

A tool for primary care providers





# **KEY MESSAGES IN BENEFIT VERSUS RISK DISCUSSION**

- > Fractures are serious and impact health as well as survival. In addition, serious side effects from medications are very rare. The benefits/side effects differ by medication and should be explained (see side panel) without losing sight of the severe consequences of fractures we are trying to prevent.
- > The significant health consequences of fractures must be considered, including pain, reduced mobility, need for assistive walking devices, loss of independence, reduced quality of life and complications such as infection, cardiovascular events, thromboembolic disease and death.
- > Drug summaries and package inserts list all side effects, but do not mention how rare many of these are.
- > Patients may have major concerns with regard to a particular side effect the reasons for this should be explored and reassurance provided if appropriate.
- > For each atypical femoral fracture potentially caused, 50 osteoporotic fractures may be prevented<sup>5</sup>.
- > Consider evaluation for secondary causes including CBC, CMP, 25-hydroxy vitamin D, 24 hour urine calcium.
- Osteoporosis is a chronic disease, just like diabetes and hypertension We can effectively treat and reduce the risk for fracture, but do not cure it. As such , it will require lifelong attention.

# **NOTES ON USE OF THIS TOOL**

- > This tool is intended to aid clinicians in communicating with patients about risk assessment and prevention of osteoporotic fractures.
- > Note that the bone infographics can be shaded to represent key statistics, e.g. risk of fracture, risk of side effects, proportion of fractures prevented.

#### References:

- 1. https://www.sheffield.ac.uk/FRAX/
- 2. US guidance (NOF):
- https://my.nof.org/bone-source/education/clinicians-guideto-the-prevention-and-treatment-of-osteoporosis
- 3. Khan, J Bone Miner Res, 2015. 30(1).
- 4. Dell, J Bone Miner Res, 2012. 27(12) 5. Adler, J Bone Miner Res. 2016. 31(1)



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US version

# **RELATIVE RISK REDUCTION IN FRACTURE WITH ANTI-RESORPTIVE TREATMENT\***

Spine: 60% Hip: 40% Non-spine: 25%

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\*hormone therapy, bisphosphonates and Denosumab

# What does my percentage risk mean?

Probability of fracture: \_\_\_\_% (e.g. FRAX®)



### Risk of rare side effects with anti-resorptives

Probability of osteonecrosis of the jaw: 0.001%<sup>3</sup> Probability of atypical femur fractures: 0.001% <sup>4</sup>

Probability of these rare side effects is minimal compared to the risk of fracture.



### **COMMON SIDE EFFECTS**

#### > Bisphosphonates

- > By enteral route: mild gastro-intestinal disturbances
- > By IV: flu-like symptoms acute and transient bone and muscle pain, as well as fever
- > SERM
  - > Leg cramps and hot flushes

### **INFREQUENT SIDE EFFECTS**

- > SERM
  - > Deep venous thromboembolism
- > Denosumab
  - > Skin rashes and infections
  - > Hypocalcemia

#### > Anabolics

- > PTH and PTHrP analogs
  - Hypercalcemia
  - Nausea
  - Dizziness and headache
  - Hypercalciuria
- > Romosozumab
  - Rare cardiovascular events

### **CONSEQUENCES OF FRACTURE**

- > Overall decrease in quality of life including:
  - > Pain
  - > Loss of independence
  - > Immobility
  - > Premature death
- > Huge impact not just on the patient, but also on caregivers, family and friends

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