ages, the number and costs of fragility fractures will increase.

The National Institute for Clinical Excellence (NICE)[v] and National Osteoporosis Guideline Group (NOGG)[vi] have set out clear guidelines for the assessment and management of people with osteoporosis. These guidelines reflect an evidence base which shows that for patients with osteoporosis, or with the risk factors for osteoporosis, optimising medication is essential to reduce the risk of sustaining a fracture, to improve quality of life and to reduce the associated economic burden on health and social care. The challenge remains in implementing these guidelines equitably across the population.

2.2 The importance of medication and adherence issues

Anti-osteoporosis medications (AOM) are highly effective in reducing the risk of fracture. The figure below demonstrates the effectiveness of AOM compared to other common conditions and treatment. It shows that while fragility fractures, along with frailty, are the third largest cause of long-term care requirements, anti-osteoporosis drugs are the second most effective treatment at reducing healthcare usage (after blood pressure medication) (Figure 1).

Figure 1 Relationship between causes of long-term care admissions and expected impact in hospital admission from secondary prevention

Comparing Institutional Care and expected benefit from secondary prevention

Reduction in healthcare use

- 0.3 — Stroke / Blood pressure[2]
- Fractures / Osteoporosis drugs[4]
- 0.2 — Heart disease/ Cholesterol[5]
- 0.1 — Parkinson / Rasagline[7], Frailty/ Exercise[3], Dementia / Anti-cholinesterase Medication
- Lung disease/ Inhalers[6]
- 0

0%   5%   10%   15%   20%

Cause of long-term care / institutionalisation (%)[1]

[1]Japanese Ministry of Health, Welfare & Labour 2019; [2]Lakhan 2009; [3]Garcia 2020, [4]Tsuda 2020, [5]Koskinas 2018; [6]Sliwka 2019, [7]Hattori 2019

However, for the medication to be effective and to minimise the risk of fracture, the medication regime must be adhered to. Medication can be prescribed for varying lengths of time depending on the individual patient. Some medications have specific requirements on how it is taken, and it is important that patients understand these. For example, to be effective some medications need to be taken first thing in the morning, at least 30 minutes before eating or drinking, and individuals should not lie down for at least 30 minutes after taking the medication and avoid any calcium containing supplements for 4 hours.

Evidence[vii viii] shows that medication adherence for osteoporosis is poor and that poor adherence is associated with a significantly increased risk of fracture. Non-adherence is usually defined as a gap in treatment (not taking medication) of between 30 – 120 days, and it is estimated that 50% of patients discontinue their medication within the first year. The reasons for non-adherence are multifactorial, including:

- Perception that medication is not required if the patient is otherwise fit and healthy
- Side effects of medication, such as nausea and vomiting
- Perception of effectiveness or benefit, as any strengthening of bones cannot be felt
- Complicated dosing instructions and specific time restrictions

A patient survey undertaken by the Royal Osteoporosis Society in 2021[i] highlighted the following:

- Less than half of patients (48%) are confident they are on the correct medication
- Only 4 in 10 patients think their medication is effective
- 57% of patients are concerned about the risks of taking their medication for prolonged periods of time

- 52% of patients are worried about the potential side effects of their medication
- 46% of patients are dissatisfied with the current level of monitoring of their condition

Non-adherence has been described[ix] as a hidden problem, undisclosed by patients and unidentified by prescribers. Whilst ensuring patients are optimised on their treatment is paramount to reducing the risk of fracture, there is no easy, direct measure of medication adherence. Patients with osteoporosis are primarily monitored by in primary care, and as such providing an easy and effective way for primary care clinicians to monitor these patients on a regular basis is crucial to preventing fragility fractures and improving patient outcomes.

2.3 Project aim

The GRASP-Osteoporosis project was a primary care based, medicines optimisation project. The primary aim was to identify patients at high risk of fragility fracture and support these patients through review and focus on appropriate medication initiation and duration of therapy. The project also aimed to improve coding within practices, by identifying patients who may have not been given an appropriate osteoporosis or fragility fracture code.

The project was a collaboration between the University of Oxford, PRIMIS (part of the School of Medicine, University of Nottingham) and the Oxford Academic Health Science Network (AHSN). The project was run as a pilot within eight GP practices within Oxfordshire, in order to test proof of concept. The outputs from this pilot shaped the case-finding tool and reporting templates, ensuring they are accurate and supportive for the clinicians using them.

3. Iterative development of project tools

The project tools comprise:

- a case-finding tool
- a reporting template
- quality improvement resources

3.1 Case-finding tool

The case-finding model was created by Dr Kassim Javaid, Consultant Rheumatologist, who is the clinical champion for the project. The model was then developed into a computable tool by the expert health informaticians and developers at PRIMIS. The tool was tested by GPs, primary care pharmacists and practice nurses.

The tool used inclusion and exclusion criteria to identify patients for whom a decision to treat with AOM had already been made, but who would benefit from a medication review. The identified patients were then stratified into groups for review based on the time from their last AOM prescription. An example of the original tool summary sheet is shown below (Figure 2).

Figure 2 Overview of original tool summary.

Practice population	■■■■	Report Reference Date: 25 February 2022
Audit Subset Population		
Patients aged 50+ with a fracture in the last 5 years and an issue of AOM ever:	**244**	

Osteoporosis Diagnosis and QOF Fragility Fracture Coding	Coded	Not Coded	Osteoporosis Prevalence
Osteoporosis Diagnosis coding for above 244 patients:	183	**61**	12
QOF Fragility Fracture coding for above 244 patients:	138	**106**	cases per 1000 patients

Suggested action: **Review your practice prevelance of osteoporosis.**
Suggested action: **Review patients in the green box and consider adding QOF fragility fracture codes to patients records for inclusion on the QOF register.**

Medication History	Has code for EOL or palliative care	Has code for bisphosphonate holiday in last 24 months	Has code for seen or referred in the last 12 months	Patients for review (excludes patients in previous columns)
Of the subset population patients who haven't had a prescription in last 9 months	1	1	1	**20**
Of those patients who haven't had a prescription in the previous 9 to 18 months	1	-	-	**46**

The suggested order for review is to review patients highlighted in the red box, followed by the amber group. This was a pragmatic decision based on the theory that patients who have stopped their medication more recently may be easier to recommence on treatment.

During the pilot, the GP practices were asked to run the tool and attend webinars to discuss the results. Following analysis of the results and feedback from practices, changes were made to the tool throughout the pilot and each iteration was subsequently run by the practices.

a) Inclusions

The key changes to the case-finding tool were:

<u>History of fracture and prescription of anti-osteoporosis medication</u>

The initial tool searched for patients who were:

- ➢ 50 years and over **AND**
- ➢ Fracture in the last 5 years **AND**
- ➢ Ever had anti-osteoporosis medication issued

The first reports from GP practices appeared to demonstrate higher than anticipated adherence rates. From analysis, the age at fracture and the medication issue period were identified as potential contributing fractures. The tool was amended to search for:

- ➢ 50 years and over (although redundant due to next clause)
- ➢ History of fracture, if aged 50 years or over at time of fracture **AND**
- ➢ Anti-osteoporosis medication issued in the last 5 years

b) Fracture codes

The initial search criteria looked for fractures coded as 'fragility fracture' or 'fracture due to osteoporosis'. This was felt to be a contributing factor to lower numbers of patients being identified for review than anticipated, as not all fragility fractures are coded as such and therefore too few patients were being identified by the tool.

Analysis from a practice population after the above two changes were made demonstrated a greater number of patients were being appropriately identified – 235 patients in the updated tool, compared to 173 in the original search.

c) Exclusions

The search tool is intended to be practical and so was designed to avoid alerting practices to patients who have certain clinical history and who would not require a review.

The initial exclusion criteria were:

- Palliative care
- Bisphosphonate holiday recorded in the previous 24 months
- Seen* or referred in the previous 12 months

*secondary care review in the last 12 months / osteoporosis treatment review in the last 12 months / outcome of osteoporosis treatment review in the last 12 months

Recognising that a secondary care review may be unrelated to a review of a patient's anti-osteoporosis medication this exclusion was dropped. Osteoporosis treatment stopped or not indicated were included to prevent the same patients being re-identified in successive searches. The project team agreed that patients who decline treatment should continue to be flagged as they could be high-risk, and it is important to continue to have the opportunity to discuss treatment with them again.

The final version of the tool uses the following exclusion criteria:

- Palliative care / chemotherapy
- Bisphosphonate holiday recorded in the previous 24 months
- Zoledronic Acid in the previous 12 months
- Osteoporosis treatment stopped
- Osteoporosis treatment not indicated

Patients who start treatment would appear in the 'adhering' group and would contribute to the adherence rate. If these patients subsequently stop taking their medication, they will appropriately appear in the non-adherence group as further review / discussion would be warranted.

d) Timescales used to classify persistence.

Initially all patients requiring a review were separated as follows (Table 1):

Table 1 Original timescales used to classify persistence.

Patients for priority review	Last prescription was 0 – 9 months ago
Patient for next review	Last prescription was 9 – 18 months ago

Recognising that there are significant differences between the time off treatment between Denosumab and other AOMs, the adherence review timescales were modified during the pilot to provide a closer match to typical medication issue schedules, with Denosumab treatment being separated from other AOMs.

The final version of the tool separated patients as follows (Table 2) (whilst the categories are split into months for ease of display on the reporting tools, the search criteria used by the tool is based on days and these are provided below):

Table 2 Final timescales used to classify persistence.

	Latest medication type		
	Denosumab	Other AOM*	Category
Last prescription was:	0 – 4 months (0 – 122 days)	0 – 3 months (0 – 91 days)	Adhering
	4– 6 months (123 – 183 days)		Adhering – bloods / injection due soon
	6 – 24 months (184 – 730 days)	3 – 24 months (92 – 730 days)	Patients for priority review: ceased medication in last 2 years
	24 – 36 months (731 – 1096 days)	24 – 36 months (731 – 1096 days)	Patients for next review: ceased medication 2 – 3 years ago
	36+ months (1097+ days)	36+ months (1097+ days)	Patients for review: ceased medication over 3 years ago

*includes patients on Zoledronic Acid whose latest prescription was over a year ago

The rationale for separating the two groups of medication is Denosumab is given on a 6-monthly basis, with a blood test required before each injection. Due to the importance of the blood test, it was agreed by the project team to incorporate a recall function into the tool to identify patients who are due their next blood test up to 8 weeks before their next injection due date. Other AOMs are often taken on a daily or weekly basis, and prescriptions are issued on a monthly or 3-monthly basis. As such these patients warrant an earlier review time for potential non-adherence.

e) Summary sheet supporting information for decision making.

As well as providing the number of patients for review in each cateory, the summary sheet provides additional useful information about the patient cohort. The sheet was updated during the pilot to improve the usefulness of it to practices.

The original version provided the following additional information (Table 3):

Table 3 Original additional information added to practice summary sheet.

Osteoporosis diagnosis	QOF fragility fracture coding
• Osteoporosis diagnosis coded • Osteoporosis diagnosis not coded • Osteoporosis prevalence per 1000 patients	• QOF fragility fracture coded • QOF fragility fracture not coded

This information can contribute towards the maintenance of the QOF osteoporosis register. The final version of the tool continued to provide this information, as well as the following (Table 4):

Table 4 Final additional information added to practice summary sheet.

Exclusion from adherence analysis	Review outcomes in the last 12 months
• Palliative care / chemotherapy • Bisphosphonate holiday in the last 24 months • Zoledronic Acid in the last 12 months • Outcome of review was to stop medication / treatment not indicated**	• Osteoporosis treatment changed • Osteoporosis treatment stopped • Osteoporosis treatment declined • Osteoporosis treatment not indicated • Osteoporosis treatment started

**The most recent recorded date for an outcome or review is used and so an outcome of stopping medication or treatment not indicated within the previous 12 months is ignored if a more recent treatment review or outcome is recorded.

An example summary sheet from the final tool is provided in Appendix 1.

3.2 Reporting template

The reporting template has been designed as a supportive aid for clinicians undertaking the osteoporosis medication reviews, with the template being pre-populated from the GP practice system. The information inputted into the template is coded back into the practice system, thereby avoiding the need for duplicate data entry.

Some minor additions were made to the template during the pilot, with the final version providing the following information:

a) Background information

Relevant diagnoses	- Fracture - Fragility fracture - Osteoporosis - Latest palliative care or care cancer pathway
Risks	- Frailty score - Frailty stage - Fall - Recurrent or unexplained fall
Investigations	- eGFR - Calcium - Vitamin D - Estimated creatinine clearance
Relevant medication plus	- Anti-osteoporosis medication: contraindications - Anti-osteoporosis medication: adverse reaction - Over the counter Vitamin D

b) Outcomes

An outcomes section was developed for use during the medication review, for clinicians to record the outcome:

- Medication management plan
- Outcomes from review:
  - treatment started
  - changed
  - stopped
  - not indicated
  - declined
- Diet, e.g. calcium intake
- Bisphosphonate holiday
- Referral, e.g. DXA scan; GP for medication review; osteoporosis specialist

c) DXA results

The DXA results section records the DXA scan results for hip and spine, including T score and if the result was normal, osteopenic or osteoporotic.

3.3 Quality improvement resources

Quality improvement is a core component of this project. It is important for practices to understand why patients are no longer adhering to their medication, and why this is not being picked up so that practice processes can be adapted in order to prevent this recurring in the future.

The structured methodology used is very similar to that used with the PINCER intervention[1], and is therefore very familiar to primary care pharmacists. It comprises three core quality improvement principles:

1. Understand the problem, identify patients at risk due to non-adherence
2. Undertake a structured review of the identified patients
3. Apply change management techniques to identify and implement quality and safety solutions

A quality improvement webinar was held with the participating practices, during which an overview of quality improvement principles and change management techniques was delivered, along with the opportunity to discuss any specific issues that had been highlighted by practices.

Some issues highlighted by practices during the pilot included:

- Inaccurate recording of bisphosphonate holidays
- Denosumab bloods/prescription process
- Housebound / nursing home patients missed Denosumab medication as they were waiting for nursing staff to deliver in their home and did not contact the practice to arrange

4. Project delivery

4.1 Engagement

The pilot ran in GP practices across Oxfordshire, all of which use EMIS. Several practices were invited to participate in the project, with nine agreeing to participate. This subsequently reduced to eight, as one practice withdrew part way through due to the participating pharmacist going on maternity leave. As such, data from practice 7 is not included in the results below.

A launch webinar was held in September 2021, the purpose of which was to introduce the overall aims of the project, discuss the requirements from each practice and to answer any questions from the practices.

4.2 Project delivery in practices

The project ran from September 2021 to December 2022. Practices were asked to run a baseline report in October 2021, and then a further four reports throughout the project. The final reports were run in December 2022. Due to the changes made to the search tool (as outlined in section 3.1) it is not possible to directly compare results from each report throughout the project. Therefore, practices were asked to run the final version of the tool with a retrospective date of August 2021 in order that a direct comparison could be made of adherence rates pre and post project.

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[1] PINCER is a pharmacist-led IT based intervention to reduce medication errors in primary care. It involves searching GP clinical systems using computerised prescribing safety indicators to identify patients at risk from their prescriptions, and then acting to correct the problems with pharmacist support.

Webinars were held throughout the project which gave an opportunity to review the results from the reports, explore issues with running the search, discuss possible changes to the search tool and reporting template, as well as addressing any clinical queries that may have arisen. These meetings also provided the platform for peer-to-peer discussion and support.

5. Measurement

5.1 Methodology

Each practice ran five reports during the pilot phase using the GRASP-Osteoporosis tools and submitted anonymised summary information to the project team for the purposes of evaluation. All practices had signed a Data Processing Agreement prior to the start of the project, which enabled anonymised project data to be shared with the project team.

Each report provided practices with a list of patients who would benefit from a review. Reviews took the form of either a desktop review or a face-to-face/telephone appointment, following which EMIS was updated as appropriate.

5.2 Metrics

At a practice level the following metrics were provided via the summary sheet (Table 5):

Table 5 Practice level metrics

• Practice population
• Audit population

• Osteoporosis diagnosis
  ▪ Coded / not coded
  ▪ Prevalence per 1000 patients

• QOF fragility fracture coding   ▪ Coded / not coded
• Number of exclusions from adherence analysis (as outlined in section 3.1)
• Number of review outcomes in the last 12 months (as outlined in section 3.1)
• Number of patients for review, split by type of medication and timeframe of last prescription (as outlined in section 3.1)

• Non-adherence percentage by
  ▪ Denosumab
  ▪ Other AOM
  ▪ All medications

During the pilot, practices provided the project team with the data included in the summary sheet. Early on it was noted that the data in the summary sheet may not be a complete reflection of the volume of work carried out by practices. This is because patients who had a review undertaken, but no outcome recorded, are intentionally not captured. In these instances practices provided the project team with additional anonymised outcome data.

Four practices also completed an audit of the reviews undertaken, including the type of review (desktop, virtual / face-to-face appointment). This additional information was analysed by the project team to understand the volume of work undertaken and the outcomes delivered.

For future roll-out, practices will continue to report via the summary sheet which provides a rich source of information at a practice level. At a project level, the data required will be the non-adherence percentage for Denosumab, other AOM and all medications. Over time, it will therefore be possible to monitor the trend in non-adherence rates. Depending on the roll-out of the project and requirements at local level, the non-adherence rates could be monitored at GP practice, PCN, or ICB level.

6. Results

6.1 Population and AOM use

 a) Baseline findings

Population and AOM use– baseline August 2021

The median practice population was 11,963 (IQR 7128, 14,181) and ranged from 4,423 to 40,499. This shows the pilot included a wide variety of practice sizes. Given osteoporosis is age related, we then compared the audit population between practices. The audit population included patients aged 50 years and over with a history of fracture and prescription of anti-osteoporosis medication in the last 5 years without the updated exclusion (as listed above). The audit population varied widely from 87 to 457 patients (mean 222 SD (120)). As expected, the audit population was proportional to the practice size (Rs = 0.93, p<0.001) (Figure 3). When the audit population was compared as a percentage of the patient population, this varied almost 2-fold from 1.1% to 2.1% of the practice population (mean 1.8% SD (0.3%)) (Figure 4), suggesting between practices, there was additional variation in audit population beyond the size of the practice, likely reflecting differences in the proportion of older patients.

Figure 3 Relationship between Audit population and Practice Population at baseline.
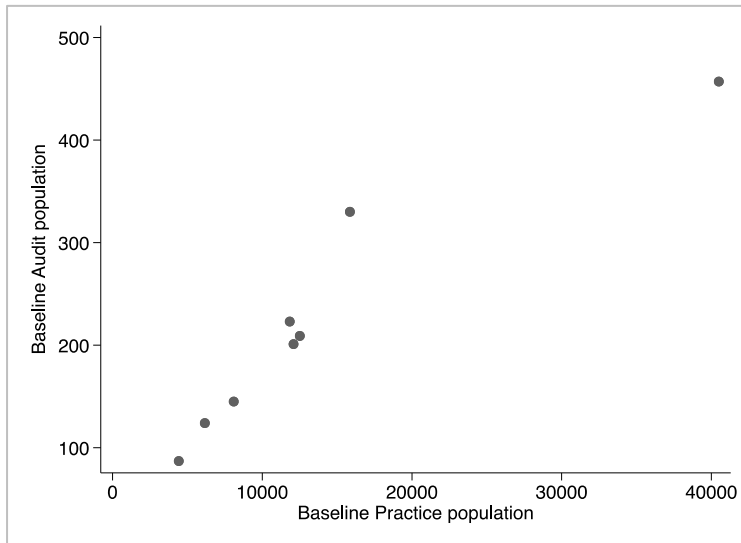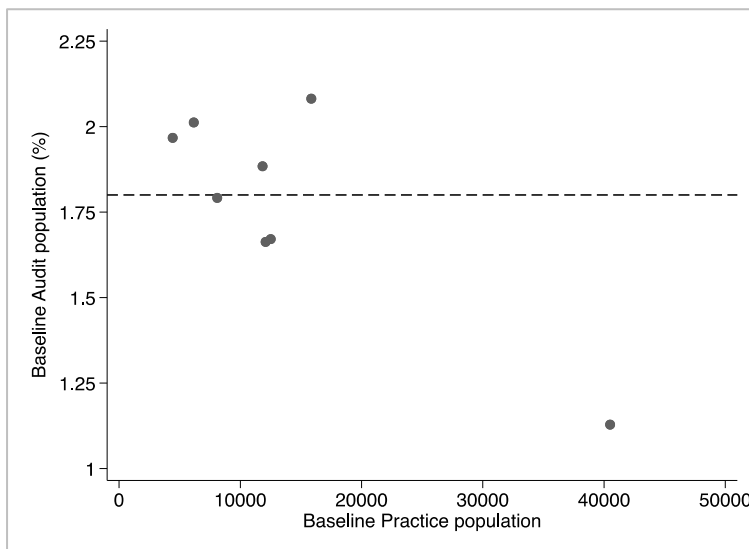

Figure 4 Variation in Audit population by practice size:

Legend: Dotted line represents mean percentage of audit/practice population

Anti-Osteoporosis Medication Use

The number of patients on denosumab at baseline varied between 17 to 98 patients per practice (median 44 (IQR 40,5, 72)). When we compared the number of patients on denosumab to the size of the audit population, the percentage of denosumab users was expected to be relatively constant, reflecting consistent application of local guidelines for when to prescribe AOMs. However, the percentage of denosumab users / audit population varied from 19.5 to 31.5% (mean 24.5% (SD 4.9)) with no relationship to audit size (Figure 5), suggesting significant variation in denosumab prescribing practice between practices.

Figure 5 Variation in the percentage of denosumab users per audit population.
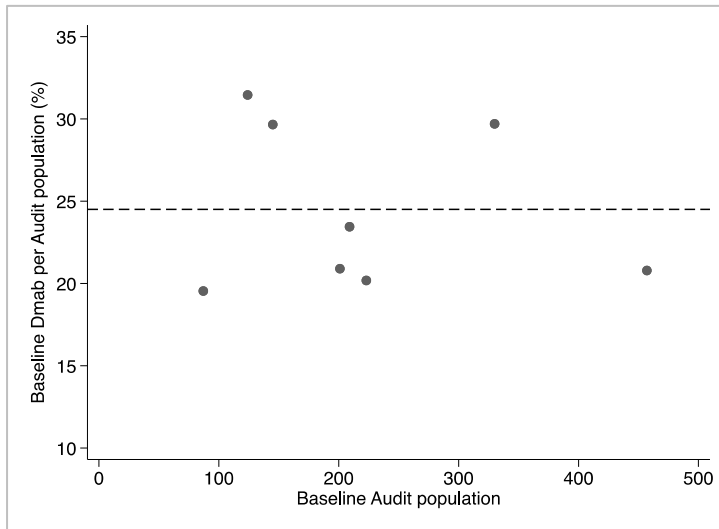
The number of patients on other AOMs varied between 61 and 256 patients per practice (mean 128 SD (61)). When we compared the number of patients on other AOMs to the size of the audit population, the percentage of other AOMs users was expected to be relatively constant, reflecting consistent application of local guidelines for when to prescribe AOMs. However, the percentage of other AOM users / audit population varied from 47.9% to 70.1% of the audit population (mean 59.7% (SD 7.0)) (Figure 6), suggesting significant variation in AOM prescribing practice between practices.

Figure 6 Variation in the percentage of other AOM users per audit population
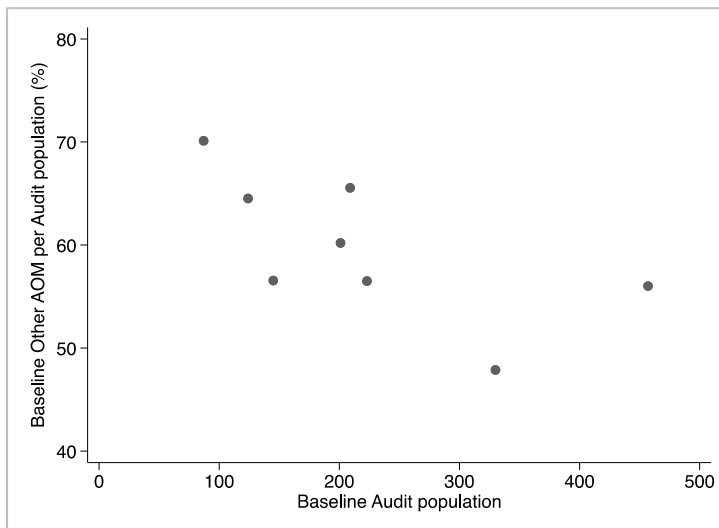
Another way to describe the prescribing patterns between GP practices is to compare the number of denosumab patients to other AOM patients per practice. If prescribing patterns are consistent, we would expect consistent percentage between GP practices. However, the percentage of denosumab users to other AOM users varied over two-fold from 27.9% to 62.0% (median 36.4% (IQR 35.2, 50.6%) (Figure 7).

Figure 7 Variation in the percentage of denosumab vs other AOM users by audit population size
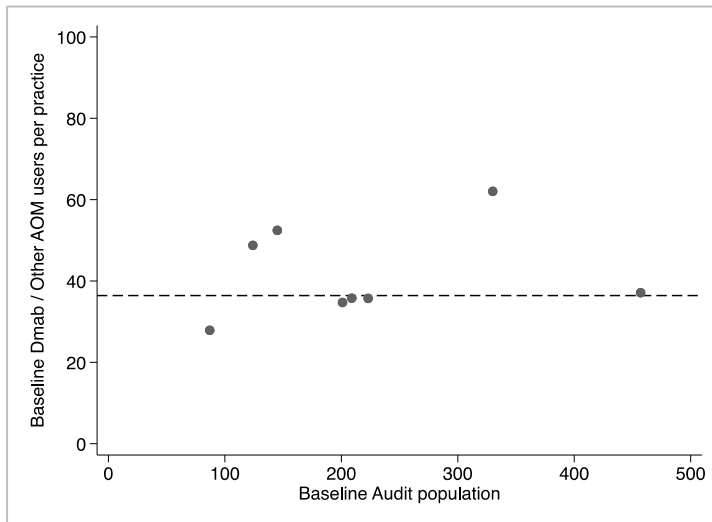
Adherence

We then calculated the baseline Denosumab adherence for each practice. This varied from 58.9% to 91.1% (median 79.3% (IQR 74.3, 86.7)) with no association with number of Denosumab patients per practice (Figure 8). In particular, one practice was an outlier with adherence of less than 60% and also had the fewest patients on denosumab. This suggests that practices with higher volumes of denosumab patients were able to deliver denosumab with high levels of adherence of almost 80%.

Figure 8 Baseline variation in denosumab adherence by number of denosumab patients in the practice.
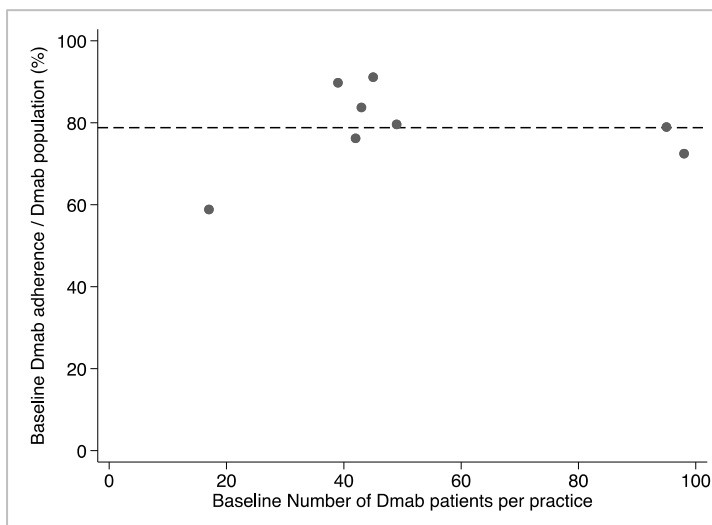
We then calculated the baseline other AOM adherence for each practice. This varied from 19.7% to 67.5% (median 62.2% (IQR 59.4, 66.1)) with no association with number of other AOM patients (Figure 9). In particular, one practice was an outlier with adherence of 20% and also had the fewest patients on other AOM.

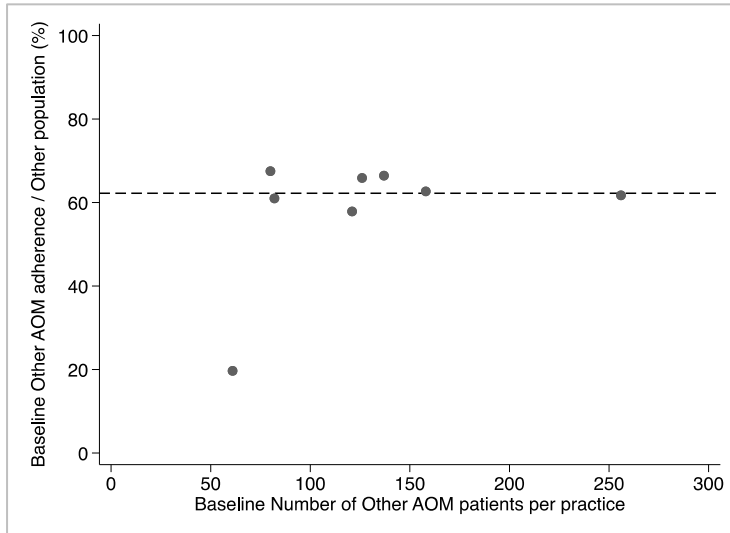*Figure 9 Baseline variation in other AOM adherence by number of other AOM patients*

Comparing the practice level adherence with denosumab vs. other AOM, demonstrated significantly higher adherence with denosumab (Signrank p=0.008) (Figure 10). This finding further supports the use of denosumab in patients at higher fracture risk where the patient harm from non-adherence is greater.

Figure 10 Comparison of baseline adherence to denosumab vs other AOM
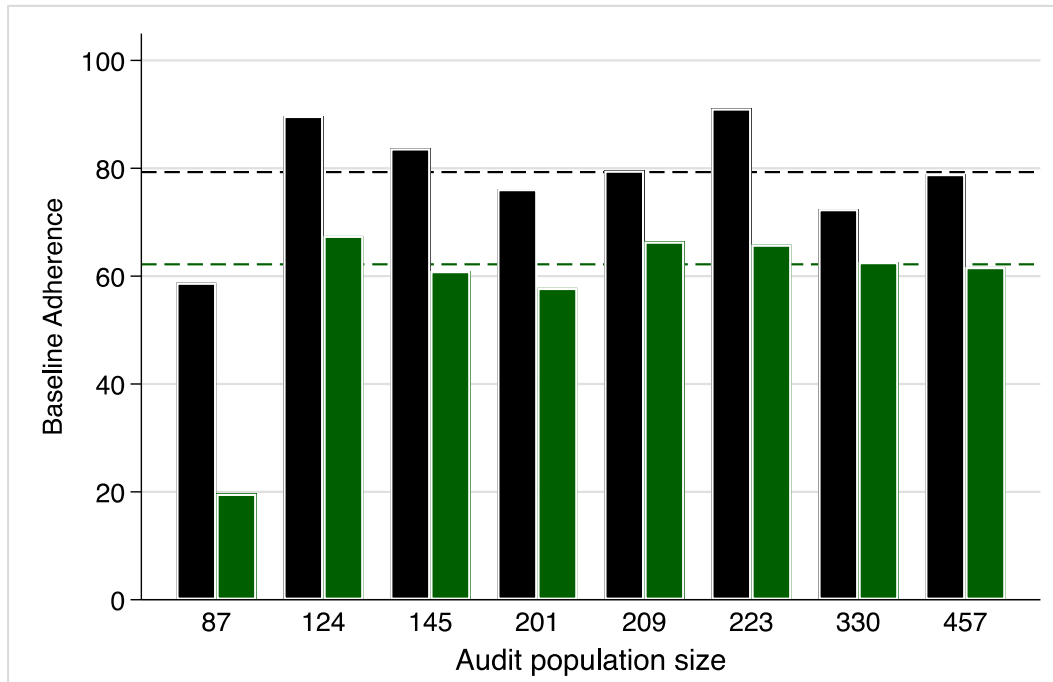
Legend:

Black bars – adherence to denosumab; black dotted line = median Denosumab adherence

Green bars – adherence to other AOMs; green dotted line = median other AOM adherence

b) Changes from August 2021 to December 2022

As outlined above, due to the changes made to the search tool during the pilot it is not possible to directly compare the outputs from all the reports. The results below are based on a comparison of the final report run in December 2022 and a report run with a date of August 2021 (prior to the pilot starting).

Population changes – practice, audit, Denosumab and other AOM users

Over the 18 months, there were 1,504 additional practice patients, 106 additional patients in the audit, 155 patients in the denosumab population and 97 patients in the other AOM population with marked variation between practices (Figure 11). All but one practice increased their audit size (one practice saw a reduction of 2 patients) and all practices had an increase in the number of patients using Denosumab. Two practices had fewer other AOM users, one practice had no change, and five practices had more patients on other AOM.

Figure 11 Absolute change in audit population, denosumab and other AOM users August 2021 to December 2022
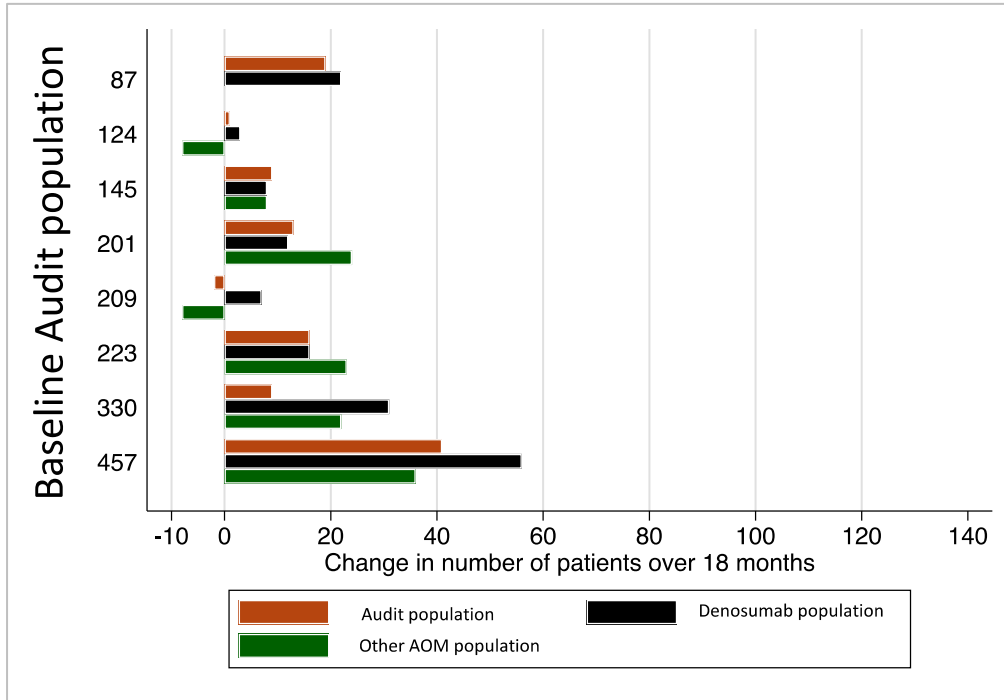
In percentage terms, over 18 months, there were small increases in practice population (+1.4%) with larger increases in audit population (+6.7%), other AOM population (+7.5%) and Denosumab population (+40.6%) (Figure 12). These increases varied between practices and exceeded differences in the audit population suggesting real changes in prescribing patterns.

Figure 12 Percentage change in audit population, denosumab and other AOM users August 2021 to December 2022
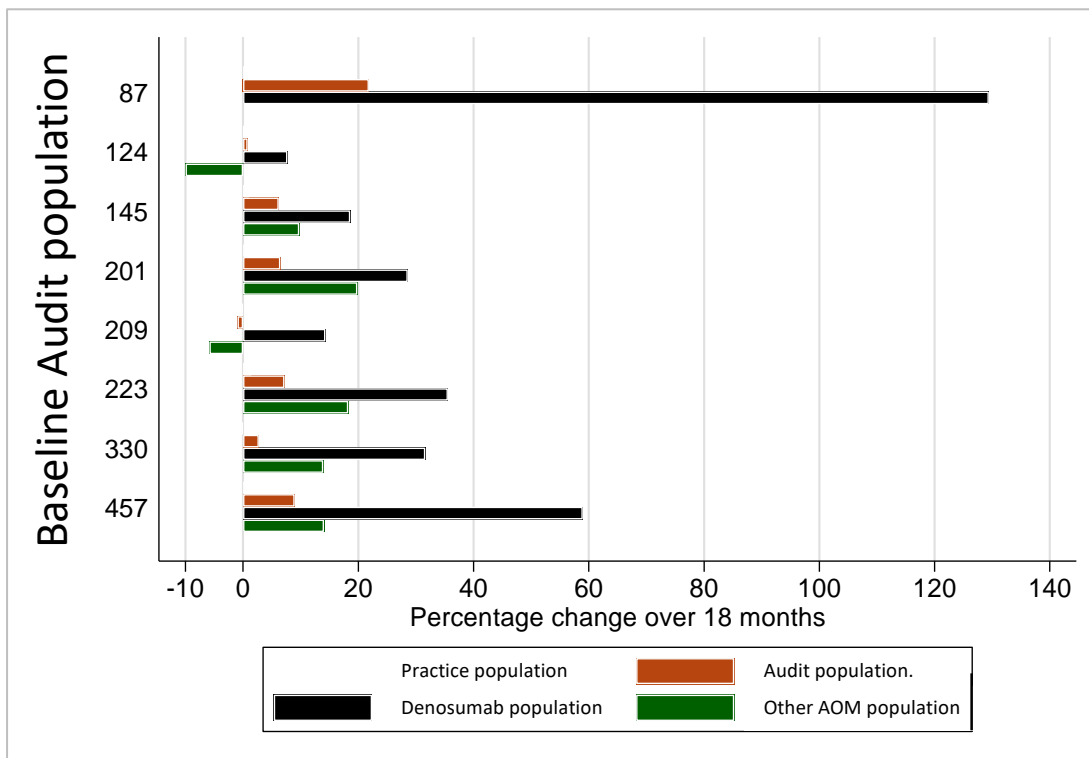
The percentage of AOM use per audit population for Denosumab and other AOM at baseline and then at follow-up 18 months later is shown in Figure 13. Overall, there was an increase of Denosumab to 31.2% of the audit population and a stable other AOM proportion of 59.7%. This figure demonstrates increases in Denosumab compared with other AOM. The increase in Denosumab was greatest in the lowest percentage prescribing practices with smaller changes in the higher prescribing practices suggesting a catchup in prescribing rather than generalized increase across all practices.

Figure 13 Percentage of Denosumab and other AOM patients per audit population at baseline and follow-up 18 months later.
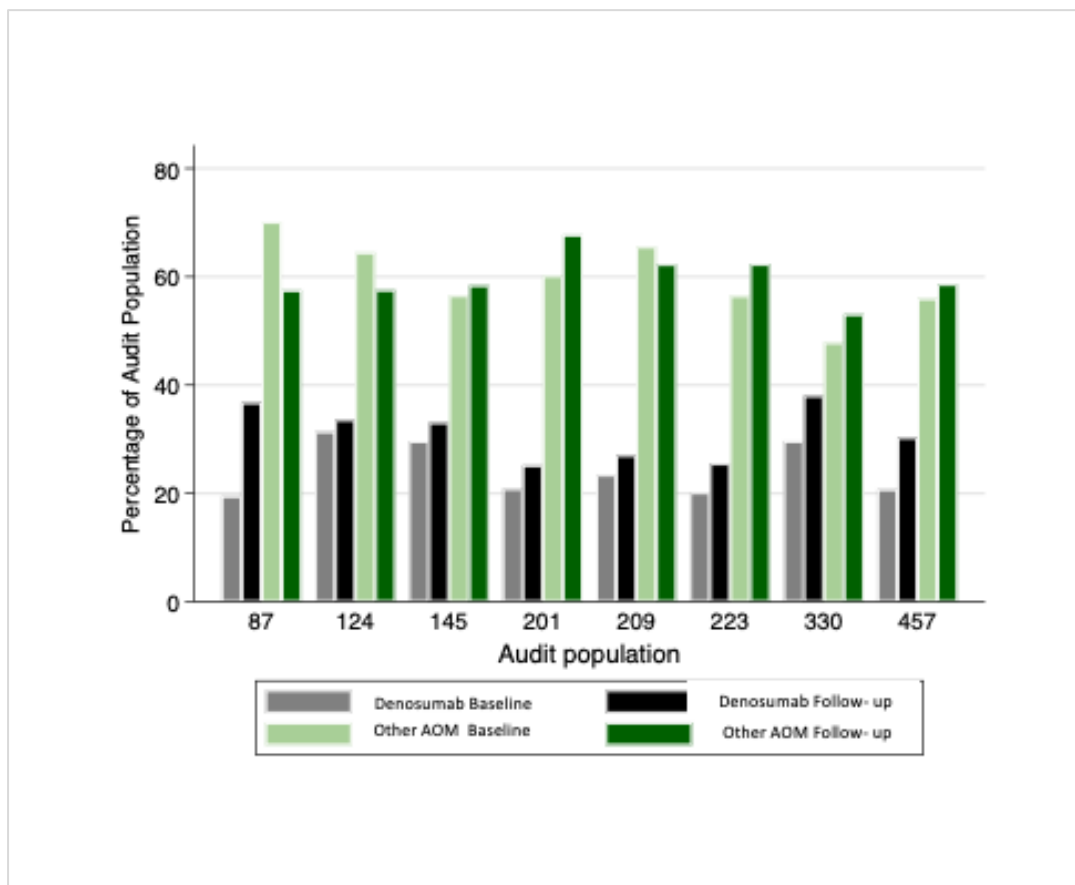
Changes in Adherence

Across all practices, there was small increase Denosumab adherence (baseline median = 79.3% & follow-up = 83.5%) and small increase in adherence to other AOMs (baseline median = 62.2% & follow-up = 65.6%) (Figure 14). However, there was a significant variability in changes in adherence to Denosumab and other AOM between practices, with the practice with the lowest adherence demonstrating the largest gains in adherence for both Denosumab and other AOMs. There were smaller changes in adherence in the other practices, despite the observed increase in both audit population and numbers of patients initiated on Denosumab and other AOMs. This suggests that running the audit increased AOM use with similar or improved rates of adherence.

Figure 14 Baseline vs follow-up adherence to denosumab and other AOM
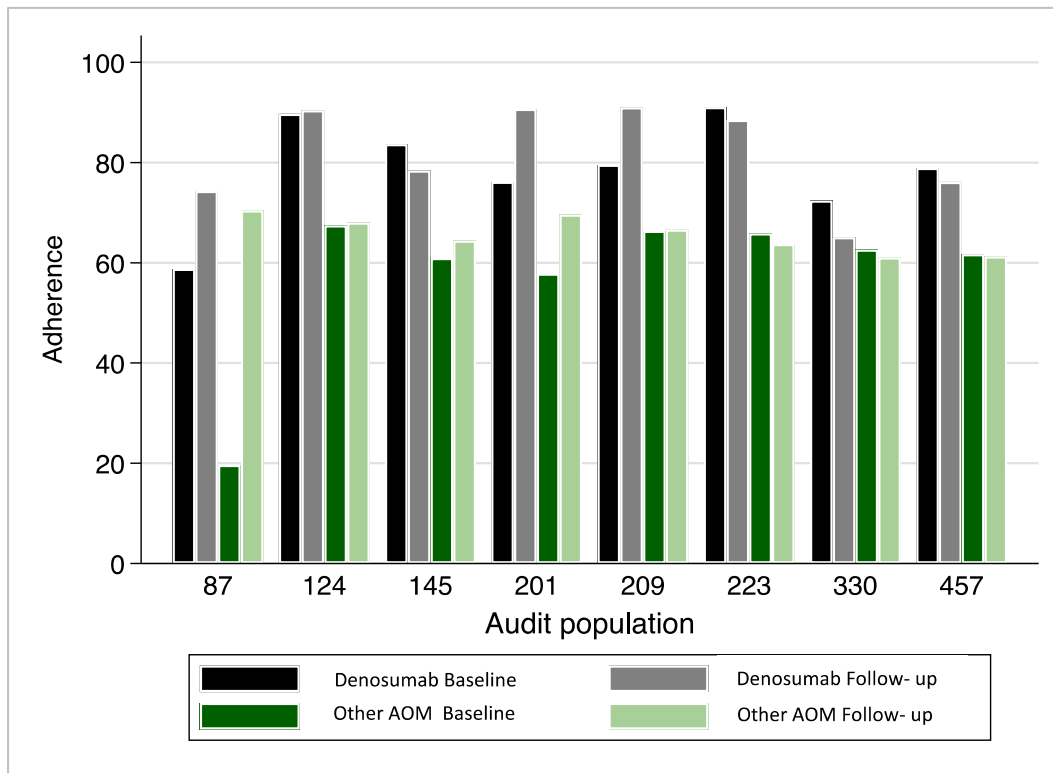
The number of practices achieving >60% and >80% adherence at baseline and follow-up shows all practices achieved 60% adherence to Denosumab and other AOM at the end of the project, but only 50% achieved over 80% adherence to Denosumab with no practices able to achieve this for other AOMs (Table 6). These results demonstrate further work is needed to improve adherence to both Denosumab and other AOMs if use of these agents is to reduce fracture risk by consistently achieving 80% adherence.

Table 6 Number of practices achieving 60% and 80% adherence to denosumab and other AOM at baseline and follow-up

	Adherence ≥60%		Adherence ≥80%	
	Baseline	End of pilot	Baseline	End of pilot
Denosumab	7/8 (88%)	8/8 (100%)	3/8 (38%)	4/8 (50%)
Other AOM	6/8 (75%)	8/8 (100%)	0	0

6.2 Osteoporosis and fragility fracture coding

a) Osteoporosis prevalence

Prevalence per 1000 patients is a common and accepted method of presenting the proportion of people affected by a particular disease and is a useful measure to help understand the potential demands on practices to manage patients. As it is based on patients being diagnosed with a particular condition, the prevalence figure is very much determined by the quality of the coding within individual practices.

The project aimed to improve coding within practices, by identifying patients who may have not been given an appropriate osteoporosis or fragility fracture code.

Overall there was an increase in the osteoporosis prevalence per 1000 patients, from 8.88 in August 2021 to 10.06 in December 2022 (Figure 15).

Figure 15 Changes in osteoporosis coding by practice
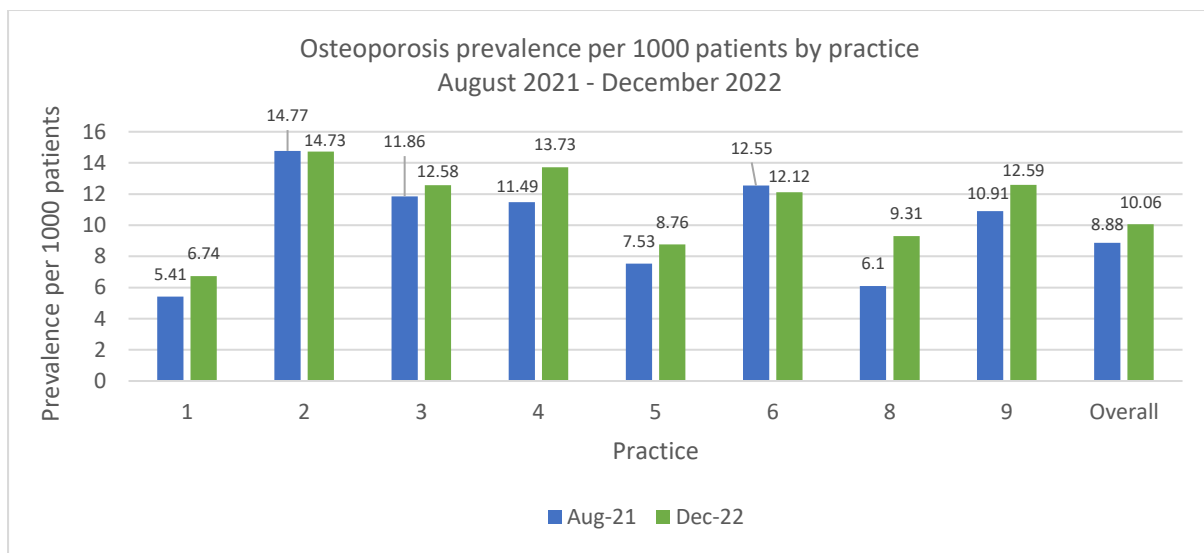
b) Fragility fracture coding

The coding of a fragility fracture is an important component of the QOF indicator related to osteoporosis. The summary sheet provides each practice with the number of patients who have a QOF fragility fracture code and the number of patients who do not have a QOF fragility fracture code but who have features suggestive of a diagnosis of fragility fracture. This provides the practice with an opportunity to improve both their coding and their QOF performance.

Overall, from August 2021 to December 2022 there was a 20.8% increase in the number of patients with a fragility fracture code (Figure 16).

Figure 16 Changes in fragility fracture coding by practice
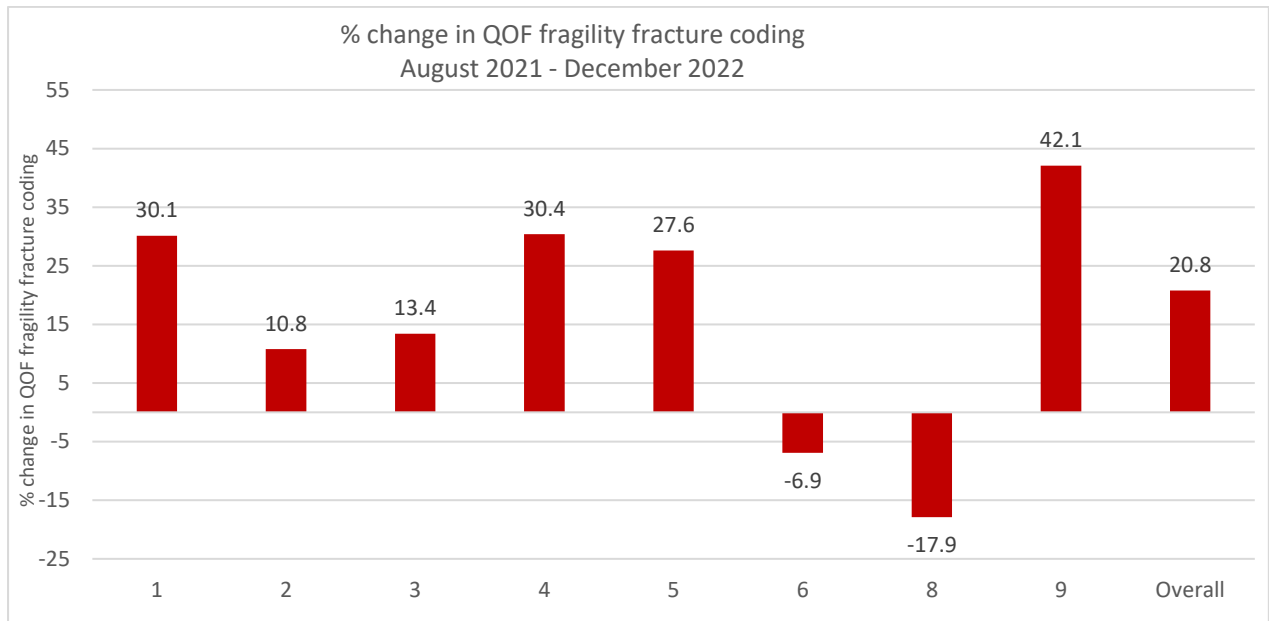
6.3 Outcomes from medication reviews

A review of the anonymised summary information from all practices and the additional mini audits from four practices has enabled the project team to understand the number of reviews undertaken during the pilot, and the outcomes from these reviews.

The patients who were reviewed as part of this project were non-adherent to their treatment regime. All patients who received a medication review with a clinician are considered to have been optimised either through a change to their medication and/or through a patient centred conversation regarding the importance of adherence. Patients who only had a desktop review undertaken were not included in the optimised figure.

a)   Outcomes from the report

A total of 162 reviews (excluding desktop reviews) were undertaken and recorded via the GRASP-Osteoporosis reporting template. The table below provides a breakdown of these by practice.
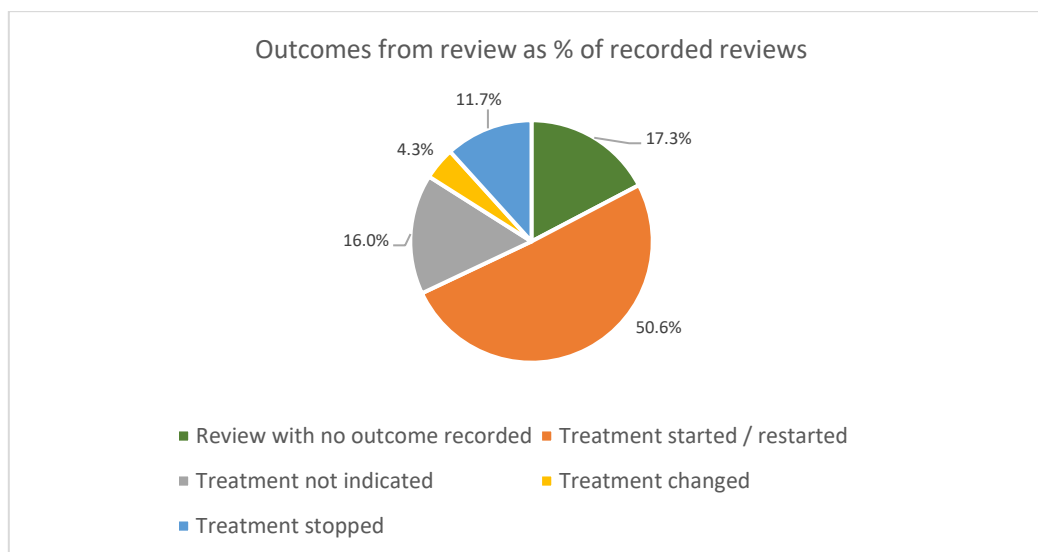
Outcomes	Practice Number								
	1	**2**	**3**	**4**	**5**	**6**	**8**	**9**	**Overall**
Review (with no outcome recorded)	2	3	4	2	4	8	3	2	28
Treatment started / restarted	14	8	10	3	9	19	2	17	82
Treatment not indicated	4	1	4	4	2	11	0	0	26
Treatment changed	2	0	0	0	1	2	1	1	7
Treatment stopped (inc. bisph holiday started)	2	3	4	4	0	3	0	3	19
TOTAL	**24**	**15**	**22**	**13**	**16**	**43**	**6**	**23**	**162**

For the 162 patients with a record of their review, treatment started / restarted was the most common outcome, with 50.6% of reviews leading to this. 17.3%, or 28 patients, had a medication review undertaken but no outcome was recorded. 45 patients had their treatment stopped or coded as not indicated. A change of treatment was the least common outcome, with only 4.3% of reviews leading to this. Overall, 89 patients either started, restarted or changed treatment after running GRASP-Osteoporosis.

The chart below highlights the outcomes as a percentage of the recorded reviews.

Outcomes from review as % of recorded reviews

- Review with no outcome recorded
- Treatment started / restarted
- Treatment not indicated
- Treatment changed
- Treatment stopped

The mini audits undertaken by four of the practices during the pilot provided some additional information. From this analysis, an additional 11 patients were reviewed and an outcome recorded. This means a total of 173 patients were optimised on treatment during the pilot project.

A further 110 desktop reviews were undertaken, but this is not counted towards the number of patients optimised as these reviews may only have resulted in a coding change. Taking into account the number of medication reviews and desktop reviews, the total number of patients screened as part of the pilot was 283.

7. Prevention of future fractures

As discussed above, anti-osteoporosis medication is highly effective at reducing the risk of fragility fracture. If one assumes that the increase in Denosumab and other AOM population was largely due to the GRASP-Osteoporosis project, given the negligible change in patient population, there was a 6.7% increase in the audit population with an additional 252 patients on AOM (155 on Denosumab and 97 on other AOMs) would result in 13 fewer fractures, including 4.8 hip fractures, within the next two years. Preventing these fractures would equate to hospital cost savings of £97,294 over a 2-year period.

When this is extrapolated to a population of 1 million, at baseline the audit population (1.8%) equates to 18,000 adults with 24.5% on denosumab with an adherence of 79.3% (3497 patients) and 59.7% on other AOM with and adherence of 62.2% (6684). The impact of the tool was to increase the audit population by 6.7% (67,000) with 31.2% on denosumab and a mean adherence of 78.3% (16,368) and 59.7% on other AOM with a mean adherence of 65.2% (26,079). This equates to an extra 12,871 patients benefitting from denosumab and 19,395 patients benefitting from other AOMs, a total of 32,266 patients.

An additional 32,266 patients, with an expected 12% risk of another fracture and a conservative 30% reduction in refracture, equates to 1162 avoided fractures (including 465 hip fractures) over 2 years. Using the reduction in hip fractures alone, this equates to a saving of £6,585,795 over 2 years based on a one-year hospital cost of £14,163[x].

Within the Oxford AHSN region, BOB ICB has a population of 1,723,447. Using the figures above, the impact of the tool could be an extra 55,609 patients benefitting from AOM (22,182 patients on denosumab and 33,427 on other AOM). This could equate to 2002 avoided fractures (including 800 hip fractures) over 2 years. Using the reduction in hip fractures alone, this equates to a saving of £11,330,400 over 2 years based a one-year hospital cost of £14,163[x].

8. Conclusions

8.1 Summary of project benefits

The GRASP-Osteoporosis pilot project has delivered proof of concept and real-world use of the bone health tool in primary care:

- The GRASP-Osteoporosis tool has been successfully implemented in 9 practices in Oxfordshire
- The use of the tool was sustained over 18 months in 8 practices that included the challenges from the COVID pandemic
- The tool has developed over 3 iterations to be more focused on detecting non-adherence in the primary care setting and supporting adherence to Denosumab
- Increased the number of patients on Denosumab (+155) and other AOM (+97) reducing inequality of access
- Clinically significant improvements of adherence in lower performing practices for both Denosumab and other AOM

- The practices screened 283 patients, either through a desktop review (60%) or face-to-face/virtual appointment (40%).
- 173 patients have been optimised on treatment, with 89 starting, restarting or changing therapy thereby minimising their risk of future fracture
- A further 45 patients had their treatment stopped or coded as not indicated
- Improved diagnosis coding for osteoporosis (+13.2%) and QOF fragility fracture coding (+20.8%)
- A projected 13 fragility fractures have been avoided in this pilot within the next two years with estimated hospital cost saving of £97,294 over 2 years
- When the results are extrapolated to a population of 1 million, the impact of the tool is an additional 32,266 patients benefitting from AOM. This would equate to 1162 avoided fractures (including 465 hip fractures) over 2 years. Using the reduction in hip fractures alone, this equates to a saving of £6,585,795 over 2 years based on a one-year hospital cost of £14,163[x]
- When the results are extrapolated to BOB ICB population of 1,723,447, the impact of the tool is an additional 55,609 patients benefitting from AOM. This would equate to 2002 avoided fractures (including 800 hip fractures) over 2 years. Using the reduction in hip fractures alone, this equates to a saving of £11,330,400 over 2 years based on a one-year hospital cost of £14,163[x]

Additionally, practices have made sustainable changes to their osteoporosis management pathways, including changing the process for managing patients on Denosumab and the recording of bisphosphonate holidays.

Feedback from practices regarding the tools was very positive, with practices valuing the project and the impact it had on patient management. Practices highlighted that the tool was very useful for identifying patients, and that it flagged patients who may not have been identified through routine practice work. Practices also valued the reporting template as it not only ensured the correct codes were used, but it facilitated more conversations with patients than would have happened routinely. Furthermore, the project provided the clinicians with robust information to take back for discussion with the wider practice team.

A SharePoint site has developed by PRIMIS and the Oxford AHSN to assist with future roll out. It is the resource area for the project providing:

- overview of the project
- overview of the importance of quality improvement and associated techniques
- data processing agreement
- instructions on how to download and use the tools
- links to relevant clinical guidance, quality improvement resources and patient information

8.2 Barriers and lessons learned

The main barriers to the project are time and capacity restraints for the clinicians undertaking the reviews particularly during the COVID pandemic. While there is a real appetite among clinicians to undertake this work, it needs to align with key priorities for practices and ideally those which

provide resource to support the work. The clinicians highlighted they have other targets to meet, including the delivery of the Investment and Impact Fund priorities.

Clinicians felt that if the improvement in adherence rates for patients on osteoporosis medication was a priority, either at a national or local ICB level, resources could be more readily identified to support the work, through improving digital tools to support staff to actively pre-empt patients who have early non-adherence – particularly for patients on Denosumab where practices have different pathways for ensuring the 6-monthly blood tests and injections are carried out. Further work is needed to review practice level differences in the patient pathway for how Denosumab and other AOMs are monitored for adherence to establish good practice examples from which other practices can learn.

The introduction of new tools was not a barrier itself, particularly as the tools are very similar in look and function to other PRIMIS tools that the practices are very familiar with.

The project identified 28 patients who had a medication review, but for whom no outcome of the review was recorded. For future roll-out, the importance of recording outcomes where appropriate will be emphasised, as this will enable practices to more readily see the work they have undertaken.

8.3 Recommendations from the project

The outcomes from this project show that:

1. There is a need for monitoring of patients on anti-osteoporosis medication as non-adherence to treatment is an issue across GP practices and will results in patient harm through avoidable fractures
2. Utilising a search tool that identifies high-risk patients for review, whilst excluding appropriate patients, enables practices to see the true extent of non-adherence within this patient cohort
3. The tool effectively improves diagnostic coding, prescribing practice and patient adherence for patient benefit and reducing inequalities.
4. The impact of the tool extends to reducing hospital emergency admissions and bed day use and costs

As a result of the findings from this project, it is recommended that ICBs consider the use of the GRASP-Osteoporosis tools as a way of improving patient care at a local level and monitoring improvements over time at a system level, and to support piloting the extension of GRASP-Osteoporosis to assist the recall of patients due their next Denosumab dose.

9. Appendix 1

Report Reference Date: *11 November 2022*

Practice Population	

Audit Subset Population	
Patients aged 50+ when they had a fracture AND who have had anti-osteoporosis medication in the L5Y	339

Osteoporosis Diagnosis	No. of patients
Osteoporosis Diagnosis Coded	198
Osteoporosis Diagnosis Not Coded	141
Osteoporosis Prevalence per 1000 patients	*12.59*

QOF Fragility Fracture Coding	No. of patients
QOF Fragility Fracture Coded	199
QOF Fragility Fracture Not Coded	140

Exclusions from Adherence Analysis	No. of patients
Palliative Care or Chemotherapy	21
Biphosphonate holiday in L24M	1
Zoledronic Acid in L12M	5
Outcome of Rx Review was to stop medication	3
Total patients excluded from adherence analysis	30

*Patients with multiple reasons for exclusion will appear in the category that is nearest the top of the table

Rx Review Outcomes in L12M	No. of patients
Osteoporosis treatment changed	1
Osteoporosis treatment stopped	3
Osteoporosis treatment declined	0
Osteoporosis treatment not indicated	0
Osteoporosis treatment started	6
Total Review Outcomes Recorded	10

Adherence Analysis for 309 non-excluded patients	Latest Medication Type				All Medications	
	Denosumab		Other AOM*		Total	What colour category represents
Patient's latest Rx was in:	0M-4M	53	0M-3M	110	163	Adhering
Patient's latest Rx was in:	4M-6M	31			31	Adhering - Bloods/Injection due soon
Patient's latest Rx was in:	6M-24M	37	3M-24M	35	72	Ceased medication in last 2 years
Patient's latest Rx was in:	24M-36M	4	24M-36M	9	13	Ceased medication 2 to 3 years ago
Patient's latest Rx was in:	36M+	4	36M+	26	30	Ceased medication over 3 years ago
TOTAL		129		180	309	
Non Adherence Percentage		35%		39%	37%	

* Includes zoledronic acid patients whose latest Rx was over a year ago

[i] Royal Osteoporosis Society, 2021. Life with Osteoporosis 2021: the untold story

[ii] National Osteoporosis Society, 2016

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[iv] NICE, 2018. NICE Impact Falls and Fragility Fractures

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[viii] Jaleel, A., Saag, K. and Danila, M., 2018. Improving drug adherence in osteoporosis: an update on more recent studies. Therapeutic Advances in Musculoskeletal Disease; 10(7): 141-149

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