

## Challenges of managing patients with osteoporosis during and after the COVID-19 pandemic in Europe

Treatments, bone densitometry, social distancing, self-isolation and bone health

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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

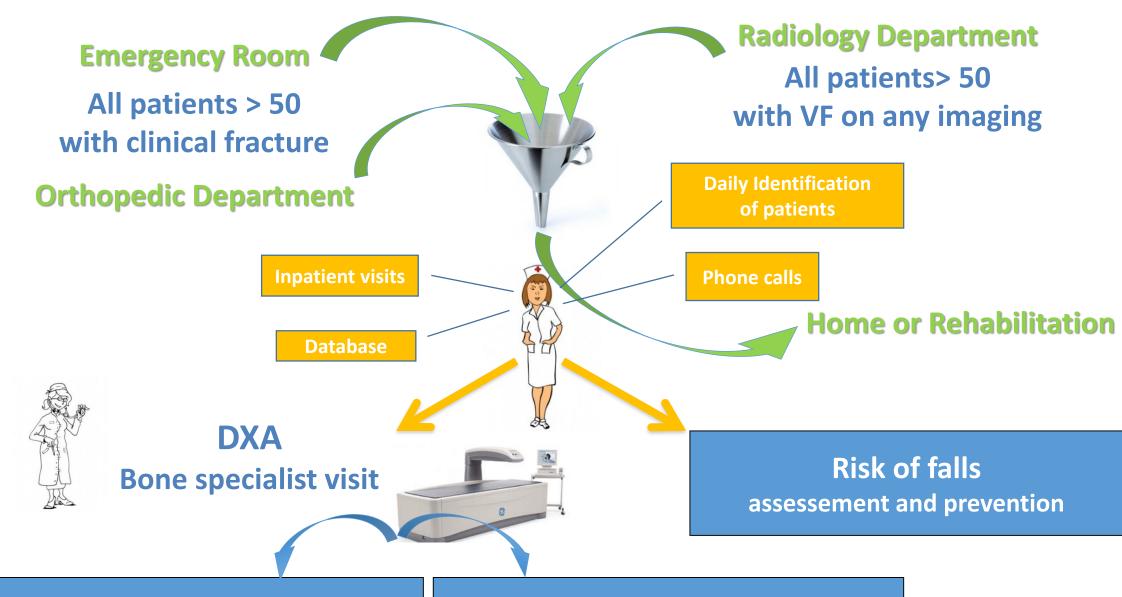
### Research grants or investigator fees

- Amgen, Bone Therapeutics, Chugai, HAC-Pharma, MSD, Novartis, Pfizer, and UCB





### The optimal fracture liaison service (FLS)



Information and coordination with GP

**Treatment** initiation & Follow up

### Simplified procedures in FLS

In exceptional circumstances of stretched hospital systems

- Establish pathways in the trauma / orthopaedic centers
  - to initiate appropriate osteoporosis therapy
  - before discharge from the orthopaedic ward,
  - to eligible patients above 65 years with a major fragility fracture of the hip, spine, humerus and pelvis
  - without a DXA scan
  - in absence of contra-indications



### Simplified procedures in FLS

### When returning to normal

 Keep a list of those patients with fragility fractures for further evaluation and treatment once services start returning to normal, ideally within 6 months after the fracture

• As hospital services restart, **be pro-active** in re-opening the DXA/VFA access **as soon as** possible



### **Prerequisite for therapy**

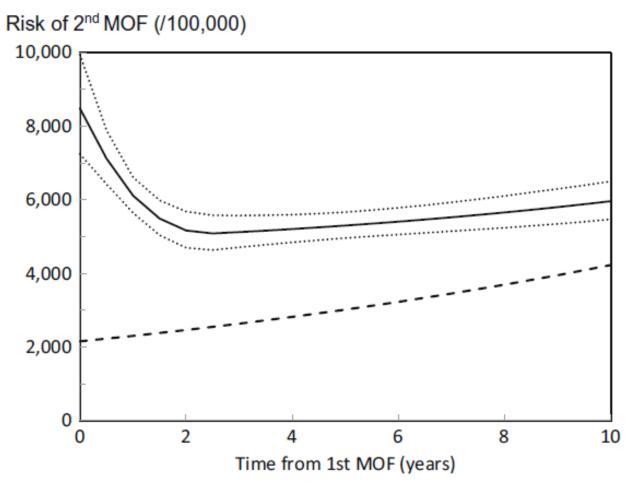
#### A minimal blood test

- normal adjusted serum calcium
- serum 250H vitamin D of at least 50 nmol/L
- Creatinine clearance of > 30 to 35 ml/mn depending on drug use



### Imminent risk of fracture

Risk of a 2<sup>nd</sup> major osteoporotic fracture after the 1<sup>st</sup> one for a woman aged 75



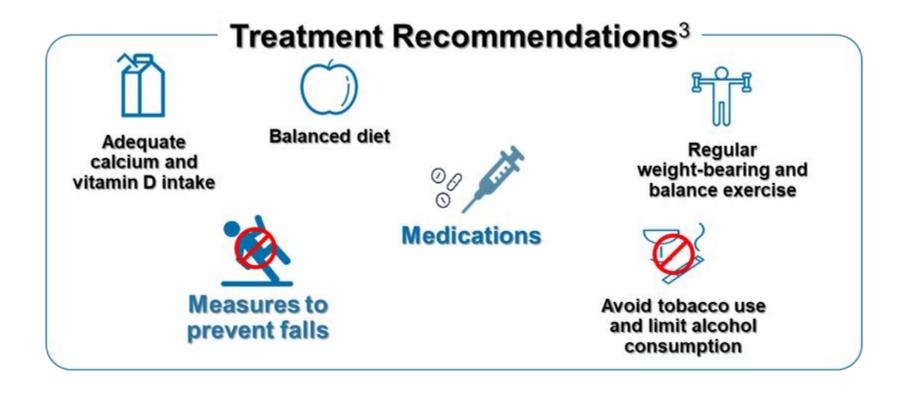
Population-based cohort of 18,872 men and women born between 1907 and 1935 in Iceland - Fractures were documented over 510,265 person-years 5038 individuals sustained one or more MOFs, of whom 1919 experienced a second MOF Knots for the spline function are set at 0.5, 2.5 and 15 years of follow-up after 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

### Initiating medications is part of a global therapeutic strategy<sup>1</sup>

Help patients to be **proactive** in their treatment rather than reactive<sup>1,2</sup>



<sup>1.</sup> Covello VT, et al. Solutions to an Environment in Peril. 2001;164-178. www.psandman.com/articles/covello.htm. Accessed February 13, 2018; 2. Besser SJ, et al. Arch Osteoporos. 2012;7:115-124; 3. Camacho PM, et al. Endocr Pract. 2016;22(Suppl 4):1-42; Image adapted with permission from Servier Medical Art. www.servier.com. Creative Commons CC-BY-3.0. Images adapted and licensed (royalty-free) from the Noun Project, Inc. www.thenounproject.com.

### **Treatment choice**

- Zoledronate can be given within 2 weeks of a hip fracture if the patient is eligible
- A fever may occur shortly after the zoledronate infusion and will be limited with paracetamol preventive use
- Special attention to appropriately schedule the next dose of denosumab
- Start with an oral bisphosphonate (ALN 70 mg per week or RIS 35 mg per week)
- Teriparatide may need brief self-injection training



### **Treatment renewal**

Patients under IV or SC drugs

- Teriparatide
  - No rebound of bone cellular activities
  - A sustained decrease in the risk of fracture following treatment withdrawal
  - Biological effects not persistent
  - Necessary to add an antiresorptive agent within 3 months



### **Treatment renewal**

Patients under IV or SC drugs

### Denosumab

- Adjustment period narrow beyond 6 months after the previous injection
- Effect quickly dissipating with a rebound in bone remodeling within a few weeks
- Denosumab next injection should not be postponed

### Zoledronic acid

• The infusion can be postponed from one to several months



### Some unknowns

- Risk of mortality following major fracture in patients having COVID 19 in the 3 months after the fracture event
- Risk of major fracture (hip, pelvis, vertebra, humerus) in osteoporotic patients who had COVID 19
- Risk of falls under social distancing and self-isolation circumstances
- Treatment use under same conditions
- Safety of anti-osteoporotic drugs during pandemic









# CHALLENGES OF MANAGING PATIENTS WITH OSTEOPOROSIS DURING AND AFTER THE COVID-19 PANDEMIC IN EUROPE

Adolfo Diez-Pérez, MD, PhD
Hospital del Mar Institute of Medical
Investigation
CIBER of Frailty and Healthy Aging



## Disclosures

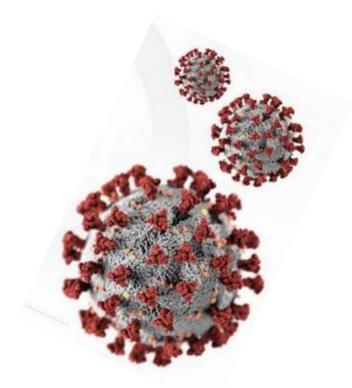
• Consultant or speaker for AMGEN, UCB, Lilly, Gilead, Theramex

Shareholder of Active Life Sci



## Agenda

- Clinical assessment
- Remote consultations/Telemedicine
- Self-injection
- Changes in practices for healthcare practitioners





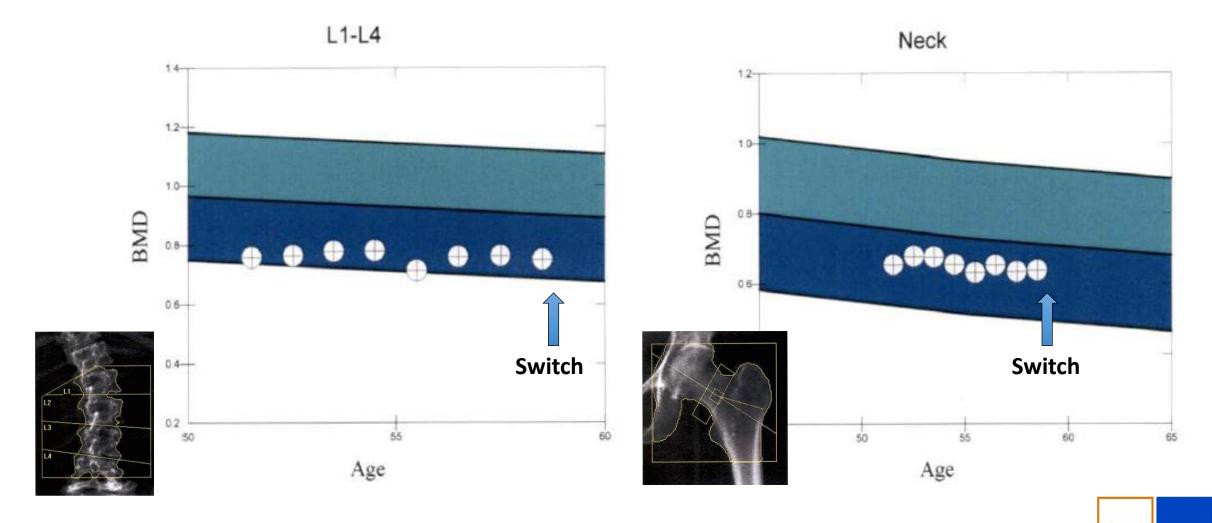
- 60 years old lady
- History of multiple fractures
- Scoliosis
- Weekly alendronate for 4 years
- Two new fractures while on treatment
- Switch to denosumab sc/6 mo, 23 months ago (3 doses)











- Five days of fever (up to 38.7°C)
- Dry cough
- General malaise
- Mild diarrhea
- SaO<sub>2</sub>: 97%
- Chest X-Ray: mild basal infiltrate
- PCR SARS-CoV-2 (COVID-19): Positive
- Next dose of denosumab scheduled in two weeks



### Remote consultation: Telehealth



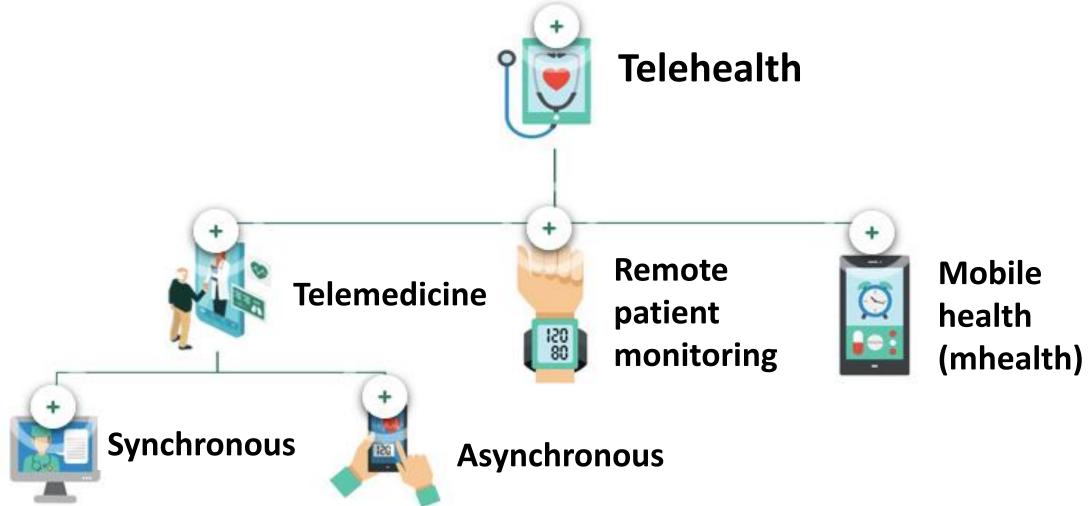
Butler JAMA 2020; 323: 2450-51

## COVID-19 transforms telehealth into an essential service

- COVID-19 has changed the paradigm of face-to-face visits, leading to an increased adoption of telehealth
- What is meant by "telehealth"?
  - Interactive, electronic exchange of information for diagnosis, intervention, or ongoing care management remotely
- Rapid expansion during COVID-19 pandemics



### Telehealth interactions





## Telehealth During Pandemics: advantages

- Remote triage
- Remote surveillance
- Continuity of chronic disease management
- Face-to-face visits only for the sickest patients
- Decreases the risk of person-to-person transmission
- Keeps the health care workforce safe
- Allow physicians symptom-free, but in quarantine, to provide patient care remotely.
- Relieve strain on the local health care workforce



## COVID-19 transforms telehealth into an essential service

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### **Telehealth modalities**









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### **Patient-provider**

**Virtual visits** 

Wearables and home exams

Secure messaging

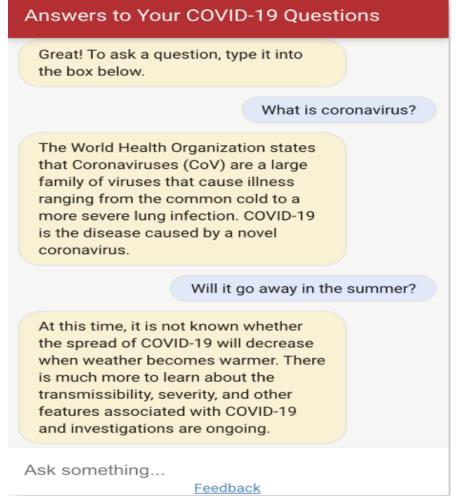


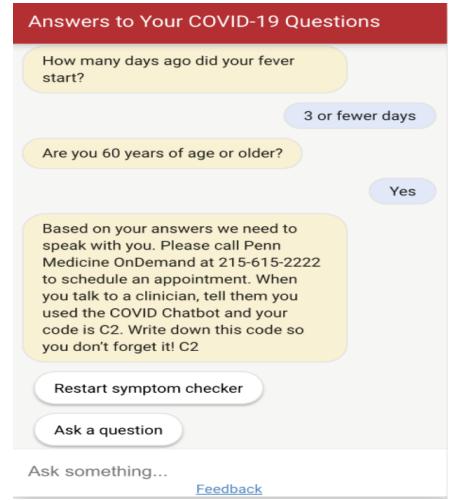
## Patient-provider service potentials

- Video visits, telephone, text, e-mail
- Mobile phone applications
- Voice-interface applications (Amazon Alexa, Google Voice, Apple Siri)
- Mobile sensors (smartwatches)
- Wearable devices
- Chatbots
- Hospital-at-Home



Chatbot on COVID-19







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**Provider-provider** 

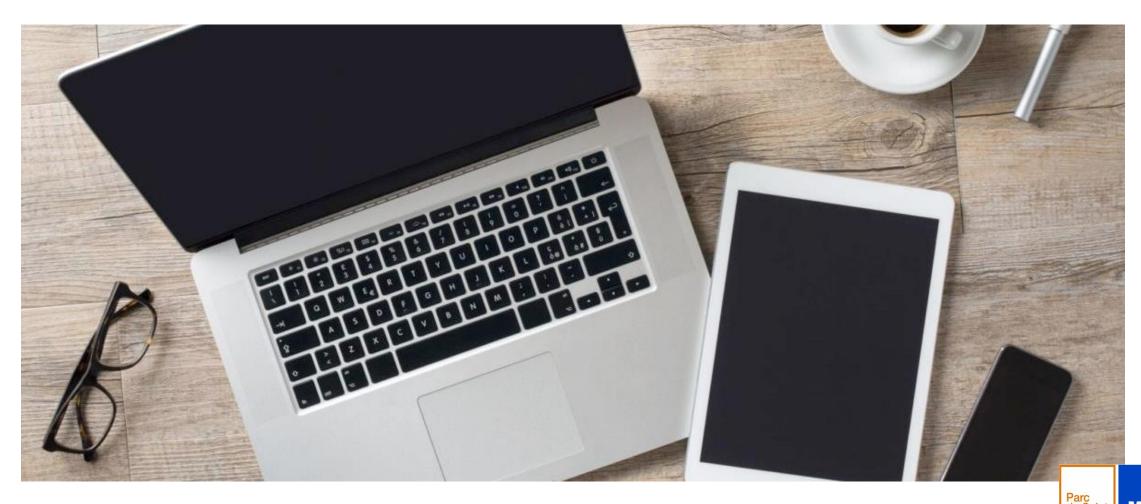
**E-consults** 

**Implantables** 

**Second opinion consults** 



## Telehealth and osteoporosis





### https://www.iofbonehealth.org/news/covid-19-and-osteoporosis

Home - News & Multimedia - News Stories -

### COVID-19 and osteoporosis

MARCH 25, 2020

Stay safe and well informed. Here we provide some helpful information for older adults and people with osteoporosis.



This article can be read in French, Japanese, Spanish, Russian, Mandarin\*, Malay\* and Farsi. As well, an Arabic-language video on COVID-19 & Osteoporosis is available (courtesy of the Saudi Osteoporosis Society)



### Clinical assessment: Initial

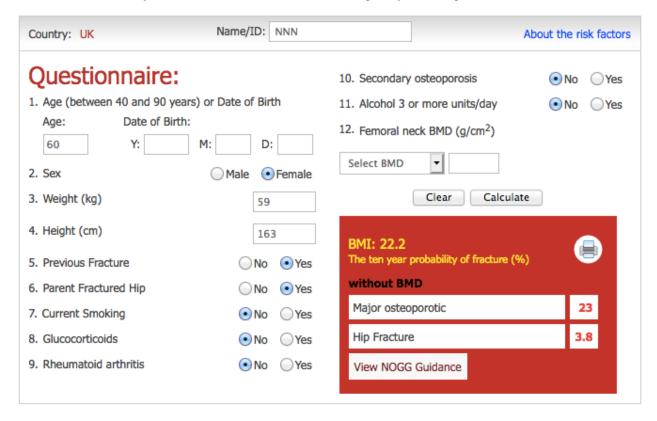
### Anamnesis

- Family history
- Previous fractures
- Risk factors (modifiable/non-modifiable): age, gender, physical activity, falls,...
- Social support, isolation, pain, depression, etc.
- Comorbidities, etc.



#### **Calculation Tool**

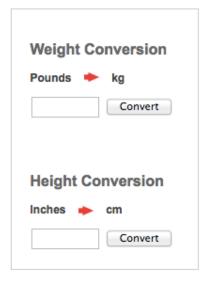
Please answer the questions below to calculate the ten year probability of fracture with BMD.







English



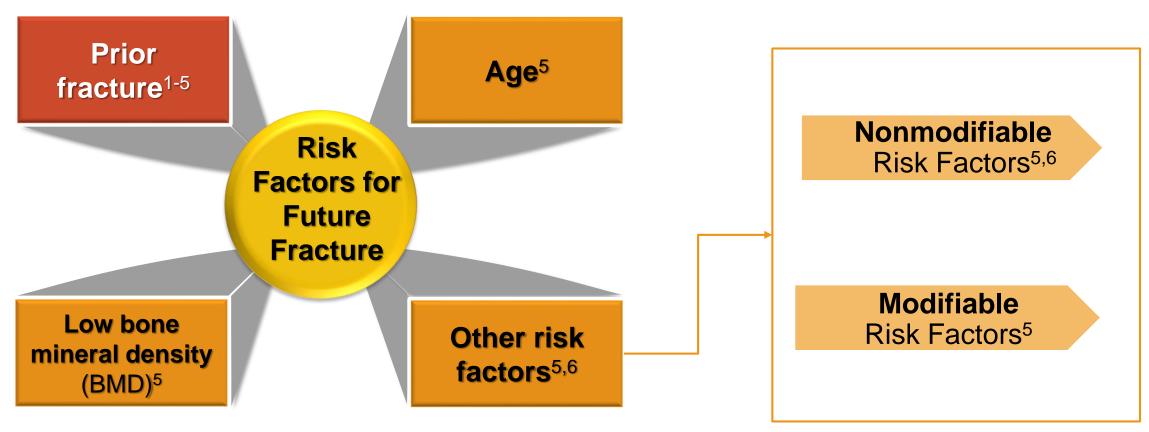
07424638 Individuals with fracture risk assessed since 1st June 2011

theros.org.uk



#### Risk factors

## Prior Fragility Fracture Is an Important Predictor of Future Fracture Risk, Along With Other Risk Factors



#### BMI=body mass index

Kanis JA, et al. Bone. 2004;35:375-382.
 Kanis JA, et al. Lancet. 2002;359:1929-1936.
 Black DM, et al. J Bone Miner Res. 1999;14:821-828.
 Eisman JA, et al. J Bone Miner Res. 2012;27:2039-2046.
 Cosman F, et al. Osteoporos Int. 2014;25:2359-2381.
 US Department of Health and Human Services. Bone health and osteoporosis: a report of the surgeon general. 2004. Rockville, MD.



## Recent Guideline Updates Provide Consistent Understanding of Fracture Risk

### **VERY HIGH RISK\***

If one or more of the below is true<sup>†</sup>:

- ☐ Fx within past 12 months<sup>1,4</sup>
- ☐ Multiple Fxs<sup>1-3§</sup>
- $\Box$  Fx while on OP Tx<sup>1</sup>
- ☐ Fx while on medication harmful to bone¹
- □ Very low T-score  $< -3.0^{1-3}$ §
- FRAX probability >30% MOF, >4.5% hip<sup>1,4</sup>

#### **HIGH RISK\***

If any of the below is true<sup>†</sup>:

- Age: postmenopausal<sup>1-4</sup> +
- $\Box$  Prior Fx (>12 mos) or<sup>1-3</sup>
- □ T-score  $\leq -2.5$  or<sup>1-3</sup>
- T-score -1.0 to 2.5
   and FRAX probability
   ≥20% MOF or ≥3% hip<sup>1-3</sup>

#### **LOW RISK\***

If all of the below are true<sup>†‡</sup>:

- ☐ Age: postmenopausal<sup>2,3</sup>
- $\Box$  No prior Fx<sup>2,3</sup>
- ☐ T-score > 1.0 and FRAX probability <20% MOF and <3% hip<sup>2,3</sup>

BMD = bone mineral density; FRAX = Fracture Risk Assessment Tool; Fx = fracture; MOF = major osteoporotic fracture; OP = osteoporosis; Tx = treatment. \*Regional and local guidelines may override certain of these criteria based on differences in FRAX data and cost-effectiveness thresholds. † If FRAX not available, major determinants of risk should include age, BMD, fractures, and medication harmful to bone. ‡ IOF-ESCEO defers to local guidelines for definitions of low risk.§ENDO requires both risk factors to be met for very high risk categorization 1.Camacho PM, et al. Endocr Pract. 2020;26:564-570. 2. Shoback D, et al. J Clin Endocrinol Metab. 2020;105(3):1-8. 3. Eastell R, et al. J Clin Endocrinol Metab. 2019;104:1595-1622.4. Kanis JA, et al. Osteoporos Int. 2020;31:1-12.

#### Clinical assessment: Follow up

- Anamnesis
  - New or worsening symptoms
  - Physical activity, falls, diet
  - Social support, isolation, depression, etc.
- Medication compliance
- Renew/change prescriptions
- Criteria for referral



## Considerations during Telehealth visits for patients with osteoporosis

 Importance of continuing therapy in patients with established bone health plans



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 Importance of continuing therapy in patients with established bone health plans

 In patients with new fracture who require DXA and lab tests to initiate therapy – consider alternate options for delivery of care



## Considerations during Telehealth visits for patients with osteoporosis

- Importance of continuing therapy in patients with established bone health plans
- In patients with new fracture who require DXA and lab tests to initiate therapy – consider alternate options for delivery of care
  - DXA may not be needed depending on type of fracture (i.e.
  - Use of online risk calculators to aid in decision making (i.e. FRAX, Garvan, American Bone Health)



## ASBMR, Endocrine Society, ACE, ECTS: Recommendations Apr 14, 2020 | Webinar

## ASBMR Webinar Panel on Treating Patients with Osteoporosis During the COVID-19 Pandemic

Matthew Drake, M.D., Ph.D., Mayo Clinic, Rochester, Minnesota, USA, Doug Bauer, M.D., University of California, San Francisco, California, USA, Bart Clarke, M.D., Mayo Clinic, Rochester, Minnesota, USA, Elena Tsourdi, M.D., Technische Universität Dresden, Germany, Elaine Yu, M.D., MMSc, Massachusetts General Hospital, Harvard Medical School, Boston, USA



#### ASBMR, Endocrine Society, ACE, ECTS: Recommendations

#### Denosumab:

Consider a delay in treatment.

If the delay exceeds one month, consider a temporary transition to an oral bisphosphonate.

• Teriparatide, abaloparatide, or romosozumab:

Consider a delay in treatment.

If the delay exceeds three months, consider a temporary transition to oral bisphosphonate.

• IV bisphosphonate:

Delays (even months) unlikely to be harmful.



#### What about our patient?



#### The patient

- She recovered from the infection in 6-7 days
- Fever and respiratory symptoms disappeared
- Denosumab dose was delayed for an extra week
- The drug was self-injected by the patient: easy and approved in all countries (except USA)



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- The drug was self-injected by the patient: easy and approved in all countries (except USA)
  - No need to contact with providers, health facilities, other patients, etc...
    - Avoids risk of transmission



#### Future development of telehealth

#### Expansion of telehealth in Europe



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News

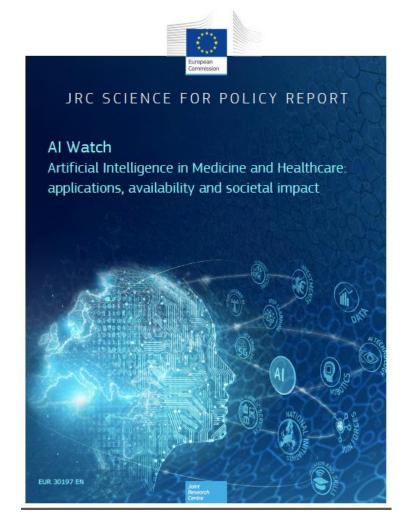
Research & Innovation News

# Telehealth services experiencing an explosion of demand due to the coronavirus

20th March 2020



#### Artificial Intelligence in Medicine and



Gómez-González, E. and Gómez, E., Artificial Intelligence in Medicine and Healthcare: applications, availability and societal impact, EUR 30197 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-18454-6,

https://ec.europa.eu/jrc/en/publication



#### EU JRC Science for Policy Report

- Artificial Intelligence (AI): a subfield of computer science where machines can imitate human intelligence
- In the USA, AI applications in Medicine can save \$150 billion in annual health costs by 2026

**Future applications** 

Fields to explore

Issues

**Potential risks** 



#### Conclusions

- COVID-19 has changed the paradigm of face-to-face visits with patients
- Decreased access to physicians during COVID-19 highlight the importance of telemedicine to ensure care continuity and fracture risk prevention
- We are at the beginning of telemedicine and AI applications in medical care

Be warm, compassionate and close to your patient!



#### Thank you very much for your attention





### Q&A



**Prof Nicholas Harvey** 



**Prof Thierry Thomas** 



Prof Adolfo Diez-Perez



#### THANK YOU

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

with support from Amgen Europe



