Completion of sections 1 – 5 would indicate a '5 criterion audit'.

A completed audit cycle would be indicated if sections 1 – 8 had been attempted.
1. REASON FOR THE AUDIT

Explain why the audit topic was chosen and that as a result of this choice there is the potential for change to be introduced which is relevant to the practice or you as an individual practitioner.

The medical practice I am working in wanted to review the management of osteoporosis patients. During this process it they identified that there was no up-to-date system in place in monitoring, reviewing and stopping oral bisphosphonate treatment within the recommended appropriate time scales. An audit on oral bisphosphonate therapy allowed the practice to benchmark current practice and re-audits allowed the practice to check their progress in improving practice. It will also demonstrate how they have improved patient care by ensuring safe and optimal treatment for this group of patients.

To ensure a clear focus and to streamline the review work, two audits were undertaken in the practice: an audit for patients who had been on oral bisphosphonate therapy for <5 years; and an audit for patients who had been on oral bisphosphonate therapy for 5 years or more. This report is for the audit focusing on patients who had been on oral bisphosphonate therapy for <5 years which I undertook.

Background Clinical Information

- Fragility or osteoporotic fractures can cause severe pain and disability leading to a reduced quality of life and decreased life expectancy. These fractures most often require hospitalisation and contribute significantly to the NHS budget. (2, 4)

- Osteoporosis is characterised by low bone mineral density (BMD), resulting in reduced bone strength and quality and therefore increasing the risk of fracture. (5)

- Bisphosphonates have an affinity for bone mineral and are readily absorbed in hydroxyapatite crystals of the bone, where they inhibit osteoclastic bone reabsorption. This inhibition allows strengthening of the bones and this has been demonstrated in various clinical trial studies. (5) In addition, not only osteoclastic activity is reduced, but bone formation during bisphosphonate treatment is of normal quality.

- The National Osteoporosis Guideline Group (NOGG) recommends the oral bisphosphonates alendronic acid or risedronate as first line treatment for fragility or osteoporotic fractures in most cases. (4) Both of these bone sparing medications are recommended as first line treatment in the local formulary. (3)

- Less than 1% of oral bisphosphonates dose is absorbed in the gastrointestinal tract. Therefore, the recommendation is to take the dose on empty stomach (overnight fast) with a glass of water and a further fast of 30 minutes (60 min for ibandronate), followed by a 30-minute upright position. This reduces the contact with the oesophagus and the risk of gastrointestinal side effects. (5)

- The British National Formulary (BNF) recommends a dose for alendronic acid 10mg daily or 70mg weekly. Risedronate dosage is either 5mg daily or 35mg weekly, while ibandronic acid 150mg is taken monthly. (6)

- However, bisphosphonate treatment can have significant adverse effects (gastrointestinal adverse effects, atypical fractures, osteonecrosis of the jaw) and unnecessary continuation of this medication should be avoided.
NICE Quality standard [QS149] states adults taking alendronate, ibandronate or
risendronate for 5 years need to have a review of treatment to determine their need for
continuous treatment. (1)

NICE CKS Osteoporosis - prevention of fragility fractures (March 2016) recommends
the review for patients for continuing treatment with bisphosphonates after 3-5 years.
Treatment with alendronic acid for patients with a high risk of an osteoporotic fragility
fracture treatment continuation is recommended for up to 10 years, and with
risendronate for up to 7 years. (2)

NICE CKS Osteoporosis as well as NOGG advise treatment continuation for more
than 5 years for patients with risk factors due to age >75 years, previous hip or
vertebral fracture, poor treatment adherence (less than 80% of treatment taken) and
one or more low trauma fracture, as well as current treatment with oral glucocorticoids
of 7.5mg or more per day. (2, 4) A reassessment of fracture risk and bone mineral
density in patients without risk factors, a DEXA (Dual Energy X-ray photon
absorbiometry) scan is recommended when continuing treatment every 3-5 years,
and if stopping treatment every 2 years. (2) NOGG recommends reviewing fracture
risk assessment in 18months to 3 years after treatment discontinuation. (4) Further
NOGG states treatment continuation beyond 10 years to be considered on an
individual basis. (4)

- NICE as well as NOGG recommend a daily calcium intake between 700mg and 1200mg
preferable through diet. In postmenopausal women and men over 50 years of age a daily
dose of 800IU of cholecalciferol is advised. Calcium and vitamin D supplementation is advised
if dietary intake is below the recommended levels. (1, 4) The local formulary recommends for
frail elderly patients (80+years) and confirmed osteoporosis via a DEXA scan to offer calcium
and vitamin D supplementation alongside bone sparing treatment with alendronic acid or
risendronate. (3) This supplementation takes into account impaired absorption due to older age
and therefore can reduce the rate of bone loss. (6)

- Further lifestyle advice includes regular weight bearing exercise, stop smoking and alcohol
consumption within recommended limits. (2, 4)

Reference:
1) National Institute for Health and Care Excellence (NICE). Quality standard [QS149]:
Osteoporosis. [homepage on the Internet]. London: National Institute for Health and Care Excellence;
2017. [updated 2017 April; cited 2017 Aug 13]. Available from:
https://www.nice.org.uk/guidance/qs149
2) National Institute for Health and Care Excellence (NICE). Clinical Knowledge Summaries:
Osteoporosis - prevention of fragility fractures. [homepage on the Internet]. London: National Institute
for Health and Care Excellence; 2016. [updated 2016 March; cited 2017 Aug 13]. Available from:
4) National Osteoporosis Guideline Group (NOGG). Clinical guideline for the prevention and
treatment of osteoporosis. [homepage on the Internet]. Sheffield: National Osteoporosis Guideline
2. AUDIT CRITERIA TO BE MEASURED

Criteria are simple, logical statements used to describe a definable and measurable an item of healthcare, e.g., Patients with type II diabetes should have a fundoscopy every 12-months. See Audit Guidance for examples of criteria if greater understanding is required. Focusing on one or two criteria makes data collection more manageable and the introduction of small changes to practice less challenging. Where available, evidence should be cited in support of criteria e.g., nGMS contract or a clinical guideline. A single criterion is acceptable for appraisal purposes.

Patients on oral bisphosphonate treatment for <5 years:

1. Patients on oral bisphosphonates treatment have a read code [Dual Energy X-ray photon absorptiometry: 58E..11] in their patient file stating the start date and recommended length of treatment. (Alternatively, if no DEXA scan is available: read code 58E..11, add: no DEXA available, indicate reason i.e. while on oral steroids)

2. Patients on oral bisphosphonate treatment have a recall (a reminder to ensure patients receive further medical advice/treatment on matters of clinical significance) in place to review continuation of treatment.

3. Patients on oral bisphosphonate treatment have been prescribed the appropriate daily/weekly/monthly dose of oral bisphosphonates.

4. Patients on oral bisphosphonate treatment are prescribed calcium and vitamin D supplementation (or have a record of the treatment being offered and refused).

5. Patients on oral bisphosphonate treatment if prescribed calcium and vitamin D, are prescribed the correct dose of calcium and vitamin D as per NICE and NOGG guidance.

Consider the number of criteria you select and condense these where possible. It can also strengthen the quality of criteria to include a timeline e.g., for criteria 2 above, patients on oral bisphosphonate treatment have a recall every 12 months.

3. STANDARDS SET

An audit standard describes the level of care to be achieved for any particular criterion eg, 90% of Patients with type II diabetes should have a fundoscopy every 12-months. Standard levels may be
influenced by the target levels contained in the nGMS contract or by discussing and agreeing the desired or ideal level of care with colleagues. State how long you estimate it will take you to reach your chosen standard(s) e.g. 3 months.

Patients on oral bisphosphonate treatment for <5 years:

1. 75% of patients on oral bisphosphonate treatment have a read code [Dual Energy X-ray photon absorbtimetry: 58E..11] in their patient file stating the start date and recommended length of treatment. (Alternatively, if no DEXA scan is available: read code 58E..11, add: no DEXA available, indicate reason i.e. while on oral steroids)

2. 75% of patients on oral bisphosphonate treatment have a recall in place to review continuation of treatment.

3. 100% of patients on oral bisphosphonate treatment have been prescribed the appropriate daily/ weekly/ monthly dose of bisphosphonates.

4. 75% of patients on oral bisphosphonate treatment are prescribed calcium and vitamin D supplementation (or have a record of the treatment being offered and refused).

5. 90% of patients on oral bisphosphonate treatment if prescribed calcium and vitamin D, are prescribed the correct dose of calcium and vitamin D as per NICE and NOGG guidance.

The estimate time to reach these standards should be achieved within 3 months.

The percentages of the standards were agreed with the lead GP. As there are currently no processes in place for monitoring and reviewing patients on oral bisphosphonate treatment, these were achievable standards and seen as able to work towards these goals.

You can include here also how you selected the standard to applied e.g. reference to a local or national guideline. Remember to link your standards to the criteria and set realistic standards i.e. is 100% realistically achievable.

4. PREPARATION AND PLANNING

Explain briefly who was involved in discussing and planning the audit, how the data were identified, collected, analysed, and disseminated and who gave you assistance at any stage of the project, e.g. with a literature review or with collecting or analysing data if this was required. Teamwork is essential to audit and evidence of this should be provided in the report.

First of all, I had a discussion with the GP who was leading on this project in the practice. We reviewed the current evidence for initiation, management and review of oral bisphosphonate treatment (as outlined in Section1). The GP approached a rheumatologist consultant to discuss further and to
seek advice on how best to manage patients being prescribed oral bisphosphonates for more than 5 years. The consultant advised that ALL patients should be reviewed and referred for a DEXA scan after 5 years of treatment. Depending on the outcome of the scan and assessment of the patient a recommendation for continuation of treatment can be made.

On discussion with the lead GP it was agreed to focus on ensuring correct coding after a DEXA scan, highlighting the recommended treatment length and follow up procedures were recorded. When reviewing the evidence for oral biphosphonate treatment I highlighted the importance of ensuring that every patient receives the appropriate dose of biphosphonate and calcium and vitamin D supplementation. In addition to aid medication reviews a record of the treatment for supplementation being offered and a refusal should be noted. For patients not offered or received a DEXA scan an addition to the read code to highlight no DEXA scan available as agreed but including recommended treatment length and follow up procedures.

On 11th October 2017 an initial search by the practice manager on the electronic patient records system (VISION) revealed that over the last 10 years, 360 patients were/are prescribed oral bisphosphonate therapy.

For my audit, the search was then refined to only identify patients who had been prescribed oral bisphosphonates in the practice in the last 5 years and to exclude patients whose repeat prescription was no longer active (i.e. the oral bisphosphonate had been stopped). This identified 183 patients.

However, after accessing the patient records, 81 patients were excluded (e.g. new patient to the practice who had actually been on the oral bisphosphonate for >5y, patients on more than 5 years of treatment). This left a total of 102 patients who were prescribed an oral bisphosphonate for <5y.

On accessing the patient’s records on VISION, I initially searched for read codes for DEXA and/or Osteoporosis. In addition, I accessed Docman to search for a record of a DEXA scan. On analysing the information on the patient’s record, I was able to clarify whether start date and recommended length of treatment have been recorded as per criteria. Further I searched for an active recall on the patients file to determine if a review for continuation of oral biphosphonate treatment is in place. Finally, I checked the therapy section on VISION to gain information if the patient is prescribed the appropriate daily/ weekly/ monthly dose of oral bisphosphonates and calcium and vitamin D supplementation.

On presenting the initial data collection to the lead GP it was decided to set up a separate audit for patients on more than 5 years of treatment. For patient less than 5 years of treatment, data if available for example on docman should be added retrospectively (i.e. start date of treatment, length of treatment) in the appropriate read codes for DEXA and/or osteoporosis. In addition, a recall should be set up to highlight the review of continuation of treatment, specifying a date for the review. For patients were no DEXA is available, data on start date of treatment, reason for treatment (i.e. oral steroid treatment), length of recommended treatment (i.e. ‘while on oral steroids’, review after 5 years) should be added in the read code for DEXA and/or osteopenia.

For patients on inappropriate dosage for oral biphosphonates an urgent referral to the pharmacist for a review should be made. For inappropriate dosage of calcium and vitamin D an invitation for a Polypharmacy review with the pharmacist should be sent to the patient.

For patients within 2 months of a 5-year oral biphosphonate treatment a referral to the lead GP to arrange a DEXA scan and a discussion on continuation of treatment can take place.
A protocol on how to record findings of a DEXA scan was agreed with the lead GP.

The data collection sheet was created and tested. On discussion with the tutor the data collection sheet was refined to ensure all patients receiving oral biphosphonate treatment were captured in the search.

5. DATA COLLECTION 1

Initial data collected should be presented using simple descriptive statistics as part of the text, in table format or using graphs (bar charts, pie charts etc.) Remember to quote actual numbers (n) as well as the percentage (%). There is no need to quote irrelevant data (e.g. age, gender, or past medical history) if it bears no relation to your chosen audit criteria. Compare and contrast your initial data with the standard(s) you set.

- Data was collected between 27.11.2017 - 11.12.2017
- Patient total N = 102
- All patients were prescribed either alendronic acid or risedronate (i.e. no patients were prescribed ibandronate or zolendronic acid)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Standard set</th>
<th>Result achieved (number and %)</th>
<th>Standard reached</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75%</td>
<td>43 (42%)</td>
<td>no</td>
</tr>
<tr>
<td>2</td>
<td>75%</td>
<td>40 (39%)</td>
<td>no</td>
</tr>
<tr>
<td>3</td>
<td>100%</td>
<td>102 (100%)</td>
<td>yes</td>
</tr>
<tr>
<td>4</td>
<td>75%</td>
<td>100 (98%)</td>
<td>yes</td>
</tr>
<tr>
<td>5</td>
<td>90%</td>
<td>98 (96%)</td>
<td>yes</td>
</tr>
</tbody>
</table>

The medical practice failed to meet two out of five set standards.
6. REASON FOR THE AUDIT

The essence of audit is to change practice in order to improve patient care and services. This section should adequately describe any change(s) that was discussed, agreed and introduced by you. The role of others in this process should also be described. An example of the change introduced should be attached in evidence as an appendix to the report, where this is possible e.g. a new or amended protocol or flow chart, or a letter that is sent to a group of patients inviting them in for a review.

The initial data collection revealed although patients are attending for a DEXA scan and are initiated on bone sparing treatment, the review of the management of their treatment is not consistent documented. In 61% of patients no recall is in place and no clear documented length of treatment is recorded in 58% of patients. This bears the risk of extended treatment without a review of treatment after 5 years.

On discussion with the GP the following recommendation was developed and shared within the medical practice.

Patients after attending a DEXA scan will have their records updated with the following information:

- Read code: Dual Energy X-ray photon absorbiometry: 58E..11

Addition of information in the notes section:

- Length of treatment (as per consultant letter)
- Any further action required (i.e. rescan)
- Record if recommendation for Calcium and vitamin D supplementation is advised (if applicable record of declined supplementation by patient)
- Recall for DEXA in x years added (as per consultant letter)
- Read code: Osteoporosis as per consultant letter

Patients starting on oral biphosphonates without prior DEXA scan will have their records updated with the following information:

- Read code: Dual Energy X-ray photon absorbiometry: 58E..11

Addition of information in the notes section:

- No DEXA scan available, state reason for oral biphosphonate treatment
- Length of treatment (i.e. ‘while on oral steroid treatment’)
- Any further action required (i.e. rescan)
- Record if recommendation for Calcium and vitamin D supplementation is advised (if applicable record of declined supplementation by patient)
- Recall for DEXA in 5 years added
- Read code: Osteopenia
Due to adding a recall for DEXA scan a regular search for patients for review of their oral biphosphonate treatment can be implemented. On discussion with the practice manager a process will be implemented to actively search for patients on a recall for a DEXA scan. The chronic disease administrator will conduct a search on DEXA recalls in the first month of every quarter of the year. The patients will be reviewed by a GP and if appropriate contacted, invited and referred to receive a follow up DEXA scan.

7. DATA COLLECTION 2

Presentation of data should be as Data One. In this section, compare and contrast the results of the second data collection with data collection one and the standard(s) you originally set. Has your standard been met or surpassed? If not, comment on why you think that is the case.

- Data was collected between 15.01 – 30.01.18
- Patient total N = 100
- 2 patients have been transferred to a different medical practice.
- All patients were prescribed either alendronic acid or risedronate (i.e. no patients were prescribed ibandronate or zolendronic acid)
- On discussion with the lead GP for standards 4 and 5 the percentage of the standards were increased from 90% to 100%. The achievement for these two standards in the first data collection was high with 98% and 96%. By raising the standards to 100% all patients should be receiving calcium and vitamin D supplementation (or record of refusal) in the correct prescribed dose as per NICE and NOGG.
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Standard set</th>
<th>Result achieved (number and %)</th>
<th>Standard reached</th>
<th>Change to data collection 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Have a read code [Dual Energy X-ray photon absorbtiometry: 58E.00] in their patient file stating the start date of oral bisphosphonate treatment and recommended length of treatment</td>
<td>75%</td>
<td>100 (100%)</td>
<td>yes</td>
<td>+ 58%</td>
</tr>
<tr>
<td>2 Have a recall in place to review continuation of treatment after 5 years</td>
<td>75%</td>
<td>100 (100%)</td>
<td>yes</td>
<td>+61%</td>
</tr>
<tr>
<td>3 Are prescribed the correct dose of oral biphosphonate (as per BNF)</td>
<td>100%</td>
<td>100 (100%)</td>
<td>yes</td>
<td>0</td>
</tr>
<tr>
<td>4 Are prescribed calcium and vitamin D supplementation (or have a record of the treatment being offered and refused)</td>
<td>100%</td>
<td>100 (100%)</td>
<td>yes</td>
<td>+2%</td>
</tr>
<tr>
<td>5 If they are prescribed calcium and vitamin D, are prescribed the correct dose (as per NICE and NOGG).</td>
<td>100%</td>
<td>99 (99%)</td>
<td>no</td>
<td>+3%</td>
</tr>
</tbody>
</table>

The medical practice failed to meet one out of five set standards.

8. CONCLUSIONS

The final section should briefly and simply summarise what the audit achieved, and what were the main learning points gained from this exercise. In doing this, the benefits achieved through the audit should be discussed along with any problems encountered with the process or findings. Some thought should also be given as to whether the audit will be repeated in future and if so when.

The audit highlighted that all patients on oral biphosphonate treatment were prescribed an appropriate dose of alendronic acid or risedronate, and most patients after the first data collection were prescribed appropriate doses of calcium and vitamin D supplementation.

The audit highlighted the inconsistency in documentation for patients in their review and management of oral biphosphonate treatment. But it also highlighted the risks of missing opportunities in reviewing patients after more than 5 years of treatment and considering discontinuation of treatment. This therefore can increase the risk for adverse effects in these patients.

The learning points from this audit are to ensure and achieve a consistent approach in recording treatment duration and follow up for oral bisphospanate treatment. By discussing and providing a recommendation on recording and documenting oral biphosphonate treatment a consistent approach was achieved. This therefore allows practice staff to be involved in recalling patients and reducing the workload for GPs. In addition, patients will benefit in receiving regular reviews and thus reducing the risks of adverse effects. The medical practice staff was engaged in the process and enthusiastic in implementation of change.

The medical practice has a high number of elderly patients and this resulted in a high volume of patient data and therefore making this audit a time-consuming process. For future audits on osteoporosis management the inclusion of the read codes 58E..11 (as stated above in the
recommendations) in the data collection allows the comparison of patient data with and without the read codes and potentially can reduce the number of patients needing to be assessed.

To follow up on implementation of the changes introduced, the audit will be repeated in 12 months’ time.