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Medical care circuits for postmenopausal patients in Spain

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Summary

Objectives: To reach a consensus on the medical care circuits of patients with postmenopausal osteoporosis (PMO), including derivation and management (assessment tools and medical tests), identifying profiles according to the opinion of bone metabolism experts, from Spain's Health Service.

Material and methods: The Delphi technique was used with two successive consultation rounds, with 38 experts in PMO management belonging to 14 scientific societies taking part in the study. Review of literature and the opinion of the scientific committee rounded out the questionnaire. The experts expressed their "desire" (1=total rejection, 9=stronger desire) and "forecast" (1=will absolutely not occur; 9=will occur with maximum probability) about the issues raised. A consensus was reached when 75% or more of the participants scored 1-3 (disagreement) or 7-9 (agreement). In addition, experts were divided up into 3 discussion groups to complement the information according to patient profiles found previously in the Delphi method.

Results: Consensus was reached on 75% of the questions. The experts established three profiles of PMO patients: no fracture, vertebral fracture and non-vertebral fracture, as well as the diagnostic and therapeutic resources recommended for these patients.

The patient without a fracture should be managed in Primary Care or Rheumatology and scales will be used to evaluate fracture risk in early stages of the disease. The patient with chronic vertebral fracture should refer to Rheumatology and Rehabilitation, and will be Rheumatology, whereas the patient with acute vertebral fracture should be treated in Orthopedic Surgery, and this is how it will possibly happen. Diagnosis of vertebral fracture patients will be based mainly on x-rays.

To assess progress, questionnaires on the functional capacity and pain scales are recommended. However, these will not be used due to the lack of time involved. The patient with non-vertebral fracture should be and will be referred to Orthopedic Surgery, with 3-4 radiographs recommended to ensure fracture consolidation.

Conclusions: Delphi method results indicate that referral of PMO patients are concentrated in Primary Rheumatology, when there is no fracture, and Orthopedic Surgery, in the case of fracture.

Key words: *postmenopausal osteoporosis, vertebral fracture, non-vertebral fracture, derivative circuits.*

Introduction

Osteoporosis is a global health problem with clinical, economic and social consequences that mainly affect postmenopausal women¹. More than 200 million people have osteoporosis, and the aging of the population may increase in this prevalence².

The most significant clinical manifestations of osteoporosis are fragility fractures, especially those of the hip, spine, forearm and humerus. However, other fractures in patients older than 50 years are considered osteoporotic, including tibia, pelvis and femur³.

In Europe, in 2000, an incidence of 3.1 million osteoporotic fractures was estimated in men and women over 50 years of age, with 620,000 hip fractures, 574,000 in the forearm, 250,000 in the proximal humerus and 490,000 vertebral fractures, among others, representing 34.8% of all osteoporosis fractures worldwide³. In 2010, the number of new fractures amounted to 3.5 million, and this number is expected to increase by 28%, with 4.5 million fractures in 2025¹.

In Spain, 35% of women over 50 years of age are affected by osteoporosis, a percentage that increases to 52% in those older than 70 years⁴. Additionally, almost 50% of women with postmenopausal osteoporosis (PMO) present one or more risk factors for osteoporotic fractures⁵, which explains an estimated incidence of 250,000 osteoporotic fractures per year, representing direct and indirect costs of osteoporotic fractures. 126 and 420 million euros, respectively⁶.

Spain is one of the countries with one of the most efficient National Health Systems, offering two well differentiated levels of care, Primary Care (PA) and Specialized Care. In general, Primary Care is the gateway to the system, except in the case of emergencies. However, given the decentralization of health services in each of the Autonomous Communities, the coordination between these two levels of care may not be as homogeneous as expected⁷.

Rheumatology (RHEU), Obstetrics and Gynecology (GYN) and Orthopedic Surgery and Traumatology (OST) are some of the specialties involved in the management of PMO. However, there is little national or international information on the referral circuit for patients with osteoporotic fractures and the professionals involved^{8,9}. The lack of consensus on referral protocols between specialized units in the management of different profiles of patients with PMO has revealed the importance of defining roles and establishing joint action protocols between specialties^{10,11}. The absence of these protocols may make it difficult to establish adequate treatments and obtain clinical benefits for patients^{8,12}.

In qualitative research, there are different methodologies available to generate discussion among experts that results in the convergence of opinions and the deduction of consensus. The Delphi technique is an efficient technique for exploring policy issues, with the aim of organizing

communication between groups to reach consensus on a particular topic¹³⁻¹⁵. On the other hand, the discussion group is a methodology that allows exhaustive approaches to a specific topic of study, where participants' perceptions facilitate in-depth understanding of the issues under study, based on the experiences and beliefs of the participants¹⁶⁻¹⁸.

The aim of this study was to reach a consensus on the medical care circuits of the patient with PMO, including the circuits of derivation and management (evaluation tools and medical tests), identifying profiles according to the opinion of experts in bone metabolism who work in Spain's Health System.

Material and methods

The Delphi technique was used with two successive rounds of consultation. In addition, three discussion groups, according to the profile of the patient with PMO, were carried out to complement the conclusions reached by this method (Table 1). These societies were responsible for selecting the participants in the study, according to the following criteria: working in the Spanish National Health System, experience related to PMO and availability to participate in the study. Thirty-eight medical specialists, experts in the clinical and therapeutic management of patients with PMO, with extensive experience in PMO prevention, diagnosis, treatment and follow-up in Spain's public health system were invited to participate. These experts belonged to different medical specialties: PC (n=6), OST (n=6), Endocrinology and Nutrition (END) (n=3), Geriatrics and Gerontology Rehabilitation (REH) (n=3), Internal Medicine (MI) (n=5), GIN (n=6) and REU (n=6). None of the participants received remuneration for responding to the questionnaire.

The Delphi Survey Method

The Delphi technique is a consensus method whose goal is to achieve general agreement or convergence of opinion on a particular topic. It is based on a highly-structured group interaction to collect data through self-completed questionnaires by participants¹⁹.

The questionnaires used during the two consultation rounds were elaborated and designed by the coordinating team of the study, under the supervision of the scientific committee or study group of the study, made up of 6 medical professionals with extensive experience, either in the management of the patient with PMO or in the study methodology. They were a series of questions that the interviewee had to rate according to a Likert scale. The content of the statements came from the systematic review of the literature⁸ and contributions from the scientific committee (Figure 1). Likewise, time was allotted so participants could comment and make suggestions on the issues raised.

The questionnaire used during the first round consisted of 35 questions, each consisting of 1 to 10 questions. The issues were organized into 5

blocks: general aspects; PMO (primary prevention, diagnosis, treatment, follow-up and rehabilitation of the patient); Fractures in PMO patients (diagnosis and outpatient fracture management, fracture hospital admission and prevention of a second fracture); derivation circuits; and observations and comments. The questions explored different aspects associated with the prevention, diagnosis, treatment and follow-up of the patient with PMO with and without fracture, as well as the criteria that should be followed to derive patients among professionals.

According to the different profiles of patients with PMO (with and without fractures) and their clinical situation, the questionnaire presented various referral circuits in a way that defined the specialties that should be involved in its driving. In addition, the use of assessment tools and medical tests was also explored in these patient groups.

Participants rated the questions on a 9-point Likert scale, according to each of the questions presented, from two perspectives: "desire" (1=total rejection, 9=strongest desire) and "prognosis" (1=no will occur at all, 9=will occur with maximum probability). A consensus was reached when at least 75% of the participants scored the questions between 7-9 (agreement) or between 1-3 (disagreement) (Figure 2).

The questionnaire used during the second round was individually designed for each of the experts. It contained those issues for which no consensus was reached during the first round, as well as the suggestions made by participants. The questionnaire presented the participant's own individual scores and the position described by the majority of the group (rank in which was the highest percentage of answers), for each of the questions. After considering these qualifications, the respondents re-scored the questions, having the opportunity to either re-award the previous grade or modify their initial responses in accordance with the results shown, in order to reach a consensus at the maximum number of questions. Thirty-seven experts participated in the second round, since one of the subjects decided not to continue in the study.

The questionnaire used during the first round of the Delphi method was answered using a restricted access web platform (June 2011), while the second-round questionnaire was sent and received via email (September 2011).

Study Groups

Taking into account the conclusions obtained through the Delphi technique, and to define and complement them with aspects not explored in

Table 1. Scientific Societies collaborated in this study

Spanish Society of Bone and Mineral Metabolism Research (SEIOMM)
Spanish Society of Rheumatology (SER)
Spanish Association for Research into Menopause (AEEM)
Study Group on Osteoporosis of the Spanish Society of Orthopedic Surgery and Traumatology (GEIOS-SECOT)
Spanish Society into Osteoporotic Fractures (SEFRAOS)
Spanish Society of Endocrinology and Nutrition (SEEN)
Ibero-American Society of Osteology and Mineral Metabolism (SIBOMM)
Osteoporosis Study Group of the Spanish Society of Internal Medicine (GTO-SEMI)
Spanish Society of Family and Community Medicine (SEMFYC)
Spanish Society of Primary Care Physicians (SEMERGEN)
Spanish Society of General and Family Physicians (SEMG)
Spanish Society of Rehabilitation and Physical Medicine (SERMEF)
Spanish Society of Geriatrics and Gerontology (SEGG)
Hispanic Foundation of Osteoporosis and Metabolic Diseases (FHOEMO)

detail, three discussion groups were held with the participating experts. Three meetings were defined according to the three profiles of PMO patients that emerged from Delphi responses. Each discussion group consisted of 6 to 8 experts, according to the most representative specialties due to their involvement in each of the profiles (Table 1):

- a) patient with PMO without fracture: AEEM (n=1), SEMERGEN (n=1), SEMFYC (n=1), SIBOMM (n=1), SEMG (n=1), y SEIOMM (n=1).
- b) patient with PMO with vertebral fracture: SEIOMM (n=1), FHOEMO (n=1), SEEN (n=1), GTO-SEMI (n=2), y SER (n=1).
- c) patient with PMO with nonvertebral fracture: SECOT-GEIOS (n=2), SEFRAOS (n=2), SEGG (n=2), y SERMEF (n=2).

Our aim was to explain and define the habitual referral circuits of the patient with PMO according to the specialties available in each center, and to specify the frequency of use of assessment tools and medical tests during the follow-up of the PMO according to the profile of the patient. Participants in the Delphi method were invited to take part in the discussion groups according to the specialties mainly involved in managing each patient profile: GIN n=2, IM n=1, PC n=3; Patient with vertebral fracture (IM n=3, REU n=2, END n=1); Patient with non-vertebral fracture (OST n=4, GER n=2, REH n=2).

Results

In all, 100% (n=38) of the experts invited to participate in the study responded to the questionnaire in the first round, whereas 97.4% (n=37) did so during the second round. The experts participating in the study had an average of 24 years (SD=9) of experience in the clinical practice of their specialty, an average of 18 years (SD=8) involved in the management of patients with PMO and visited a median of 40 patients with PMO per month (Range: 10 - 200).

A consensus was reached in 75% of the questions posed by the Delphi technique, 73.6% from the "desire" perspective and 76.4% from the "prognosis" perspective.

As a result of the comments provided by the Delphi participants in the space provided in the questionnaire for this purpose, three distinct profiles of patients with PMO were identified: patients without fracture, those with vertebral fracture and those with non-vertebral fracture.

Patient with PMO without fracture

Derivation Circuits

In Delphi, experts reached consensus that AP (83.3%) and Rheumatology (77.8%) should be the specialties preferably involved in managing patients with PMO without a fracture, without achieving a consensus in the "prognosis" (Figure 3). Additionally, in the discussion group it was detailed that, in clinical practice, the high prevalence of this patient pro-

Figure 1. Diagram of the study methodology

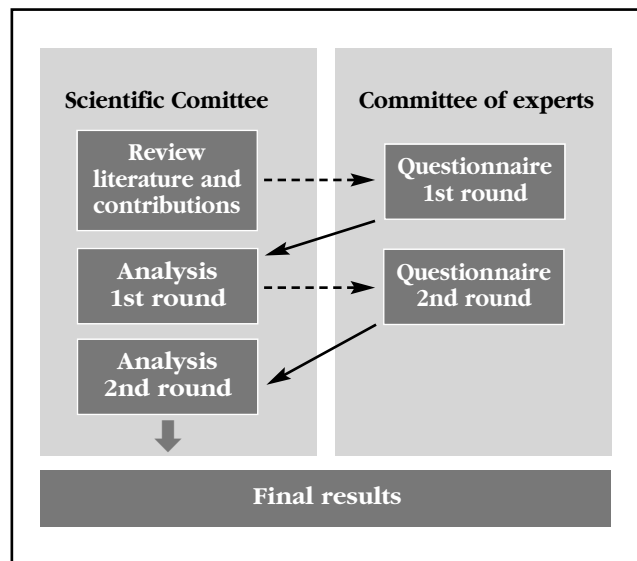
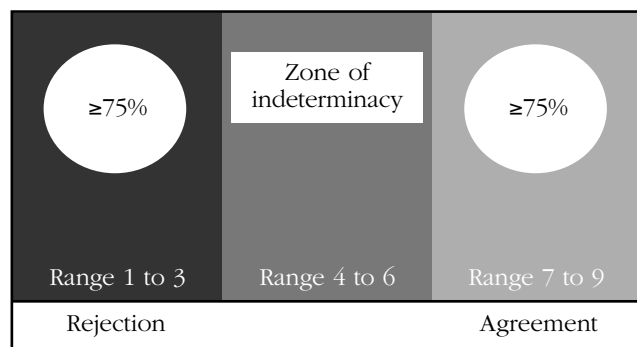


Figure 2. Definition of consensus



file implies that the described specialists would not be able to treat the entire population, so these patients should be managed by PA when Possible without being referred to other specialties. Moreover, GER should be the specialty responsible for the management of elderly patients when possible, and in case of absence of Geriatrics Service in the health center, these patients should be followed by PA.

Regarding clinical situations such as early symptomatic or surgical menopause, Delphi demonstrated that these patients should be and will be referred to Gynecology (86.5% and 83.3%, respectively) (Figure 3). The discussion group added that in the event that this clinical situation is associated with thyroid disease, the patient should be referred to NDT.

In the Delphi consultation, the experts reached consensus in both "desire" (78.4%) and "prognosis" (75.78%) that REU should be and will be the reference specialty of patients with PMO and high risk of fracture. The discussion group argued that AP should be the reference specialty, but in case patients require specific treatment or monitoring that cannot be assumed by PA, the reference specialty would become Rheumatology or a specialized referral unit (when available).

When patients with PMO present a significant loss of bone mineral density despite receiving pharmacological treatment, REU should be (81.1%) and (88.9%) the reference specialty; While in patients with poor physical condition, muscle weakness, functional restriction, risk of falls, need for orthopedic evaluation, vertebral deviation or chronic refractory incapacitating pain, Delphi participants pointed out that REH should be the reference specialty (up to 80%), Without reaching consensus in the "prognosis" perspective (Figure 3).

Assessment Tools

The experts indicated that the osteoporosis evaluation scales should be used (89.2%), without reaching a consensus in the "prognosis". In addition, therapeutic adherence (89.2%), fracture risk (88.9%) and functional capacity (78.4%) should be evaluated during follow-up of patients with PMO, reaching consensus in the "prognosis" (Only with respect to the use of fracture risk scales (75.7%). In addition, the discussion group recommended and specified the frequency with which these tools should be administered: the Morisky-Green questionnaire should be used to assess adherence one month after the start of treatment and during each follow-up visit; FRAX® or QFracture® would be used to assess the risk of fractures in the early stages of the disease (prior to initiating drug treatment); The functional capacity would be evaluated during the initial visit and annually, without specifying any specific tool (according to availability); Analogue visual scales for examining pain should be applied as often as possible. It was commented that no tool is usually used to evaluate satisfaction with treatment, indicating that it is usually not evaluated; No specific instrument is used to assess health-related quality of life (HRQL), indicating that it is only assessed during clinical research. In all cases, the results of these evaluations should be incorporated into the patients' medical records.

Medical Tests

Regarding medical tests, the results of the Delphi method showed that the bone densitometry, used for the evaluation of the evolution of the PMO, should be performed in periods less than two years. However, no consensus was reached on the definition of a specific period. For its part, the discussion group specified that it would be necessary to perform a bone densitometry and a dorso-lumbar x-ray every two years and to measure the size of the patient at each visit.

Patient with PMO and vertebral fracture

Derivation Circuits

In patients with acute vertebral fracture, the Delphi consultation indicated that OAT should be the reference specialty from both perspectives ("desire": 86.5% and "prognosis": 80.6%) (Figure 3). The discussion group established that in case of hospital admission, OST should be the specialty, but that the management of the patient with PMO should be under the responsibility of REU, IM or GER, or of a Bone Metabolism Unit or Fracture Liaison Service (FLS), where available.

In patients with chronic vertebral fractures, the experts pointed out in the Delphi that REU (83.8%) and REH (77.8%) should be the reference specialties. However, all patients will be referred to REU (75%) (Figure 3). The discussion group indicated that the patient diagnosed with PMO with chronic vertebral fracture should be managed by REU and REH.

In addition, in the discussion group, the experts mentioned that COT together with the specialists in bone metabolism should diagnose the vertebral fracture. Additionally, if the patient needed hospitalization, it would require multidisciplinary units (Fracture Unit or FLS). The experts detailed that these units should consist mainly of specialists in TOC and bone metabolism, as well as by REH, Pain Unit (if available) and GER or IM (for the management of clinical situations that are not exclusive to bone metabolism, such as co-morbidities) (Figure 4). As for outpatient management of vertebral fractures (including treatment), the Primary Care unit should be responsible, should there be experienced staff. Otherwise, the patient should be referred to an expert in bone metabolism. Finally, the specialist diagnosing vertebral fracture should be involved in the prevention of subsequent fractures.

The discussion group also pointed out that REH should be the reference specialty in the case of patients with vertebral fracture and functional restriction secondary to immobilization and pharmacological treatment, or if orthopedic measures are required. Those patients with vertebral fracture and chronic pain refractory to pharmacological treatment should be managed by two groups of specialists, Unit of Pain (or IM, depending on availability) in coordination with REH for pain management and by REU in coordination with IM or experts in bone metabolism (depending on hospital availability).

Assessment Tools

For the evaluation of the progression of the patient with fracture, questionnaires should be used on functional capacity (83.9%) and pain scales (80.7%); However, in Delphi, no consensus was reached on the "prognosis". The discussion group explained that functional capacity, pain and HRQoL are usually measured in the clinical research setting, but in standard practice this involves substantial time investment, although it is considered to be very useful.

Medical Tests

The diagnosis of fracture should be based on radiographs (97.3%), symptoms (89.2%), physical examination (86.5%) and medical history (83.7%). From the "prognosis" perspective, the experts mentioned that the diagnosis of fracture will be based on radiographs (91.9%), symptoms (83.8%), and physical examination (83.8%). The discussion group concluded that the most important medical tests to evaluate the patient with vertebral fracture should include radiographs and bone densitometry during the first year and size (measured by stadiometer) at each medical visit. Subsequently, a bone densitometry every two or three years.

Patient with PMO and without vertebral fracture Derivation Circuits

In the Delphi consultation, OST was mentioned as the reference specialty for patients with non-vertebral fracture (hip or distal radius) and with acute femoral fracture (100% for both perspectives), and for patients with fractures in other locations ("desire": 91.7% and "prognosis": 94.4%) (Figure 3).

The discussion group established that during the acute phase OST should be the reference specialty. The diagnosis of non-vertebral fracture in patients with PMO should be performed by OST in such a way that the severity of the fracture can be assessed and appropriate treatment and rehabilitation recommended. Hospital admission requires multidisciplinary units (Fracture Unit or FLS) that include OST, REH, GER or IM, Social Services and Nursing (Figure 5). Primary care should be involved in the outpatient management of these patients once the acute process has been controlled. In addition, PC should be the specialty in charge of preventing successive non-vertebral fractures.

Assessment Tools

Experts agreed in the focus groups that functional capacity should be systematically evaluated until stability is achieved. Minimal revisions should be made at the beginning, during and at the end of the fracture process. The evaluation of HRQoL should be done systematically, although the experts recognize that it consumes a lot of consultation time.

Medical Tests

The experts recommended 3 to 4 radiographs per year (first, third, sixth and twelfth month), especially when the fractures are located in the hip or tibia, in such a way as to ensure consolidation of the fracture after discharge.

Discussion

This study provides new information on referral circuits and specialties that should be involved in the management of patients with PMO with and without fracture. To define reference criteria between specialties, it has been shown that a distinction should be made between the type and location of fractures, defining three patient profiles: patients without fracture, vertebral fracture, and non-vertebral fracture.

The most significant conclusion obtained from the consensus is the importance of defining bypass circuits that should be followed during each phase of the management of patients with PMO according to the profile of each patient and their clinical situation. However, discussion groups have pointed out that in clinical practice the selection of the referring physician and the patient care process depends on the local availability of the services.

The high prevalence of patients with PMO without fracture makes it difficult for specialties such as REU to assume full responsibility for their management; Therefore, much of the attention to this population is delegated to Primary Care. However, the extensive knowledge required for this task and the constant overload of work to which PC

professionals are subjected means that monitoring of patients with PMO in clinical practice depends greatly on the situation of the health center, staff availability and professional experience²⁰.

Regarding patients with PMO and vertebral fracture, the experts point out that it is necessary to involve different specialties, highlighting the role of orthopedic surgeons and experts in bone metabolism in the diagnosis of fracture. The availability of experts in bone metabolism, defined as "the specialists with the most knowledge about osteoporosis in the health center", will depend on the local situation of each center. From the point of view of patient management, the acute or chronic nature of the fracture leads us to consider a distinction of roles between the different specialties. In the consensus of experts, the OST should be and will continue to be the reference specialty in the case of acute fracture. On the other hand, in the supplementary discussion groups, experts emphasize the importance of OST in those patients requiring hospital admission, whereas REU, IM or GER and Bone Metabolism Units would be the specialties of choice for fracture management. Finally, REU and REH would be the reference specialties for patients with chronic fractures. This may be explained by the differences of opinion in the experts regarding the management of the PMO itself, which requires specialists with high knowledge on osteoporosis, its treatment and associated comorbidities; as well as in terms of fracture management, which will require knowledge about fracture treatment and pain control, a distinction of knowledge clearly identified in the literature^{21,22}.

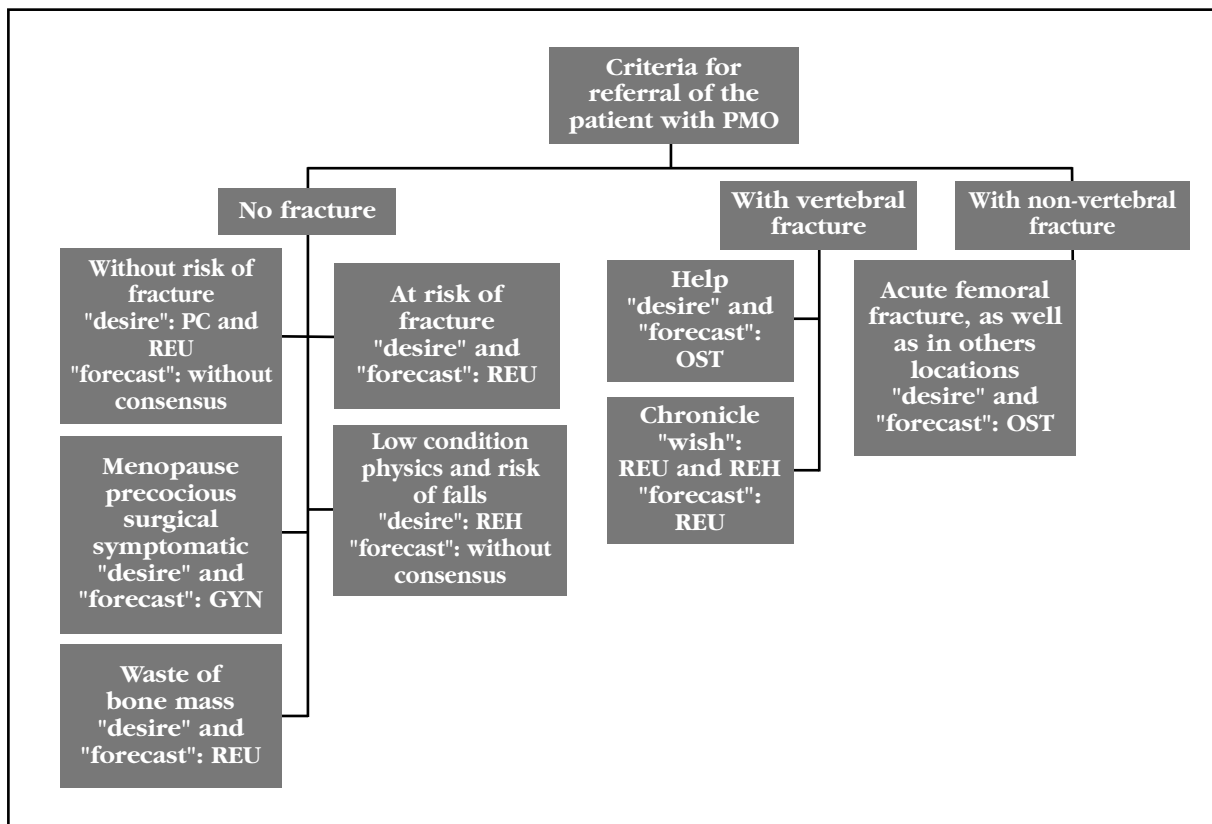
Furthermore, patients with non-vertebral fracture should be referred to OST for stabilization of the fracture, but Primary Care should be responsible for its management and follow-up once the acute process is completed. Another fundamental aspect identified by the experts is the need to create multidisciplinary units for the management of patients with PMO and fractures, particularly during hospital admission (Fracture Unit or FLS). The creation of these multidisciplinary teams could be useful in the design of new strategies to optimize the use of health resources and improve the clinical management of patients with PMO^{23,24}. Fracture Units or FLS provide clinically and cost-effective care in patients with osteoporosis with fragility fractures²⁵. In Glasgow, UK, the Fracture Unit has contributed to a 7.3% reduction in hip fractures over 10 years, compared with a 17% increase in England²⁵. In Italy, the implementation of a Fracture Unit made up of multidisciplinary teams has been shown to reduce major complications from 21% to 45%, while readmissions to the hospital at 6 months decreased by 20% and the mortality rate by 3%²⁶. Patients treated at the Fracture Unit in the Netherlands had a significantly lower mortality and a lower risk of non-vertebral fractures than those not treated in this service, with a reduction of 35% and 56%, respectively, for more than two years follow-up²⁷. Therefore, the Fracture Unit or FLS seems to be a successful

method for reducing the number of subsequent fractures and premature mortality after fracture.

Coordination among specialists is paramount during the management of patients with PMO and fractures, since the specialist who must assume patient management once the fracture has consolidated is still not defined. This lack of standardization of roles of each specialist may be associated with a delay in the treatment of this patient profile¹². Therefore, programs are needed for the detection and study of patients with fractures, who establish guidelines for care and follow-up²⁸.

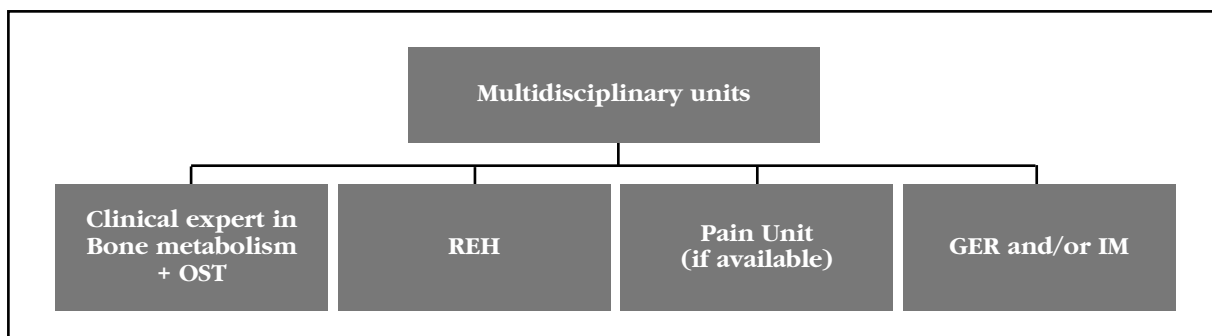
Finally, another aspect highlighted in this study is the need to use and standardize evaluation tools to explore the evolution of the patient with PMO, as well as the risk of fractures, functional capacity, pain, therapeutic adherence, treatment satisfaction or HRQL. Regarding this last aspect, the experts identified the work overload as the cause of the insufficient use of HRQL measurement instruments in the usual clinical practice. However, the recommendations arising from the discussion groups allow establishing minimum requirements for the future.

Figure 3. Consensus reached ("desire" and "prediction") in the Delphi Method concerning the derivation circuits of the patient with PMO



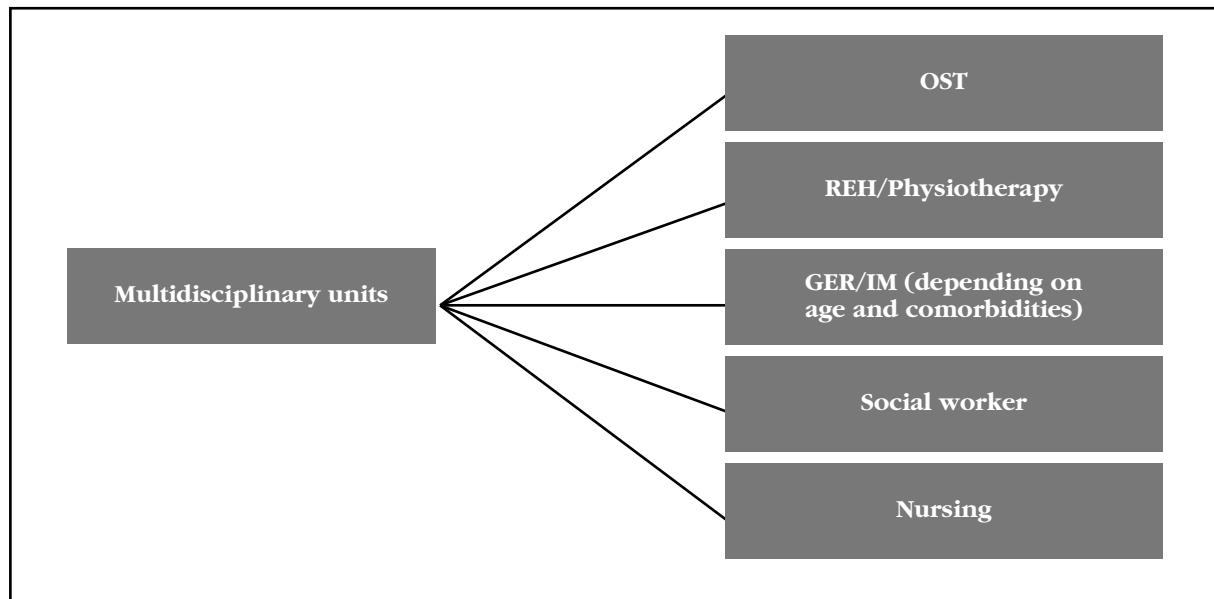
PMO: postmenopausal osteoporosis; PC: Primary Care; OST: Orthopedic Surgery and Traumatology; REU: Rheumatology; REH: Rehabilitation; GYN: Obstetrics and Gynecology.

Figure 4. Specialties proposed in the study group of experts for the formation of multidisciplinary units in managing the patient with vertebral fracture



OTS: Orthopedic and Traumatology Surgery; REH: Rehabilitation; GER: Geriatrics and Gerontology; IM: Internal Medicine.

Figure 5. Specialties proposed in the discussion group of experts for the formation of multidisciplinary units in the management of patients with non-vertebral fractures that require hospitalization



OST: Orthopedic Surgery and Traumatology; REH: Rehabilitation; GER: Geriatrics and Gerontology; IM: Internal Medicine.

The study is subject to the advantages and disadvantages of the consensus technique used^{29,30}. The characteristics of the Delphi technique allow minimizing reciprocal influence among the participants and allow a good functioning with a heterogeneous group of participants, also preserving their anonymity¹⁹. The participation of physicians of different specialties involved in the management of patients with PMO reflects the usual practice and provides extensive information on the clinical and therapeutic management of osteoporosis. However, the panel of experts may not necessarily be representative of the usual clinical practice in Spain, given the differences between Autonomous Communities. Thus, the information presented must be analyzed in context, since the data included represent the Spanish population and may not be extrapolated to other populations. Another limitation of this study is that the list of items presented in the questionnaires reflects the scientific evidence and the opinion of the experts at the time of its elaboration and may require an update as soon as new scientific information on the management of patients with PMO. However, there are still gaps in the medical care of the patient with fracture and the referral of patients with difficulties to the corresponding specialists³¹. Therefore, the information provided by this study contributes to the literature on managing patients with PMO. It highlights the multiple opportunities for improvement in the field of follow-up of patients with PMO.

On the one hand, the lack of referral circuits per patient profile in each department or health area and, on the other hand, the need to specify the criteria for conducting clinical tests and evaluating patient-centered results for each profile. In

conclusion, the information gathered in both Delphi and in the discussion groups provides a guide to optimize patient care with PMO in Spain's Health System.

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Conflict of Interest: Authors Javier del Pino Montes, Josep Blanch, Xavier Nogués, María Jesús Moro and María del Carmen Valero declare that they have no conflict of interest in this study. Laura Canals works in Amgen S.A. Luis Lizán works for an independent research institution and was paid compensation for his contribution in developing and coordinating the original Research Project, as well as for the drafting of this manuscript.

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