UNIVERSITY OF MANCHESTER NATIONAL PRIMARY CARE RESEARCH AND DEVELOPMENT CENTRE AND UNIVERSITY OF YORK HEALTH ECONOMICS CONSORTIUM (NICE EXTERNAL CONTRACTOR)

Development feedback report on piloted indicator(s)

QOF indicator area: Osteoporosis

Pilot period: 1st October 2010 – 31st March 2011

Potential output: Recommendations for NICE Menu

Contents

Piloted indicator(s)

1. The practice can produce a register of patients (men and women) aged ≥50-74 years with a fragility fracture, with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010).
2. The percentage of men and women aged ≥50-74 years, with fragility fracture, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.
3. The percentage of (men and women) aged ≥75 with fragility fracture, who are currently treated with an appropriate bone-sparing agent.
4. The percentage of (men and women) aged ≥50-74 years with fragility fracture, a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

Number of practices participating in the pilot: 30

Number of practices withdrawing from the pilot: 3[1]

Number of practices where staff were interviewed: 29

Assessment of clarity, reliability, acceptability, feasibility, and implementation

Clarity

Indicator wording as stated, rated as clear and unambiguous by the RAM panel.

The NHS IC has confirmed that they have been able to write Business Rules (and/or an Extraction Specification)

Indicator	Feasibility	Reliability	Implementation
Whole set	3	4	3

[1] 3 practices withdrew late in the pilot. 2 were still able to give comments about the indicators.

Reliability[2] and Feasibility

Comments	Response	NHSIC Summary
General Document issued by P Amos has re-defined this indicator. See Appendix C	Appreciate comments on the recommendations	The implementation of the recommendations in the Appendix will require a major re-write of the piloted business rules.
The recommended option doesn't insist on the use of 'fragility fracture' read codes.		
Do we exclude people who already have a diagnosis of osteoporosis?		
There are concerns around patient compliance with the taking of bone sparing agent.		
If this indicator is for men and women the wording only needs to specify patients – clarity can be in the guidance		

Acceptability

General comments

All except one practice were very positive about this indicator set. The less positive practice was ambivalent because the GP felt *"this is good practice, we've had the DES and shouldn't we be doing this anyway?"*

Specific comments indicator 1 (≥50-74 register/DXA)

The starting age and the inclusion of both men and women were both felt appropriate.

Three practices felt that QOF guidance would need to include pathways for men to ensure that all practices were doing the same (since this would be a relatively new practice and beyond the recent Directly Enhanced Service).

Specific comments indicator 2 (+bone sparing)

[2] NHSIC provide guidance on whether the piloted indicators are, from a business rule perspective, suitable to become 'live' indicators. A notional 'scoring' system is used:

1. No problems to implement in live with other indicators
2. Minor re-work before it can go live with other indicators
3. Major re-work but do-able without recourse to anyone outside of the process
4. Major considerations to be made before the indicator can go live - possibly need to speak to CFH / suppliers
5. Not feasible

The main comment about bone sparing agents was their variable tolerability. Practices suggested that this could be addressed through lower thresholds.

Specific comments indicator 3 (≥75 = bone sparing)

As above, the main comment about bone sparing agents was their variable tolerability. Practices suggested that this could be addressed through lower thresholds.

There were no other acceptability issues with this indicator.

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

Almost all practices said that this was routine for all patients on bone sparing agents over the age of 50 and felt that inclusion in QOF *"would be good because it would make you sit down and do it 100% of the time since at the moment we don't have a protocol and if this was in QOF we would."*

There were however concerns expressed in four practices about the tolerability of calcium and vitamin D preparations: *"Only about 30% of my patients actually persist in taking it".*

Only one practice tried to assess dietary intake before prescribing.

It was also emphasised that calcium and vitamin D was routine for all patients on bone sparing agents aged over 75 as well.

Acceptability recommendation for indicator 1(≥50-74 register/DXA)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of acceptability* that would preclude the indicator from being recommended for publication on the NICE menu of indicators.

Acceptability recommendation for indicator 2 (+bone sparing)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of acceptability* that would preclude the indicator from being recommended for publication on the NICE menu of indicators.

Acceptability recommendation for indicator 3 (≥75 = bone sparing)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of acceptability* that would preclude the indicator from being recommended for publication on the NICE menu of indicators.

Acceptability recommendation for indicator 4 (≥50-74 with calcium and vitamin D)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of acceptability* that would preclude the indicator from being recommended for publication on the NICE menu of indicators

Implementation

Assessment of piloting achievement

The practice can produce a register of patients (men and women) aged ≥50-74 years with a fragility fracture, with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010).

Register 1a for *fragility* fracture;

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Total number of patients on register	1	0	
Mean number of patients on register	0.0625	0	

Register 1b for fracture;

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Total number of patients on register	7	2	
Mean number of patients on register	0.4375	0.1111	

The time frames for OP indicators 1 was 12 months for the baseline and 6 months for the final upload.

The time frames for OP indicators 2 and 3 were 12 months for the baseline and 6 months for the final upload.

1a.Osteo Pilot 3 Indicator 1a: The practice can produce a register of patients (men and women) aged ≥50-74 years with a **fragility fracture**, with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010).

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Total number of patients on register	0	0	
Mean number of patients on register	0	0	

1b.Osteo Pilot 3 Indicator 1b: The practice can produce a register of patients (men and women) aged ≥50-74 years with a **fracture**, with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010).

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Total number of patients on register	5	0	
Mean number of patients on register	0.3125	0	

Assessment of piloting achievement

The percentage of men and women aged ≥50-74 years, with fragility fracture, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.

2a. Osteo Pilot 3 Indicator 2a: The percentage of men and women aged ≥50-74 years, with **fragility fracture**, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.

	Baseline	Final	Number of practices uploading data at both baseline and final
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[3]	0	0	
Mean practice numerator	0	0	
Mean score[4]	0	0	

2b. Osteo Pilot 3 Indicator 2b; The percentage of men and women aged ≥50-74 years, with a **fracture**, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.

	Baseline	Final	Number of practices uploading data at both baseline and final
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[5]	0.3125 (5)	0	
Mean practice numerator	0.1875 (3)	0	
Mean score[6]	60%	0	

Assessment of piloting achievement

The percentage of (men and women) aged ≥75 with fragility fracture, who are currently treated with an appropriate bone-sparing agent.

[3] The average number of people across practices eligible for inclusion in the indicator population
[4] The average achievement across practices for the indicator
[5] The average number of people across practices eligible for inclusion in the indicator population
[6] The average achievement across practices for the indicator

3a. Osteo Pilot 3 Indicator 3a: The percentage of (men and women) aged ≥75 with **fragility fracture**, who are currently treated with an appropriate bone-sparing agent.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[7]	5.62 (90)	6.67 (120)	
Mean practice numerator	2.50 (40)	3.12 (56)	
Mean score[8]	44.4%	46.7%	

3b. Osteo Pilot 3 Indicator 3b: The percentage of (men and women) aged ≥75 with a **fracture**, who are currently treated with an appropriate bone-sparing agent.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[9]	176.0 (2816)	175.4 (3158)	
Mean practice numerator	39.8 (637)	38.3 (689)	
Mean score[10]	22.6%	21.8%	

Assessment of piloting achievement

The percentage of (men and women) aged ≥50-74 years with fragility fracture, a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with

[7] The average number of people across practices eligible for inclusion in the indicator population
[8] The average achievement across practices for the indicator
[9] The average number of people across practices eligible for inclusion in the indicator population
[10] The average achievement across practices for the indicator

bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

4a. Osteo Pilot 3 Indicator 4a: The percentage of (men and women) aged ≥50-74 years with **fragility fracture**, a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[11]	0	0	
Mean practice numerator	0	0	
Mean score[12]	0	0	

4b. Osteo Pilot 3 Indicator 4b : The percentage of (men and women) aged ≥50-74 years with a **fracture**, a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[13]	0.25 (4)	0	
Mean practice numerator	0.25 (4)	0	

[11] The average number of people across practices eligible for inclusion in the indicator population
[12] The average achievement across practices for the indicator
[13] The average number of people across practices eligible for inclusion in the indicator population

Mean score[14]	100%	0	

Supplementary information

Indicator 5a: The percentage of (men and women) aged ≥75 years with fragility fracture, who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[15]	3.25 (52)	3.88 (70)	
Mean practice numerator	2.81 (45)	3.28 (59)	
Mean score[16]	86.5%	84.3%	

Indicator 5b: The percentage of (men and women) aged ≥75 years with fracture, who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

	Baseline	**Final**	**Number of practices uploading data at both baseline and final**
Population	139561	147152	
Number of practices uploading data	16	18	16
Mean practice denominator[17]	44.0 (704)	44.2 (795)	
Mean practice numerator	35.8 (573)	35.7 (643)	

[14] The average achievement across practices for the indicator
[15] The average number of people across practices eligible for inclusion in the indicator population
[16] The average achievement across practices for the indicator
[17] The average number of people across practices eligible for inclusion in the indicator population

Mean score[18]	81.4%	80.9%	

Summary:

The pilot register was very tightly constructed to include the pilot timeframes, type of fracture and also current OP recorded after the fracture and a DXA scan. This lead to a very small register, which had an impact on subsequent indicator uploads.

The use of bone sparing agents in men and women aged ≥75 years was relatively common pre pilot.

The use of calcium and vitamin D supplements in men and women aged ≥75 years was very common pre pilot (over 80% and in line with the qualitative data).

Changes in practice organisation

Specific comments indicator 1 (≥50-74 register/DXA)

The only recurring negative comment from a minority of practices was the change in thinking and coding required to code *fragility fractures* since this is relatively new practice and in a minority of practices, clinicians disagreed over the definition of a fragility fracture. *"We struggled at first with coding fragility fractures, but the practice manager created a register from notes and a system for reviewing casualty forms that helped."*

Specific comments indicator 2 (+bone sparing)

None

Specific comments indicator 3 (≥75 = bone sparing)

None

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

None

Resource utilisation and costs

Specific comments indicator 1 (≥50-74 register/DXA)

Many practices commented that if this indicator becomes part of live QOF, then the waiting times for DXA scans are likely to become very long.

Specific comments indicator 2 (+bone sparing)

There was a concern expressed in two practices that GPs might end up prescribing more expensive but better tolerated monthly preparations in response to this indicator.

Specific comments indicator 3 (≥75 = bone sparing)

None

[18] The average achievement across practices for the indicator

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

None

Barriers to implementation

Specific comments indicator 1 (≥50-74 register/DXA)

All pilot practices had access to DXA scans. Patients found scanning facilities easy to get to in all except one practice (a more rural area).

Specific comments indicator 2 (+bone sparing)

There are drug tolerability issues (see above)

Specific comments indicator 3 (≥75 = bone sparing)

There are drug tolerability issues (see above)

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

There are drug tolerability issues (see above)

Assessment of exception reporting

Specific comments indicator 1 (≥50-74 register/DXA)

A minority of practices commented that younger men may not understand the importance of this indicator.

Specific comments indicator 2 (+bone sparing)

None

Specific comments indicator 3 (≥75 = bone sparing)

A minority of practices commented that people with dementia would probably be exception reported from this indicator.

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

None

Assessment of potential unintended consequences

Specific comments indicator 1 (≥50-74 register/DXA)

None

Specific comments indicator 2 (+bone sparing)

None

Specific comments indicator 3 (≥75 = bone sparing)

None

Specific comments indicator 4 (≥50-74 with calcium and vitamin D)

None

Implementation recommendation for indicator 1(≥50-74 register/DXA)

There are barriers/risks/issues/uncertainties identified from the pilot in terms of implementation that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Implementation recommendation for indicator 2 (+bone sparing)

There are barriers/risks/issues/uncertainties identified from the pilot in terms of implementation that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Implementation recommendation for indicator 3 (≥75 = bone sparing)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of implementation* that would preclude the indicator from being recommended for publication on the NICE menu of indicators.

Implementation recommendation for indicator 4 (≥50-74 with calcium and vitamin D)

There is a high degree of confidence that there are no major barriers/risks/issues/ uncertainties identified from the pilot *in terms of implementation* that would preclude the indicator from being recommended for publication on the NICE menu of indicators.

Assessment of overlap with existing QOF indicators and potential changes to existing QOF indicators

None

Overall recommendation for the complete indicator set

There are barriers/risks/issues/uncertainties identified from the pilot that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Suggested amendments to indicator

- The practice can produce a register of patients aged ≥50-74 years with a fragility fracture, with a diagnosis of osteoporosis confirmed on DXA scan. (i.e. remove the pilot date).
- The percentage of patients aged ≥50-74 years, with fragility fracture, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.
- The percentage of patients aged ≥75 with fragility fracture, who are currently treated with an appropriate bone-sparing agent.

And either add the phrase “who are treated with calcium and vitamin D supplements in the previous 15 months” to indicator 2 and 3 or only put the first 3 indicators (above) forward and include the issue of calcium and vitamin D supplements in the QOF guidance.

If we were to include the additional wording to the indicator , where a patient declines or is intolerant to calcium and vitamin D (as was relatively common from the pilot) then practices will have to exception report against the entire indicator (practices can't exception report against one component of the indicator i.e. the calcium and vitamin D component). This would lead to a very large proportion of the target population being exception reported.

Appendix A: Indicator details

Recommendation(s) presented & prioritised by the Advisory Committee

NICE technology appraisal 161 (Osteoporosis – secondary prevention of osteoporotic fragility fractures in postmenopausal women)	NICE recommendations 1.1 – 1.4
SIGN clinical guideline 71 (Management of Osteoporosis)	SIGN recommendation 6.6.1 To reduce fracture risks at all sites, men with low BMD and /or history of one or more vertebral fractures or one non-vertebral osteoporotic fracture should be treated with oral alendronate (10mg + 500mg +/- 400 IU vitamin D Daily
SIGN clinical guideline 71 (Management of Osteoporosis)	SIGN recommendation 6.5.1 To reduce hip fracture risk, frail elderly women who are housebound should receive oral calcium 1,000-1,2000mg daily + 800 IU vitamin D.

Summary of Committee considerations (taken from the Committee minutes)

The Committee was asked to consider information presented in a briefing note on the topic of secondary prevention of fragility fractures. The Committee noted that it had previously considered this topic for indicator development, including an Equalities Impact Assessment form, but had not made a recommendation to proceed to indicator development due to concerns about the availability of services across the UK, concerns about a potential overlap with an existing Directed Enhanced Service (DES), and concerns that the evidence previously presented was for one specific pharmaceutical agent.

The Committee agreed that there was strong clinical and cost effectiveness evidence to support indicator development in this area.

The NEC advised that indicator development would need to focus on a prospective register of fragility fractures. The Committee agreed that a prospective register would be appropriate.

The Committee considered that there were potential barriers to implementation, such as older people who live in rural areas and who may have to travel long distances for secondary dual energy X-ray scanning (DXA) scanning.

The Committee agreed that indicator development should include both men and women. The appropriate age range should be explored as part of the indicator development process. The Committee agreed that the co-prescribing of calcium and vitamin D supplementation should be considered in indicator development.

NICE technology appraisal 161:	Recommend to progress for development

recommendations 1.1 – 1.4	
SIGN clinical guideline 71: recommendation 6.6.1	Recommend to progress for development

Pre-RAND indicators

1. The practice can produce a register of patients (men and women) aged ≥50 years with a history of fragility fracture (sustained after 1 October 2010)

2. The practice can produce a register of patients (men and women) aged ≥50 years with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010)

3. The percentage of men and women aged ≥50 years in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent

4. The percentage of men and women aged between 65 and 74 years in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent

5. The percentage of (men and women) aged ≥75 with osteoporosis, who are currently treated with an appropriate bone-sparing agent

6. In patients aged ≥50 years (men and women) with a confirmed diagnosis of osteoporosis, confirmed on DXA scan, who are currently treated with bone sparing agents, the percentage of patients who have a record of a medication review in the previous 15 months

7. In patients aged between 65 and 74 (men and women) with a confirmed diagnosis of osteoporosis, confirmed on DXA scan, who are currently treated with bone sparing agents, the percentage of patients who have a record of a medication review in the previous 15 months

8. In patients aged ≥75 (men and women) with osteoporosis who are currently treated with bone sparing agents, the percentage of patients who have a record of a medication review in the previous 15 months

9. In patients aged ≥75 (men and women) with a history of fragility fracture who are currently treated with bone sparing agents, the percentage of patients who have a record of a medication review in the previous 15 months

10. The percentage of (men and women) aged ≥50 years with a confirmed diagnosis of osteoporosis, confirmed on DXA scan, who are treated with bone sparing agents in whom calcium and vitamin D intake has been considered

11. The percentage of (men and women) aged ≥50 years with a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months

12. The percentage of (men and women) aged between 65 and 74 years with a confirmed diagnosis of osteoporosis, confirmed on DXA scan, who are treated with bone sparing agents in whom calcium and vitamin D intake has been considered

13. The percentage of (men and women) aged between 65 and 74 years with a confirmed diagnosis of osteoporosis, confirmed on DXA scan, who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months

14. The percentage of (men and women) aged ≥75 years with a confirmed diagnosis of osteoporosis, who are treated with bone sparing agents in whom calcium and vitamin D intake has been considered

15. The percentage of (men and women) aged ≥75 years with a confirmed diagnosis of osteoporosis, who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months

Final indicators as piloted

1. The practice can produce a register of patients (men and women) aged ≥50-74 years with a fragility fracture, with a diagnosis of osteoporosis confirmed on DXA scan (after 1 October 2010).

2. The percentage of men and women aged ≥50-74 years, with fragility fracture, in whom osteoporosis is confirmed on DXA scan, who are currently treated with an appropriate bone-sparing agent.

3. The percentage of (men and women) aged ≥75 with fragility fracture, who are currently treated with an appropriate bone-sparing agent.

The percentage of (men and women) aged ≥50-74 years with fragility fracture, a confirmed diagnosis of osteoporosis, confirmed on DXA scan , who are treated with bone sparing agents, who are treated with calcium and vitamin D supplements in the previous 15 months.

Appendix B: Secondary Prevention of Osteoporotic Fragility Fractures

Introduction

The NICE QOF Advisory Committee recommended that consideration be given to developing a number of indicators that would identify those patients who would benefit from receiving treatment for secondary prevention of osteoporotic fragility fractures. Having identified those patients, further indicators would identify whether those who might gain benefit had actually received the necessary treatment, assuming they were not excluded from such treatment for any of the agreed exclusion criteria.

During the process of operationalising the indicators for the purposes of the piloting exercise a number of issues have been identified that impact the feasibility of implementing these proposed indicators within GP clinical systems.

The purpose of this paper is to identify the issues, discuss their impact and propose some solutions.

The documented discussion below is a summary of a number of internal workshops and has been informed by the following documents:

- NICE technology appraisal guidance 161 (amended)
- NICE QOF Advisory Committee supporting papers

The committee members are asked to either approve the recommendations made at the end of this paper or choose one of the alternate options

Identification of Issues:

The technical appraisal (T161 amended January 2011) has the following to say about osteoporosis and fragility fracture:

Fragility fracture is the clinically apparent and relevant outcome in osteoporosis (referred to as 'osteoporotic fragility fracture' in the following text). It is often referred to as a low-trauma fracture; that is, a fracture sustained as the result of a force equivalent to the force of a fall from a height equal to, or less than, that of an ordinary chair. In the absence of fracture, osteoporosis is asymptomatic and often remains undiagnosed. Osteoporotic fragility fractures occur most commonly in the vertebrae, hip and wrist, and are associated with substantial disability, pain and reduced quality of life.....

Following the NICE Advisory Committee and RAND process the following indicators were proposed:

- The practice can produce a register of patients (men and women) aged ≥50-74 years with a **fragility fracture**, with a diagnosis of osteoporosis confirmed on DXA scan
- The percentage of (men and women) aged ≥75 with **fragility fracture**, who are currently treated with an appropriate bone-sparing agent

Creation of the register in order to achieve the requirements of the indicator includes identification of the following:

- A record of fragility fracture (clinically apparent osteoporotic fracture)
- A positive DXA scan (T score of -2.5 standard deviations)
- A diagnosis of osteoporosis

From the perspective of extracting this information from the record we only require a record of fragility fracture and a positive DXA scan, as the positive DXA scan confirms the diagnosis of osteoporosis.

The following issues have been identified:

- Ambiguity between NICE guidance within the technical appraisal and the wording of the indicator
- Current clinical practice and the clinical record keeping processes do not fully support the requirements of the register
- Availability of current Read Code terms
- Ambiguity between NICE guidance within the technical appraisal and the wording of the indicator

As stated in 2.1 above the concept of a 'fragility fracture' is based upon a clinical judgement that the fracture is a low impact fracture and therefore secondary to coexistent osteoporosis, however, the indicator for those between the ages of 50 and 74 requires confirmation of osteoporosis.

Therefore it would be possible to have clinically diagnosed a fragility fracture, based upon the definition of a low impact fracture but then to have this diagnosis put in question if the DXA scan does not support osteoporosis. Under these circumstances the best we can assert at the time of the fracture is that the patient has a 'suspect' fragility fracture.

Current clinical practice and the clinical record keeping processes do not fully support the requirements of the register:

The normal sequence of events for a patient who suffers a fracture is as follows*:*

- Patient sustains fracture and is taken to A&E
- Patient has x-ray that confirms fracture
- Fracture is treated
- Patient is admitted or discharged as appropriate

If admitted:

- May undergo DXA scan if suspicion of osteoporosis
- Discharged to home
- GP receives discharge letter with diagnosis of fracture and osteoporosis if present, however, the absence of a diagnosis may

simply imply that it has not been considered or investigated (Note: it is rare for the discharge letter to explicitly state the diagnosis of a fragility fracture)

- Patient may or may not be prescribed bone sparing agents dependent upon a diagnosis of osteoporosis

If discharged by A&E:

- GP receives letter confirming fracture (Note: it is rare for the A&E letter to explicitly state the diagnosis of a fragility fracture)

At the local practice:

- Neither the discharge letter or A&E letter are likely to be specific about the circumstances leading to the fracture and even less likely to suggest a fragility fracture
- A record of the fracture is made in the patient notes
- A record of osteoporosis is made in the patient notes if diagnosed by the hospital
- A record of bone sparing agents if prescribed

When the patient or their notes are reviewed by the GP there may be a suspicion that the fracture is secondary to osteoporosis, if this is the case, the patient will be sent for a DXA scan

- The result of the DXA scan may be recorded either as a T score or a diagnosis of osteoporosis if present
- If osteoporosis was confirmed it would be rare for the GP to record the fact that the original fracture was likely to be a fragility fracture
    - If it were to be recorded as a fragility fracture it would be necessary to date the diagnosis back to the date of the original fracture diagnosis.

- Investigation of the records of 2.7 Million patients in 114 practices comprising 240 Million consultations over a 10 year period revealed 1,578 instances of the term fragility fracture being recorded. (note that during this period there will have been 1.8 Million fragility fractures in England and Wales)

Availability of current Read Code terms:

The following Read Codes exist in V2 to support fragility fracture:

N331M Fragility fracture due to unspecified osteoporosis

N331N Fragility fracture

In addition there are the following terms which might imply a fragility fracture:

N3313 Osteoporosis of disuse with pathological fracture

N3316 Idiopathic osteoporosis with pathological fracture

N3318 Osteoporosis + pathological fracture lumbar vertebrae

N3319 Osteoporosis + pathological fracture thoracic vertebrae

N331A Osteoporosis + pathological fracture cervical vertebrae

N331H Collapse of cervical vertebra due to osteoporosis

N331J Collapse of lumbar vertebra due to osteoporosis

N331K Collapse of thoracic vertebra due to osteoporosis

N331L Collapse of vertebra due to osteoporosis NOS

Only the first 2 terms specifically confirm a fragility fracture the latter terms that include the diagnostic term of osteoporosis may or may not suggest a fragility fracture. The diagnostic criteria for the fragility fracture rely upon the circumstances of the trauma, not the diagnosis of osteoporosis.

The options for recording a fragility fracture are:

- Record the site of the fracture **AND** the fact that it was a fragility fracture

S304. Pertrochanteric fracture

N331N Fragility fracture

- **OR** Create a new term:

NRC Pertrochanteric fragility fracture

(Note: It would be necessary to create new Read Codes for all of the common fragility fractures of the wrist spine and hip)

Recording the results of the DXA scan is currently supported by Read Codes:

- The following Read Codes require a value for the T score:

58E2. Forearm DXA scan T score

58E8. Heel DXA scan T score

58EE. Hip DXA scan T score

58EK. Lumbar spine DXA scan T score

58ES. Femoral neck DEXA scan T score

- The following Read Codes incorporate the finding of osteoporosis:

58E4. Forearm DXA scan result osteoporotic

58EA. Heel DXA scan result osteoporotic

58EG. Hip DXA scan result osteoporotic

58EM. Lumbar DXA scan result osteoporotic

58EV. Femoral neck DEXA scan result osteoporotic

Options for each of the proposed indicators:

Indicator *- The practice can produce a register of patients (men and women) aged ≥50-74 years with a fragility fracture, with a diagnosis of osteoporosis confirmed on DXA scan*

<u>There are 3 options available for identifying the target population required for this register:</u>

Option 1 *– Using existing Read Codes, insist on the presence of the term 'fragility fracture' AND a positive DXA scan, either by looking for a T score of less than or equal to -2.5 SD or for the term that confirms the finding of osteoporosis by DXA scan. (Note: the diagnosis of osteoporosis is not required to support this register)*

The implications of option 1 are:

- The GP should record the accurate details of the fracture at the earliest opportunity
- The GP will be required to retrospectively record fragility fracture **OR**
- The GP assumes a fragility fracture at the time and then has to amend the record retrospectively if the DXA scan is negative
- Additional work load required to retrospectively code fragility fracture
- Does support the wording of the indicator

- The business rules look for presence of fragility fracture and positive DXA scan

Option 2 *– Request additional Read Codes to include all common fragility fractures, insist on recording 'fragility fracture of .....' at the earliest opportunity followed by confirmation of osteoporosis by DXA scan.*

The implications of option 2 are:

- The GP assumes a fragility fracture at the time and then has to amend the record retrospectively if the DXA scan is negative
- Only a single Read Code required to accurately record the site of the fracture and the fact that it is a fragility fracture
- Does not support good record keeping practice – retrospective record keeping and/or amendment
- Significant number of new Read Codes required
- Does support the wording of the indicator
- The business rules look for presence of fragility fracture and positive DXA scan

Option 3 *– Record only the details of the fracture and then the results of the DXA scan*

The implications of option 3 are:

- GP records the details of the fracture accurately
- No requirement to record fragility fracture
- Supports good record keeping practice
- More accurately reflects the clinical process
- Supports the spirit of the indicator

Good record keeping practice for the purposes of managing the patient require accurate recording of the fracture, therefore, if it is decided that we must record that this was a fragility fracture there will need to be new codes for all of the commonly affected vertebrae, wrist and hip fractures that include the concept of fragility.

Indicator *- The percentage of (men and women) aged ≥75 with fragility fracture, who are currently treated with an appropriate bone-sparing agent*

The technical appraisal (T161 amended January 2011) has the following to say about osteoporosis and fragility fracture in those over the age of 75:

'If a woman aged 75 years or older has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.'

For the purposes of this discussion we are only interested in the requirement to identify the target population for the register. As indicated above the criteria for inclusion in this register is the clinical judgement that the fracture sustained is a fragility fracture as defined in 2.1 above and confirmation by DXA scan is not required.

There are 2 options available for consideration:

Option 1 *– Record the accurate details of the fracture and record separately the fact that it was judged to be a fragility fracture.*

The implications of option 1 are:

- GP records the details of the fracture accurately
- GP records fragility fracture at the same time
- Small additional workload required to record fragility fracture
- Does support the wording of the indicator

Option 2 *- Request additional Read Codes to include all common fragility fractures, insist on recording 'fragility fracture of .....'*

- Only a single Read Code required to accurately record the site of the fracture and the fact that it is a fragility fracture
- Significant number of new Read Codes required
- Does support the wording of the indicator

Appendix C: Details of assessment criteria for piloted indicators

This appendix provides details for each of the assessment criteria used in the report to provide the basis of the pilot feedback, assessments and recommendations.

Clarity

Clarity measures whether the indicator wording is clear and unambiguous. This is assessed and rated by the RAM[19] panel, in terms of the ability to write business rules (and/or an extraction specification) for the indicator. Clarity may also take into account the attribution of the indicator, that is whether it is applicable to primary care and performed within the practice.

Reliability

Reliability measures how closely multiple formats or versions of an indicator produce the same result. Each indicator undergoes compulsory reliability testing (how closely multiple versions of a test produce the same result).

Data elements obtained through automated search strategies of electronic health records are verified against and compared with a reference manual review strategy for obtaining the data elements, and a report is compiled. Reasons for any discrepancies between electronic extraction and manual reviews are then investigated and documented. This procedure is undertaken for each indicator in a small number of practices.

During the analysis, development and execution of the extraction software, issues are documented and a statement on the level of change required to subsequent business rules is prepared.

Acceptability

Acceptability measures how acceptable the activity is to both the assessors and those being assessed, for example that the activity is perceived as good clinical practice without any major barriers, risks or issues. Assessment might examine any conflicts with national guidance, variation in preferences of engagement with patients, concerns in relation to exception reporting, frequency of prescribing or undue focus on one area of care.

Feasibility

Feasibility measures the ability of the clinical practice to interpret an indicator's definitions and technical specifications and integrate them into both clinical practice and health information systems, and generate performance reports within a reasonable time frame and budget. A technical feasibility

[19] In the initial stages indicators in development go through a rigorous two-stage consensus process: a modified RAND/UCLA Appropriateness Method (RAM). This is the only systematic method of combining expert opinion and evidence (Naylor, 1998) and feeds consultation with experts in each clinical area as appropriate in to the development process.

assessment will include the ability to extract data from the pilot practices using business rules, and/or an extraction specification via an extraction software provider (PRIMIS+) at the appropriate times, using the technical solution for each extract.

Assessment will also include an outline of any exception reporting codes necessary or subsequent changes to the business rules for indicators to operate functionally in live QOF.

Implementation

Implementation measures several factors which may have an impact on a practice and/or patient during the piloting of an indicator.

An assessment of piloting achievement measures the current baseline and any changes in baseline including the degree of confidence that the baseline is representative of the expected national baseline. The assessment will also report if the baseline has been supplemented with GPRD/THIN[20] data.

Changes in practice organisation measures any necessary changes required to create, use, and maintain the capacity to report on an indicator. These changes might involve IT, staffing, workflow structure, processes, policies, culture, inter-organisational relationships, and physical or financial capital critical to the cost effectiveness analysis.

Resource utilisation and costs measures the resource impact the indicator has on a practice. This may require engagement and consultation with practices through qualitative face-to-face methods, for example work load diaries, interviews and focus groups or quantitative methods exploring the extracted data from the piloted indicators.

Barriers to implementation measure any major barriers which would make the indicator unreasonably difficult to implement in practices or in live QOF. This may include requirements to make fundamental changes to practice organisation, unfeasible data collection or any unacceptable impact of unintended consequences. Assessment might examine barriers encountered in data collection, whether there was a lack of existing templates, the completeness of data and any missing data, and whether the indicator requires the reporting of new data items or concepts that are not routinely captured as part of current practice.

The implementation assessment will also take into account the overlap with existing indicators, and the extent of any overlap. For instance, whether the indicator partly or completely duplicates activities covered by other indicators in the same or a separate clinical domain.

An assessment of exception reporting measures the susceptibility of an indicator to high levels of exception reporting. This may include engagement

[20] The Health Improvement Network (THIN) is a partnership of organisations which develop primary care systems. The general practice research database (GPRD), developed by THIN, is a database of anonymised patient records from information entered by general practices in their clinical systems.

issues, relevance of the indicator to certain groups, contraindications, and the accessibility of patients (namely those who are housebound or in a nursing home). The rate of exception reporting for the piloted indicator will include the extent to which exception reporting levels are within the expected range.

Unintended consequences are unforeseen effects of QOF measurements on processes of care, patient outcomes, and/or the functioning of the wider healthcare system. They may be positive in nature, for example encouraging general quality improvement, or negative, such as diversion of effort, disruption to clinical or organisational workflows, susceptibility to monetary gain, potential harm to patients, inappropriate standardisation of care or local practice, and undue focus on process. This may require auditing of patient exception reporting and referral rates to other health and social care sectors, and exploration of the reasons for these at an individual level including patient socio-demographic variables if available.