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## Ukrainian FRAX: criteria for diagnostics and treatment of osteoporosis

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**Abstract. Background.** Nowadays, FRAX® algorithm is an informative method for evaluation of the risk of osteoporotic fractures, implemented in European and American guidelines for osteoporosis management. However, there are differences in “intervention thresholds” for antiosteoporotic treatment, which depend on the country, the model of health care system and the reimbursement for treatment. Ukrainian version of FRAX appeared in Ukraine in 2016, but the thresholds for intervention have not yet been developed. The purpose of the study was to determine the “thresholds” for the pharmacological treatment of osteoporosis and for additional diagnostic examination of Ukrainian population using national FRAX model. **Materials and methods.** 3790 outpatients aged 40–90 years (mean age 61.9 ± 10.0 years) were examined. The development of the “thresholds” for intervention and additional assessment of the bone using dual-energy X-ray densitometry (DXA) based on the methodology adopted by the National Osteoporosis Guideline Group in UK, which is further used in European guidelines. **Results.** There was an increase of the “threshold” for pharmacological intervention (“upper threshold”) with age from 6.6 % at the age of 40 to 13 % at the age of 75–85 years. The “lower threshold” (threshold for additional examination) increased significantly from 2.4 % at the age of 40 to 6.9 % in women aged 85 years. The evaluation strategy begins with an analysis of the history of low-traumatic fracture. In its presence, a decision to start antiosteoporotic treatment without DXA should be made. In patients without history of fracture, calculation of fracture risk according to FRAX is required. When the risk exceeds the limit of the “upper threshold” antiosteoporotic treatment without DXA is recommended, when its values below the limit of “lower threshold” — additional examination or treatment is not required. In case of intermediate risk of fracture a DXA should be conducted with a reassessment of fracture risk and management tactics. **Conclusions.** The effectiveness of FRAX principles which uses in European guideline, but with particularities of the epidemiology of osteoporotic fractures in Ukraine, has been proved. Although this approach is cost-effective in other countries, its use in Ukraine may differ and may need to be further explored with an economic assessment of costs and benefits.

**Keywords:** FRAX®; osteoporosis; borderline intervention; treatment; diagnosis; risk of osteoporotic fractures

### Introduction

As of today, the timely diagnostics of osteoporosis and its complications is extremely important. In the recent years, FRAX® (Fracture Risk Assessment Tool) algorithm is an essential osteoporotic fracture risk measurement tool, ever-increasingly implemented into the clinical practice as an evaluation method of a 10-year probability (risk) of major osteoporotic fractures (hip and humerus, forearm and clinically important vertebral fractures) and, separately, of hip fractures for people aged 40 years and older [1].

At the present moment, it is established that the bone mineral density (BMD) parameter, measured by the dual-energy X-ray absorptiometry (DXA, previously DEXA), is a significant, though not unique, criterion of osteoporotic fracture risk assay. Furthermore, if during the 1990s its reduction ( $T \leq -2.5$  SD) was considered one of the key factors in favor of antiosteoporotic treatment's initiation, now it is confirmed that fractures may occur under ‘osteopenia’ or normal BMD values. In this regard, other factors gain more prominence at the moment; those referred to as ‘osteoporosis and osteoporotic fracture risk factors’ and contributing to the risk calculation. The studies of vari-

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ous osteoporosis risk factors and their roles provided a rich evidence base and helped establish their input into the fracture occurrence [2], laying ground for the FRAX algorithm. This algorithm enables the calculation of a 10-year probability of major osteoporotic and hip fractures, considering age, body mass index (BMI) and various clinical fracture risk factors, with/without femoral neck BMD.

The FRAX questionnaire development and validation is extensively described by the national and international authors [1, 3, 4, 5]. As of today, the calculation of a 10-year probability of osteoporotic fractures according to the FRAX is an important criterion of determining the treatment initiation and urgency of additional instrumental examination for the patients, described in the European and American guidelines [6, 7].

The healthcare providers started using the FRAX as tool of major osteoporotic fracture risk evaluation back in 2008, though its development was ongoing since the early 2000s [3]. At the Ukrainian Scientific Medical Center of Osteoporosis, the FRAX algorithm has been actively applied to evaluate the major osteoporotic fracture risk since 2010 [4]. Our studies based on the application of FRAX models, developed for other countries, to the Ukrainian men and women showed that in order to evaluate the fracture risk any models are applicable; however, it is the country-specific threshold values for treatment initiation or additional examination that are relevant [8, 9]. Furthermore, our findings reveal that the criteria used in the US (and some other) guidelines for the treatment initiation (20 or more for all osteoporotic fractures, and 3 or more for the hip fractures) may not be applied to assay the fracture risk of the Ukrainian population, because when the neighboring countries' models were applied (at that time, Ukraine had no model of its own), the received values were much higher [10]. In order to avoid this, we've developed and suggested our own intervention criteria, based on the Austrian FRAX model [8, 11], and those were successfully applied up to the original Ukrainian FRAX model's creation.

In the summer of 2016, the scientists of State Institution "D. F. Chebotarev Institute of Gerontology NAMS", Ukraine, and Ukrainian Scientific Medical Center of Osteoporosis adapted the questionnaire, originally drafted in English, to be used in Ukrainian. In the fall of the same year, thanks to the authors of the present paper, the newly-created Ukrainian model was posted on the official FRAX webpage (<https://www.sheffield.ac.uk/FRAX>). It was based on numerous epidemiological studies held during 1997-2002 and 2011-2012 by the members of the Ukrainian Association of Osteoporosis, with assistance of the Ukrainian Association of Orthopedists and Traumatologists. The national FRAX model was the first and only model able to forecast a 10-year risk of major osteoporotic fractures in the Ukrainian population. Its development was based on certain risk factor coefficients suggested by the original FRAX model, as well as age and sex-bound osteoporosis prevalence (including proximal hip fracture prevalence) values received during the epidemiological studies. While developing the model, the authors consid-

ered  $\beta$ -coefficient values to be similar to the ones earlier presented in the metaanalyses [3, 8].

At present, the FRAX algorithm is presented in the open online access (<http://www.shef.ac.uk/FRAX>), in 35 languages for 65 countries, with 71 models. It is a 12-item questionnaire, where the ultimate (and optional) item concerns the femoral BMD (Fig.1). As of now, over 25 thousand fracture risk calculations according to the Ukrainian FRAX model are made at the respective webpage.

As it was earlier mentioned, the key practical value of the FRAX for the clinical endeavors=lies in its major osteoporotic fracture prognostication capacity. However, considering the regional varieties, different approaches to the patient management, at present there are various criteria to the antiosteoporotic treatment initiation (intervention threshold) and the BMD values' evaluation (additional examination threshold). A recent systemic analysis published by a team of FRAX developers [5] presents the intervention thresholds of various populations, and the differences observed in countries with different models of healthcare provision and treatment cost rebates are rather significant. It is only recently the Ukrainian FRAX model obtained its own intervention thresholds, calculated according to the epidemiological context of major osteoporotic fractures. This is the subject of the present paper.

**The aim** of the present study is to establish the pharmacological treatment and additional diagnostic examination thresholds for osteoporosis based on the Ukrainian FRAX model.

## Materials and methods

In order to assess the pharmacological treatment and additional diagnostic examination thresholds for the osteoporotic fracture risk in the Ukrainian women, the scientists of State Institution «D. F. Chebotarev Institute of Gerontology NAMS of Ukraine», and Ukrainian Scientific Medical Center of Osteoporosis examined 3790 female outpatients, aged 40-90 years (mean age (M  $\pm$  SD) – 61.9  $\pm$  10.0 years). Of all the examined, 71 persons presented dubious data on the secondary osteoporosis underlying causes and thus were excluded from the study.

The study was approved by the Institute's Ethical Committee (17.05.2017, Protocol №5) and held from 05.2017 to 05.2019. All the examined signed a voluntary informed consent form to participate, being the subjects to the respective diagnostic examination procedures.

Of the examined women, 3209 (84.7 %) persons were postmenopausal (the mean age of menopause – 48.4  $\pm$  5.2 years, menopause duration – 15.3  $\pm$  8.9). The key anthropometrical parameters (height, weight) were measured by the routine tools, and the BMI index calculated according to a universal formula (the parameters were, respectively: height – 162.1  $\pm$  6.5 cm, weight – 73.1  $\pm$  14.5 kg, BMI – 27.8  $\pm$  5.3 kg/m<sup>2</sup>).

A 10-year probability of major osteoporotic fractures (MOF) and of hip fractures (HF) was calculated according to the Ukrainian FRAX version, presented at the

official FRAX webpage (<https://www.sheffield.ac.uk/FRAX>), with and without BMD measurement.

The DXA was used to measure the femoral neck BMD; the T- and Z-scores were calculated at the two machines (PRODIGY, GEHC Lunar, Madison, WI, USA and DISCOVERY Wi, Hologic, Inc., USA).

Our approach to the establishment of intervention and the DXA-enabled additional bone diagnostic examination thresholds took inspiration from the FRAX-based methodology, approved by the National Osteoporosis Guideline Group (NOGG) in the UK [12, 13], and later recommended by the European guidelines [6].

The criterion determining the **recommended pharmacological intervention (intervention threshold)** in women was a history of a fragility fracture, as numerous recent guidelines on the osteoporotic patient management consider it a key risk factor for the postmenopausal women and older men. According to the WHO, a fragility fracture is a fracture occurring due to a fall from one's own height or lower [14]. Among its risk factors, there is height, sex, a low BMD, a family history of osteoporosis, a history of fractures etc. Most often, fragility fractures damage vertebrae, proximal hip and distal forearm (radius), as well as humerus, pelvis, ribs etc.

Considering the fact that a history of fragility fracture was accepted to be a risk adequate for the treatment initiation, an intervention threshold for women without a history of fractures was established with an age-related 10-year

major osteoporotic fracture risk parameter, equivalent to that of women with a history of a fragility fracture, according to the Ukrainian FRAX model. The measurements considered the BMI of 25 kg/m<sup>2</sup>.

In order to develop the **BMD testing thresholds**, we took into account two approaches, earlier used for adaptation of other FRAX models [12, 13]:

1) a threshold probability, under which no treatment or additional DXA examination is to be considered (a 'lower evaluation threshold');

2) a threshold probability, over which the treatment is recommended irrespective of the BMD values (a 'upper evaluation threshold').

A 'lower evaluation threshold' was established to rule out the DXA examination, intended to measure the BMD, in women with no clinical risk factors, as recommended by the numerous European guidelines [6], whereas a 'upper evaluation threshold' is necessary for minimizing the probability of a high-risk patient's being re-classified and relegated to a low-risk group, based on the risk factors only. In this case, additional information on BMD is not required [15].

A 'upper evaluation threshold' was taken to be 1.2 times over the 'intervention threshold'. A similar approach is used in the UK [16]. A 'lower evaluation threshold' was established according to the age-related 10-year osteoporotic fracture risk probability, equivalent to the one of persons with no clinical risk factors.

Figure 1. The FRAX algorithm webpage

While *elaborating the evaluation strategy*, intended for the women with a history of a fragility fracture, those women were considered candidates for treatment, even without an additional DXA BMD measurement. The women who had no history of a fragility fracture received the recommendations, similar to a 10-year major osteoporotic fracture risk probability of the previous age group in this age sub-group.

When their probability was lower than a 'lower evaluation threshold', women were not treated. When a 10-year major osteoporotic fracture risk probability exceeded a 'upper evaluation threshold', persons were considered subjects to treatment. When a 10-year major osteoporotic fracture risk probability was between a 'lower' and 'upper' evaluation thresholds, women were referred for the additional BMD measurements, after which the fracture risk got reassessed. At the follow-up evaluation of major osteoporotic fracture risk which included the femoral neck BMD values, the women were considered subjects to treatment if their 10-year fracture probability was higher than the 'intervention threshold', even with normal BMD or osteopenia according to DXA.

## Results

Analysis of 10-year major osteoporotic fracture risk probability values, according to the FRAX, showed their significant increase with age, except for the 10-year major osteoporotic fracture risk probability values of women aged 80-89 years, considering the BMD measurements. Furthermore, a 10-year fracture probability with the BMD measurements included was higher than the corresponding one without BMD for all age groups, except for the age group of 80-89 years.

Our findings prove that the pharmacological intervention threshold ('upper evaluation threshold') grows with age: from 6.6 % at the age of 40 years to 13 % at the age of 75 years. Further on (up to 85 years), this threshold did not increase in a certifiable manner, while the women of 90 years had it somewhat reduced (to 12 %). Despite the

above-mentioned fact, the lower evaluation threshold was growing significantly: from 2.4 % at the age of 40 years to 6.9 % in the women of 85 years. It was only in the group of 90-year-olds that it diminished (Table 1, Fig. 2). The mean FRAX value for the major osteoporotic fractures, unless the BMD was left unmeasured, was 8.7 % in our model, while the 'upper' and 'lower' intervention thresholds amounted to 4.6 and 10.5 %, respectively.

Our analysis of the examined cohort confirms that 51.3 % of women had a fragility fracture and thus required an antiosteoporotic treatment without BMD measurements. On further study, it was established that 1.5 % (0.7 % of total examined population) of women had a risk over the 'upper evaluation threshold' and also required treatment, while 61 % (29.7 % of total examined population) had it under the 'lower evaluation threshold' and did not require treatment. Women with an intermediate risk made 37.6 % (18.3 % of total examined population) and required a further BMD measurement in order to decide upon the tactics of management. Out of those, 12.9 % had a low risk, while 5.4 % had a high one.

Risk characterization and requirement of the BMD measurement relied on the age. With advancing age, the number of women with a history of fragility fractures grew (from 34.3 % in the age of 40-49 years to 66.3 % in the age of 70-79 years, mean value – 52.4 %), as well as the requirement of osteoporotic treatment (44.1 % in the age of 40-49 years to 66.8 % in the age of 80-89 years, mean value – 58.2 %). Despite this, the number of women with a moderate fracture risk, requiring BMD measurements, diminished with age (from 34.8 % in the age of 40-49 years to 8.4 % in the age of 70-79 years, mean value – 18.6 %).

*The strategy of managing women*, taking into account osteoporotic fracture risk, starts with analyzing a history of fragility fractures. If there is one, antiosteoporotic treatment may be started without any BMD measurements. Woman who had no history of fragility fractures require an evaluation of major osteoporotic fracture risk, accord-

**Table 1. A 10-year probability of major osteoporotic fractures in women, depending on their age, and intervention thresholds in the Ukrainian FRAX model, %**

Age (years)	'Lower evaluation threshold' (%)	'Intervention threshold' (%)	'Upper evaluation threshold' (%)
40	2.4	5.5	6.6
45	2.7	6.1	7.3
50	3.1	6.7	8.1
55	3.5	7.5	9.1
60	4.0	8.3	10
65	4.4	8.8	11
70	5.0	9.6	12
75	6.0	11	13
80	6.7	11	13
85	6.9	11	13
90	6.0	10	12



ing to the FRAX and their age, sex and clinical factor risk parameters. If their risk exceeds the ‘upper evaluation threshold’, antiosteoporotic treatment is recommended without DXA (however, DXA may be performed to monitor a further treatment progress). If their risk does not reach the ‘lower evaluation threshold’; the woman needs no additional examination or treatment. If the subject has an intermediate risk, she needs DXA examination with a follow-up reassessment of fracture risks and management tactics (Figure 3).

Thus, the Ukrainian woman of postmenopausal age (60 years) does not require DXA examination and BMD measurement if her 10-year major osteoporotic fracture probability is lower than 4 %. The treatment should be recommended (with no BMD measurement to evaluate the fracture risk) if her 10-year major osteoporotic fracture probability is higher than 10 %. However, DXA may be advised to monitor the effectiveness of antiosteoporotic treatment. Moreover, if this risk is from 4 to 10 %, additional BMD evaluation and fracture risk reassessment is required. If the DXA results reveal osteoporosis, treatment is required. If, on the other hand, osteopenia or normal BMD is revealed, major osteoporotic fracture risk should be reassessed according to the age-related ‘intervention threshold’. Subjects of 60 years who have undergone DXA examination require treatment if their 10-year major osteoporotic fracture probability is 8.3 % or over, irrespective of osteopenia or normal BMD values.

If the fracture risk is made only of clinical risk factor calculation (age, sex etc.), and does not include BMD measurements, the mentioned thresholds concern only the treatment or additional DXA examination recommendations.

It should also be emphasized that evaluation thresholds that include the additional examination (age-related interval between the upper and lower thresholds) may be used only if the femoral neck BMD measurements are available, any other region (lumbar spine or forearm BMD) or other diagnostic tool findings (ultrasound densitometry or computer tomography) should not be used.

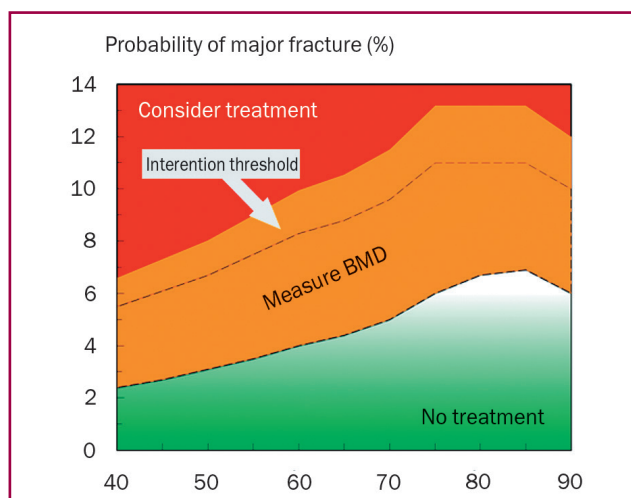


Figure 2. The additional examination or antiosteoporotic treatment thresholds in women depending on their age, according to the Ukrainian FRAX

## Discussion

At present, there are three strategies of choosing the initiation point of osteoporotic treatment that are accepted by most (though not all) European and US guidelines.

1. Low T-score ( $\leq -2.5$  SD, defined as ‘osteoporosis’ by the WHO criteria) of lumbar spine, hip or femoral neck. It is measured by DXA and referred to as universal instrumental criterion for the postmenopausal women and men aged 50 years and over. The risk evaluation among the younger women of reproductive age and men (under 50) is performed according to Z-score. Its falling behind  $< -2.0$  SD is described as ‘under the scale anticipated for the present age’, which is not a diagnosis. As such, it requires a further examination to determine the causes of BMD reduction.

2. A history of fragility fracture for men and women of a postmenopausal age [5, 6, 13] is an indication for the pharmacological intervention without taking BMD measurements in many guidelines. However, some countries (Canada, USA, Japan and Scotland) recommend the initiation of treatment only in case of vertebral and hip fractures [5].

3. High risk of osteoporotic fractures, calculated by the FRAX, for patients with a low BMD (T-score from  $> -2.5$  to  $\leq -1.0$  SD) [5, 7]. The decision on antiosteoporotic treatment initiation is to be made, according to most recent guidelines; various managing strategies may be opted for.

Nowadays, when developing intervention thresholds according to the FRAX, three approaches were applied: a) using fixed values; b) age-related approach, c) hybrid models (various successions of two previous approaches) (Figure 4).

The fixed thresholds were determined by the discriminating tests on the epidemiology of fractures (Hong Kong), medico-economical evaluations (USA, Switzerland), osteoporosis frequency (China) and analysis of treatment cost recovery (Japan, Poland) [5]. The age-related intervention thresholds were first developed by

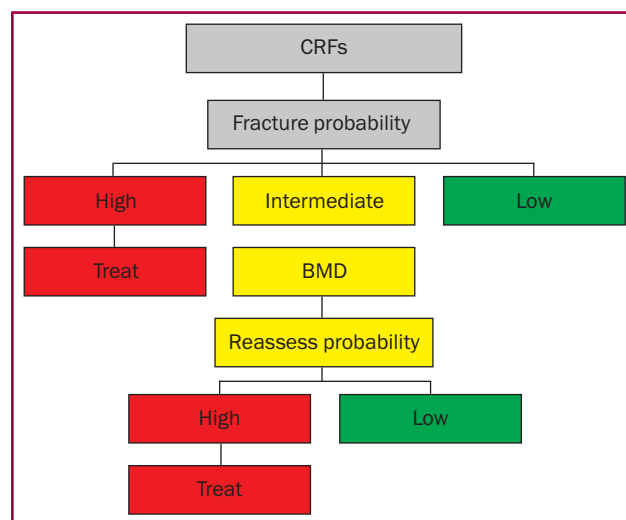


Figure 3. Strategy of managing women depending on the major osteoporotic fracture risk

NOGG in the UK, to be later introduced by other European countries and implemented within the acting European guidelines on postmenopausal osteoporosis management [6].

Among the countries with fixed values, the intervention threshold is lowest in China (4 % for major osteoporotic fractures, 1.3 % for hip fractures).

Numerous guidelines by various US societies (National Osteoporosis Foundation [7], Endocrine Society [17], American College of Obstetricians and Gynecologists [18], North American Menopause Society [19], Family practice [20], National Comprehensive Cancer Network (NCCN) [21], Institute for Clinical Systems Improvement [22]) and Canadian societies (Osteoporosis Canada [23], Ministry of Health, British Columbia [24], Society of Obstetricians and Gynecologists of Canada [25]) set threshold at 20 %. At the same time, another US societies (US Preventive Services Task Force [26], Michigan Quality Improvement Consortiu [27], American Academy of Family Physicians [28], Institute for Clinical Systems Improvement [29]) recommend a much lower additional BMD examination threshold (9.3 %).

The guidelines by the National Osteoporosis Foundation (NOF, 2014) [7] suggest the following criteria for antiosteoporotic treatment initiation in postmenopausal women and men of 50 years and over:

1. Hip or vertebral fracture (clinical or asymptomatic);
2. T-score of the hip, femoral neck or lumbar spine of  $< -2.5$  SD (by DXA examination);
3. Low BMD (T-score the hip, femoral neck or lumbar spine between  $-1.0$  and  $-2.5$  SD) by DXA, a 10-year probability of hip fractures of  $\geq 3$  and of major osteoporotic fractures of  $\geq 20$  by the FRAX.

Similar criteria are recommended by the Endocrine Society for men (2012) [17].

The above-mentioned criteria were somewhat elaborated by the US National Bone Health Alliance® (NBHA), with 45 member societies, representing Centers for Disease Control and Prevention (CDC), the National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH) and US Food and Drug Administration (FDA) [30].

Those guidelines included the following diagnostic benchmarks for postmenopausal women and men of 50 years and older, suffering from osteoporosis:

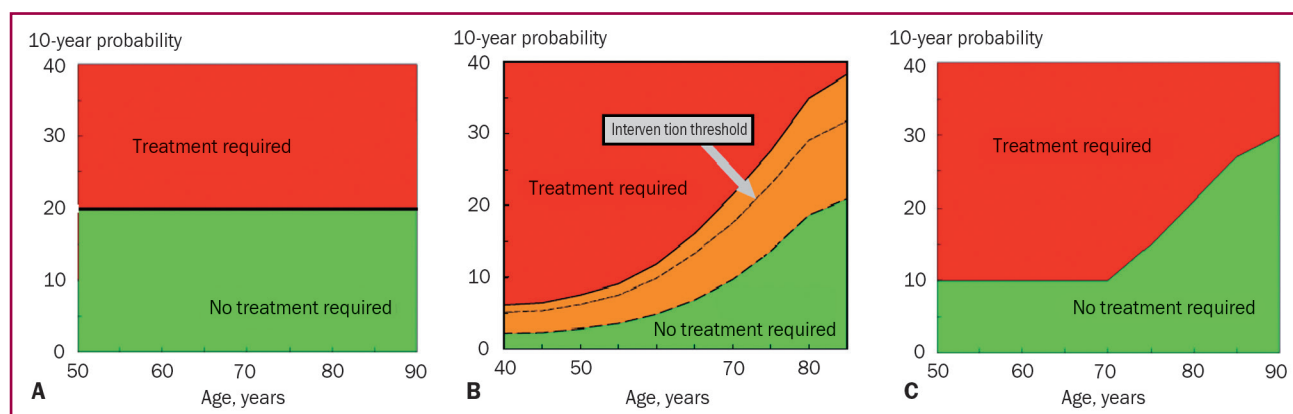
1. Hip fracture (irrespective of BMD measurements);
2. T-score of lumbar spine or hip  $\leq -2.5$  SD;
3. Osteopenia (T-score from  $> -2.5$  to  $\leq -1.0$  SD) and a previous clinical or morphometrically confirmed vertebral fracture, proximal humerus, pelvis or, in some cases, distal forearm fracture;
4. 10-year probability of hip fracture by the FRAX is  $\geq 3$  % and 10-year probability of major osteoporotic fractures is  $\geq 20$  %, subjects have osteopenia (T-score from  $> -2.5$  to  $\leq -1.0$  SD) [30].

A similar 10-year major osteoporotic fracture risk threshold of 20 % is recommended by some national societies in Slovakia [31], Slovenia [32], Hungary [33], Portugal [34], Spain [35, 36], Greece [37], Austria [38] and Belgium [39].

A somewhat lower intervention threshold (15 %) is recommended in Japan (Japan Osteoporosis Society; Japanese Society for Bone and Mineral Research; Japan Osteoporosis Foundation) [40] and Switzerland [41]. Some countries (Finland [42], North Korea [43]) and the US (American College of Rheumatology (ACR) [44]) use two criteria – most commonly 10 and 20 % [5].

As it was already mentioned, at the present moment the recent European guidelines [6] on postmenopausal osteoporosis management rely upon an age-related approach to major osteoporotic fracture risk evaluation. A similar approach was used while developing antiosteoporotic treatment thresholds for the Ukrainian population. If most European guidelines consider the osteoporotic risk factor evaluation to be valid with a restricted use of DXA examination and antiosteoporotic treatment may be prescribed without the latter, the US guidelines stand by the BMD measurements [7]. Along with the European countries [6], we suggest DXA examination for those patients who have a moderate or high fracture risks according to the FRAX. This approach is considered valid only on condition of optimized X-ray densitometry use.

Reassessment of osteoporotic fracture risk after the BMD measurements (from moderate to high or low) is more common in cases when this risk evaluated without



**Figure 4. FRAX models with various approaches to intervention threshold setting.**

**Notes: A - using fixed values, B - age-related model, C - hybrid model.**

DXA examination is moderate. However, the validity of reassessment drops with probability getting further away from the intervention thresholds [15]. This approach was tested and confirmed in the UK and Canada [15, 45, 46].

The above-mentioned approach suggests that high-risk patients whose BMD was not measured will provide a better response to pharmacological intervention, and it was confirmed by the earlier studies [47-49], thereby making this approach financially viable [50].

Our study has several **limitations**: despite the size of its cohort (3790 examined female outpatients), the study was performed at one center (Ukrainian Scientific Medical Center of Osteoporosis) which is a specialized health-care provider intended for the osteoporotic patients. Thus, this sample may not be considered fully representative of Ukraine as a whole. Furthermore, a large number of previous fractures and low BMD also reflected on the findings.

It is worth mentioning that some significant osteoporosis risk factors (height loss, chest kyphosis, low Calcium and Vitamin D concentrations in the daily diet, high risk of falls, glucocorticoid treatment and their doses) are not included into the FRAX algorithm, although they affect the rates of bone loss and osteoporosis risk. Their additional analysis along with a 10-year probability of osteoporotic fractures may raise the information value of this instrument and should be recommended in the clinical practice.

## Conclusions

Our study confirmed the effectiveness of the FRAX evaluation principles, used by the European societies in their guidelines, though adapted considering the epidemiological situation in Ukraine. It is evident that by extending the indications for osteoporosis treatment (not only relying in T-score of -2,5 SD by DXA) and including the results of osteoporosis risk evaluation we increase the number of patients requiring the treatment and face economic repercussions. Despite its economic effectiveness demonstrated in other countries, Ukraine may embrace this approach somewhat differently, and thus it requires a further study with evaluation of economic costs and benefits.

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**Conflicts of interests.** Authors declare the absence of any conflicts of interests and their own financial interest that might be construed to influence the results or interpretation of their manuscript.

**Data availability.** All data used to support the results of this study are stored at and available from the corresponding author upon request.

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**Резюме. Актуальність.** На сьогодні алгоритм FRAX® є інформативним методом оцінки ризику остеопоротичних переломів, імплементованим в європейські й американські рекомендації щодо менеджменту остеопорозу. Проте існують відмінності щодо меж втручання для антиостеопоротичного лікування, що залежать від країни, моделі надання медичної допомоги та повернення коштів за лікування. Власна модель FRAX з'явилась в Україні в 2016 році, проте межі втручання досі розроблені не були. **Мета дослідження:** визначити межі для фармакологічного лікування остеопорозу та додаткового обстеження населення України за допомогою національної моделі FRAX. **Матеріали та методи.** Обстежено 3790 амбулаторних жінок віком 40–90 років (середній вік —

61,9 ± 10,0 року). Розробка меж втручання та додаткової оцінки стану кісткової тканини з використанням двоенергетичної рентгенівської денситометрії (ДРА) передбачала застосування методології, прийнятої National Osteoporosis Guideline Group у Великій Британії, яка використана і в європейських рекомендаціях. **Результати.** Встановлено зростання з віком межі для фармакологічного втручання (верхня межа) з 6,6 % у 40 років до 13 % у 75–85 років. Нижня межа втручання (необхідність обстеження) вірогідно збільшувалась з 2,4 % у 40 років до 6,9 % у жінок віком 85 років. Стратегія оцінки починається з аналізу в анамнезі низькотравматичного перелому. За його наявності приймається рішення про початок антиостеопоротичного лікування без проведення ДРА. За відсутно-

сті перелому в анамнезі необхідна оцінка ризику переломів за FRAX. При перевищенні верхньої межі рекомендовано антиостеопоротичне лікування без проведення ДРА, при його значеннях менше за нижню межу — додаткове обстеження чи лікування не потрібні. За умови наявності проміжних показників ризику необхідне проведення ДРА з переоцінкою ризику переломів і тактики ведення. **Висновки.** Доведено ефективність використання принципів оцінки FRAX, що застосову-

ються в європейських рекомендаціях, але з урахуванням епідеміології остеопоротичних переломів в Україні. Незважаючи на те, що даний підхід є економічно ефективним в інших країнах, його застосування в Україні може відрізнятися і потребує подальшого вивчення з економічною оцінкою затрат і переваг.

**Ключові слова:** FRAX®; остеопороз; межа втручання; лікування; діагностика; ризик остеопоротичних переломів

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### Украинская версия FRAX: критерии диагностики и лечения остеопороза

**Резюме.** *Актуальность.* На сегодняшний день алгоритм FRAX® является информативным методом оценки риска остеопоротических переломов, реализованным в европейские и американские рекомендации по менеджменту остеопороза. Однако существуют различия относительно границ вмешательства для антиостеопоротического лечения, зависящие от страны, модели оказания медицинской помощи и возвращения средств за лечение. Собственная модель FRAX появилась в Украине в 2016 году, однако границы вмешательства до сих пор разработаны не были. **Цель исследования:** определить границы для фармакологического лечения остеопороза и дополнительного обследования населения Украины с помощью национальной модели FRAX. **Материалы и методы.** Обследовано 3790 амбулаторных женщин в возрасте 40–90 лет (средний возраст — 61,9 ± 10,0 года). Разработка границ вмешательства и дополнительной оценки состояния костной ткани с использованием двухэнергетической рентгеновской денситометрии (ДРА) предусматривала применение методологии, принятой National Osteoporosis Guideline Group в Великобритании, которая использована и в европейских рекомендациях. **Результаты.** Установлено повышение с возрастом границы для фармакологического вмешательства (верхняя граница) с 6,6 % в 40 лет до 13 % в 75–85 лет. Нижняя гра-

ница вмешательства (необходимость обследования) достоверно увеличивалась с 2,4 % в 40 лет до 6,9 % у женщин в возрасте 85 лет. Стратегия оценки начинается с анализа в анамнезе низкотравматического перелома. При его наличии принимается решение о начале антиостеопоротического лечения без проведения ДРА. При отсутствии перелома в анамнезе необходима оценка риска переломов по FRAX. При превышении верхней границы рекомендуется антиостеопоротическое лечение без проведения ДРА, при его значениях меньше нижней границы — дополнительное обследование или лечение не нужны. При наличии промежуточных показателей риска необходимо проведение ДРА с переоценкой риска переломов и тактики ведения. **Выводы.** Доказана эффективность использования принципов оценки FRAX, применяемых в европейских рекомендациях, но с учетом эпидемиологии остеопоротических переломов в Украине. Несмотря на то, что данный подход является экономически эффективным в других странах, его применение в Украине может отличаться и требует дальнейшего изучения с экономической оценкой затрат и преимуществ.

**Ключевые слова:** FRAX®; остеопороз; граница вмешательства; лечение; диагностика; риск остеопоротических переломов