



2019 surveillance of osteoporosis: assessing the risk of fragility fracture (NICE guideline CG146)

Surveillance report

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Surveillance decision

We will update the guideline on [osteoporosis: assessing the risk of fragility fracture](#) (NICE guideline CG146).

The following table gives an overview of how evidence identified in surveillance might affect each area of the guideline, including any proposed new areas.

Section of the guideline	New evidence identified	Impact
<i>Targeting risk assessment</i>		
Population at risk	Yes	No
<i>Methods of risk assessment</i>		
Intervention thresholds	Yes	Yes
Vertebral fractures diagnosis and assessment	Yes	Yes
High-dose systemic glucocorticoids	Yes	Yes
<i>Research recommendations</i>		
FRAX and QFracture in adults receiving bone protective therapy	Yes	Yes
Using GP Practice lists to identify people at high risk	Yes	Yes

Reasons for the decision

This section provides a summary of the areas that will be updated and the reasons for the decision to update.

Methods of risk assessment

- Intervention thresholds. A key concern from topic experts is the lack of clarity about thresholds for treatment which poses a problem in clinical practice. Although the original scope for osteoporosis: assessing the risk of fragility fracture (CG146) did not cover thresholds for intervention, other pieces of NICE guidance do cite thresholds, which differ as they were developed using different methods. In the NICE quality standard on osteoporosis (QS149), intervention thresholds were adapted from the National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis which, in turn, are derived from FRAX (for details see [quality statement 2](#)). Until July 2019, the NICE technology appraisal on bisphosphonates for treating osteoporosis (TA464) included intervention thresholds which were determined from the levels of absolute fracture risk at which bisphosphonates were cost effective. In response to concerns raised by the MHRA that these thresholds included in TA464 may lead to wider use of bisphosphonates (oral and intravenous) in a population at low risk of fracture, outside of the supporting evidence, the recommendations were reviewed and amended. TA464 no longer includes information on the absolute risk level at which oral bisphosphonates are recommended and advises that bisphosphonates should be prescribed according to the recommendations in CG146 which defines who is eligible for osteoporotic fracture risk assessment, and QS149 which defines thresholds and the circumstances and preferences of individual people. See the [review decision paper](#) for full information. The NICE technology appraisals team are currently assessing non-bisphosphonates for treating osteoporosis (ID901) (expected publication date to be confirmed). Experts highlighted that a guideline definition of intervention thresholds with consideration of non-pharmacological interventions would be valued and would be the groundwork for consistency across NICE guidance. The emphasis from TA464 on applying the TA guidance in conjunction with the guideline and related quality standard emphasises the need for evidence-based thresholds to be determined within NICE guidelines.

- **Vertebral fractures.** Vertebral fractures are one of the most common fragility fractures and are associated with decreased life expectancy. Topic expert feedback highlighted that the diagnosis and assessment of vertebral fractures are not addressed in CG146. It was also noted that although the two tools recommended in the guideline (FRAX and QFracture) assess the risk of fragility fracture, they may underestimate fracture risk in people with previous vertebral fracture(s). We identified a relevant ongoing study which aims to develop a checklist for use in primary care for identifying undiagnosed osteoporotic vertebral fractures in women with back pain (see [ongoing research](#)). Results are expected in June 2021 and we will pass the details of this study to the developers responsible for updating the guideline.
- **High-dose oral or high-dose systemic glucocorticoids** is considered a major risk factor for fragility fractures. CG146 defines a high-dose of systemic glucocorticoid treatment as 7.5mg/day for 3 months, whereas QS149 defines a high-dose as 5mg/day for 3 months. There is no clear reason for this discrepancy, and this should be addressed in the update of CG146.
- [Bindex for investigating suspected osteoporosis \(MIB106\)](#) provides advice for the use of Bindex for investigating suspected osteoporosis. This technology is not currently addressed in CG146 and could be considered in the update.

Research recommendations

We also identified new information that might have an impact on the following recommendations:

- **Using GP practice lists to identify people at high risk.** New evidence suggests that community-based screening strategies might reduce the number of hip fractures in high risk populations.
- **FRAX and QFracture in adults receiving bone protective therapy.** Topic experts agreed that the reassessment of fracture risk after 3–5 years of bisphosphonate treatment is not well considered in the current guideline. It was also noted that the NICE guideline on [multimorbidity: clinical assessment and management \(NG56\)](#) already recommends discussing whether bisphosphonate should be stopped after 3 years of treatment considering the benefits and harms of bisphosphonates, the risk of fracture, life expectancy and patient choice. Therefore, although no specific new evidence was identified, advice on risk assessment during bone protective treatment would be valued by the system.

The section targeting risk assessment should be included in the update so that recommendations can reflect any changes in risk factors since the original guideline was published.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in [osteoporosis: assessing the risk of fragility fracture](#) (NICE guideline CG146) remain up to date. The 2019 surveillance followed the static list review process, consisting of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy.
- Consideration of evidence from previous surveillance.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.

For further details about the process and the possible update decisions that are available, see [ensuring that published guidelines are current and accurate](#) in developing NICE guidelines: the manual.

Evidence considered in surveillance

Cochrane reviews

We searched for new Cochrane reviews related to the guideline. We found 1 relevant Cochrane review published between 1 September 2011 and 4 February 2019.

The Cochrane review evaluated the impact of the use of steroidal contraceptives on bone mineral density and risk of fracture in women. There was insufficient evidence to determine the impact. Women using steroidal contraceptives are not a target population for assessment of fracture risk in NICE guideline CG146. The findings of the Cochrane review do not have an impact on the current guideline recommendations.

NIHR signals

We checked for NIHR signals, and we found 1 relevant systematic review ([Poly et al. 2019](#)). The systematic review assessed the impact of the treatment with proton pump inhibitors on the risk of hip fracture. Twenty-four observational studies were included. PIP therapy was associated with an increased risk of hip fracture. The findings of the study support the current guideline recommendations.

Studies highlighted by topic experts

One study was highlighted by topic experts ([Shepstone et al. 2018](#)). This is a randomised controlled trial that compared a community-based screening programme of risk of fracture using FRAX with usual care. A total of 6,233 women aged 70–85 years identified from 100 GP practices in the UK were included. Participants were identified through a primary care list. The intervention reduced the incidence of hip fractures, but no differences were identified in the reduction of all osteoporosis-related fractures, all clinical fractures, mortality, quality of life or anxiety. This study is relevant because NICE guideline CG146 includes a research recommendation about using GP practice lists to identify people at high risk.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 1 study was assessed as having the potential to change recommendations. This study is:

- A back pain checklist (Vfrac) for use in primary care to identify older women with back pain due to undiagnosed broken bones in the back – [ISRCTN16550671](#)
 - One of the aims of this observational study is to develop a checklist for identifying undiagnosed osteoporotic vertebral fractures in women with back pain. The intention to publish date is 30 June 2021.

We will share the details of this study with the developers responsible for updating the guideline so that they can evaluate the impact of any published results.

Search and selection strategy

No further specific literature searching was needed in any of the sections of the guideline because the initial intelligence gathering and feedback from topic experts strongly

indicated that an update of the guideline is needed.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their speciality. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to the guidelines.

We sent questionnaires to 11 topic experts and received 7 responses. Five experts indicated the guideline should be updated. Issues highlighted by topic experts included:

- Intervention thresholds. Topic experts suggested that the scope of the guideline needs to include intervention thresholds, so all the NICE products could link more consistently.
- Vertebral fracture diagnosis and assessment. One topic expert considered that the diagnosis and assessment of vertebral fractures should be included in NICE guideline CG146. The expert highlighted the recent publication of the National Osteoporosis Society's [Clinical guidance for the effective identification of vertebral fractures](#). We identified an ongoing study in this area (see [ongoing research](#)).
- Provision of information to patients at risk of fracture. A topic expert felt that a more holistic approach, including patients' priorities, is needed in the guideline. NICE is currently developing a guideline on sharing decision making (expected publication 2021) which will be relevant to this area. The topic expert also highlighted the importance of other areas not considered in NICE guidance including non-pharmacological interventions (for example diet and exercise) and patient-important outcomes (for example pain, fear of fracture or QALYs), currently not covered within the scope of CG146.

Other sources of information

None identified.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to update all of the guideline, we did not consult with stakeholders.

See [ensuring that published guidelines are current and accurate](#) in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that an update is necessary.

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