Effective patients monitoring strategies
(when, who, what, how)

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Disclosures

- **Fees for lectures and consultancy**
  - Abbvie, Amgen, Arrow, BMS, Chugai, Expanscience, Gilead, HAC-Pharma, LCA, Lilly, Medac, MSD, Pfizer, Thuasne, TEVA and UCB

- **Research grants or investigator fees**
  - Amgen, Bone Therapeutics, Chugai, HAC-Pharma, MSD, Novartis, Pfizer, and UCB
Effective patients monitoring strategies
(when*, who, what, how)

*BPF Standards 1 to 4: Identification, Evaluation, Timing and Vertebral Fracture
The optimal fracture liaison service (FLS)

Emergency Room
All patients > 50 with clinical fracture

Orthopedic Department

Inpatient visits

Database

Radiology Department
All patients > 50 with VF on any imaging

Daily Identification of patients

Phone calls

Home or Rehabilitation

Risk of falls assessment and prevention

DXA Bone specialist visit

Information and coordination with GP

Treatment initiation & Follow up
Hospitalization for fragility fractures in Auvergne-Rhône-Alpes

Public and private hospitals managing fragility fracture patients

Source: PMSI – tous régimes
Program « PRADO orthopedic / bone fragility »
Objective: reducing hospitalization rate for next fragility fractures

Hospital Medical Team
- Evaluate patient eligibility to the program PRADO
- Inform the patient of his eligibility and asks for consent to Social Security Employee visit
- Decide patient outcome

General Practitioner
- Post-fracture management including pharmacological and non-pharmacological treatments

Health Care Professionals

Patient >50 y.o
Hospitalized for a fragility fracture

Social Security Employee
- Presents the program and gives information on patient management
  - If patient agrees:
  - Gets patient’s consent and HCPs selected by the patient
  - Gives information leaflet on fragility fracture and osteoporosis management

Informs patient’s GP of patient’s participation to the program, gets 1st visit appointment in the week following return to home
- Contacts HCPs and organizes future patient’s management with them
Alternative FLS: an open structured network
Effective patients monitoring strategies (when, who*, what, how)

*BPF Standards 5 to 7: Assessment guidelines, Secondary causes, Falls prevention
Evaluating fracture risk
The key factor risks

- Age
- Evaluating risk of falls (> 70 ans)
- Previous fracture and its recency
- BMD assessment
Population pyramid of patients hospitalized in France for fracture

Hospitalizations for hip fractures

Hospitalizations for wrist fractures

Source 2013: CNAMTS – PMSI MCO – Régime général et SLM
Evaluating risk of falls

- A previous fall in the last 3 to 6 months

- In the absence of previous fall, easy tests to perform:
  - Get up and go test (> 14 sec)
  - Unipodal test
  - Sternal push test

- Falls prevention service including assessment and intervention program (> 70)

http://www.americangeriatrics.org/healthcareprofessionals/clinicalpractice/
clinicalguidelinesrecommendations/2010
Second hip fracture after a 1\textsuperscript{st} hip fracture

Time effect

Period estimates of incidence of second hip fracture by time from first fracture

Cumulative distribution of time from first to second fracture

Men (square) and Women (circle)
Values are poisson regression-based estimates and 95\%CI of rate per 1000 person years (py)

Men (square) and Women (circle)
Point estimates and 95\%CI are Kaplan-Meier-based estimations

Nymark T. Osteoporos Int 2006;17: 1353–7
Imminent risk of fracture
Risk of a 2\textsuperscript{nd} major osteoporotic fracture after the 1\textsuperscript{st} one for a woman aged 75

Population-based cohort of 18,872 men and women born between 1907 and 1935 in Iceland - Fractures were documented over 510,265 person-years. 5038 individuals sustained one or more MOFs, of whom 1919 experienced a second MOF.
Knots for the spline function are set at 0.5, 2.5 and 15 years of follow-up after the first fracture.
The dashed line is the risk of first MOF in whole population (n = 18,872) for a woman 75 years at baseline.

Johansson H. Osteoporos Int 2017;28:775–780
The effect of age on the risk of subsequent major osteoporotic fracture

Population-based cohort of 18,872 men and women born between 1907 and 1935. Fractures were documented over 510,265 person-years. 5038 individuals sustained one or more MOFs, of whom 1919 experienced a second MOF. The hazard ratio (HR with 95%CI) compares the risk against that of the general population when allowing the population to age with time (e.g. the individual aged 80 after 60 months compared with population aged 85).
No improvement in standardized mortality rate after major fractures over time

Dubbo Osteoporosis Epidemiology Study 1 (DOES 1; born before 1930): 1989 – 2004
Dubbo Osteoporosis Epidemiology Study 2 (DOES 2; born after 1930): 2000 – 2014
Assessment of Bone Mineral Density

- Evaluation of bone loss that already occurred
- Help in diagnosis of bone fragility depending on bone fracture location and circumstances of the event
- Useful before therapeutic decision
- VFA: Two fracture risks at once
Prognostic ability of BMD measurement

Initial and refracture probability

5-year mortality probability

Age 60-74 Years

Women

Men

Initial and Refracture Probability

Age 75+ Years

Women

Men

5-year Mortality Probability
Outil de Calcul

Veuillez répondre aux questions ci-dessous pour calculer la probabilité de fracture sur 10 ans sans ou avec DMO.

**Questionnaire:**

1. Âge (entre 40 et 90 ans) ou Date de Naissance
   - Âge: ____________
   - Date de Naissance: ____________

2. Sexe
   - M: Masculin
   - F: Féminin

3. Poids (kg)
   - ____________

4. Taille (cm)
   - ____________

5. Fracture antérieure
   - Non
   - Oui

6. Parents ayant eu une fracture de la hanche
   - Non
   - Oui

7. Actuellement Fumeur
   - Non
   - Oui

8. Glucocorticoides
   - Non
   - Oui

9. Polyarthrite rhumatoïde
   - Non
   - Oui

10. Ostéoporose secondaire
    - Non
    - Oui

11. Alcool trois unités par jour ou plus
    - Non
    - Oui

12. DMO du Col Fémoral (g/cm²)
    - ____________
    - Choisissez BMD:

A propos des facteurs de risques

**Weight Conversion**

- Pounds ➔ kg
  - ____________
  - Convert

- Height Conversion
  - Inches ➔ cm
  - ____________
  - Convert

**FRAX® Outil d'Evaluation des Risques de Fractures**

00335312
- Individuals with fracture risk assessed since 1st June 2011

06250669
- Individuals with fracture risk assessed since 1st June 2011
# 2018 up-date on French guidelines on postmenopausal osteoporosis management

<table>
<thead>
<tr>
<th>Based on T score (lowest value)</th>
<th>Severe fractures (femur, vertebra, humerus, pelvis)</th>
<th>Non severe fractures</th>
<th>No fracture and risk factors of osteoporosis or falls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T &gt; -1</strong></td>
<td>Specialist opinion</td>
<td>No treatment</td>
<td>No treatment</td>
</tr>
<tr>
<td><strong>T ≤ -1 &amp; &gt; -2</strong></td>
<td>Treatment</td>
<td>Specialist opinion</td>
<td>No treatment</td>
</tr>
<tr>
<td><strong>T ≤ -2 &amp; &gt; -3</strong></td>
<td>Treatment</td>
<td>Treatment</td>
<td>Specialist opinion</td>
</tr>
<tr>
<td><strong>T ≤ -3</strong></td>
<td>Treatment</td>
<td>Treatment</td>
<td>Treatment</td>
</tr>
</tbody>
</table>

Briot K. Joint Bone Spine 2018;85:519–30
Effective patients monitoring strategies (when, who, **what***, how)

*BPF Standards 7 to 10: Falls prevention, Health & life-style assessment, Medication*
Initiating medications is part of a global therapeutic strategy\textsuperscript{1}

Help patients to be \textbf{proactive} in their treatment \textbf{rather than reactive}\textsuperscript{1,2}

**Treatment Recommendations\textsuperscript{3}**

- **Adequate calcium and vitamin D intake**
- **Balanced diet**
- **Regular weight-bearing and balance exercise**
- **Medications**
- **Avoid tobacco use and limit alcohol consumption**
- **Measures to prevent falls**

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Efficacy
Treatment recommendations

- **In patients with hip fracture**, consider zoledronic acid in first line as it demonstrated its anti-fracture efficacy in these circumstances (Grade A).

- **In patients with two prevalent vertebral fractures**, teriparatide can be prescribed in first line (Grade A).

- **In women below 65 with an indication of AO treatment**, raloxifene can be recommended if non-vertebral risk is low, especially in the absence of the following criteria:
  - Low T-score at the hip
  - Risks of falls
  - Previous non-vertebral fracture (Grade A)

Briot K. Joint Bone Spine 2018;85:519–30
Treatment recommendations

- **In a woman below 60 ans** with climacteric syndrome and osteoporosis without severe fracture, Hormonal treatment can be proposed (Grade A).

- **In case of very low BMD (T ≤ -3)** with or without fracture, therapeutic strategies with the aim of a BMD T-score target above -2 have to be considered:
  - Zoledronic acid
  - Therapeutic sequence of Denosumab followed by a bisphosphonate
  - Therapeutic sequence of Tériparatide followed by antiresorptive drug

(Professional agreement)
Effective patients monitoring strategies (when, who, what, how*)

*BPF Standards 11 to 13: Communication, Long-term management, Database*
Long-term management in a FLS

Defining the respective roles

- FLS leader
- Radiologist
- Orthopedic surgeon
- Specialist
- Payer
- FLS Coordinator
- Fall service
- General Practitioner
- Patient
Long-term management in a FLS

Who is responsible for delivering monitoring?

- FLS questionnaires to the Capture the Fracture programme

- Results
  - 322 FLS completed section S of questionnaire
  - 278 / 322 (86%) had a monitoring pathway
  - Only 10% FLSs monitored both before 6 months and after 12 months
## Patient follow-up under treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>New fracture</th>
<th>New risk factors</th>
<th>Adherence</th>
<th>Tolerance</th>
<th>Height</th>
<th>Spine assessment</th>
<th>BTM</th>
<th>1st BMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>3 to 6 months after treatment initiation</td>
<td>2 to 3 years</td>
</tr>
<tr>
<td>Denosumab</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>Injection réalisée ?</td>
<td>2 to 3 years</td>
</tr>
<tr>
<td>Risedronate</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>3 to 6 months after treatment initiation</td>
<td>2 to 3 years</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Raloxifene</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>6 to 12 months after treatment initiation</td>
<td>2 to 3 years</td>
</tr>
<tr>
<td>Hormonal Tt</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>3 to 12 months after treatment initiation</td>
<td>2 to 3 years</td>
</tr>
<tr>
<td>Zoledronic Ac</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>1/year</td>
<td>Height loss / Back pain</td>
<td>Perfusion réalisée ?</td>
<td>2 to 3 years</td>
</tr>
</tbody>
</table>
Treat to target strategy

- A valid target is a BMD value above which the fracture risk is down to an acceptable level.
- Absence of bone loss (BMD change $\leq 0.03g/cm^2$) is the minimal objective for all patients.
- In patients with low femoral BMD before treatment, the target is to bring back femoral BMD T-score $>-2$.

Adapted from Faulkner KG. *J Bone Miner Res.* 2000;15:183-187

Cosman F. *J Clin Endocrinol Metab.* 2014
Ferrari S. *Osteoporos Int.* 2015
Ferrari S. *J Bone Miner Res* 2019
Briot K. *Joint Bone Spine* 2018;85:519–30
When stopping the treatment?

- A break in the treatment after 3 to 5 years is recommended only if all following conditions are present (professional agreement):
  - No fracture under treatment,
  - No new risk factors,
  - No significant decrease in BMD
  - Femoral T score above -2

- Treatment holiday may be at risk and continuing patient follow-up is mandatory with reevaluation within 2 years
**Effective patient monitoring strategies**

- Establish a coordinated pathway for all osteoporotic patients
- Assess the level and the imminence of future fracture risk
- Regularly evaluate needs, benefits and risks of therapies
- Communicate widely and clearly define respective roles
- Keep in mind it is only a part of osteoporosis scope
Q & A
THANK YOU

On behalf of IOF, we thank you for your participation in this webinar