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ORIGINAL ARTICLE

Clinical and demographic factors determining patient fracture risk decision point (FRDP): The improving risk communication in osteoporosis (RICO) project

Mitali Sharma[1] · Charlotte Beaudart[2,3] · Patricia Clark[4] · Saeko Fujiwara[5] · Jonathan D. Adachi[6] · Alexandra Papaioannou[6] · Osvaldo D. Messina[7,8] · Suzanne N. Morin[9] · Lynn Kohlmeier[10] · Xavier Nogues[11] · Carolyn Leckie[6] · Nicholas C. Harvey[12,13] · John A. Kanis[14,15] · Jean-Yves Reginster[3,16] · Mickael Hiligsmann[2] · Stuart L. Silverman[1,17]

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Abstract

Summary This study aims to understand how osteoporosis medication acceptance varies across countries with differing guidance on treatment threshold and influence of clinical and demographic factors. A total of 79.2% accepted treatment at a fracture probability at or below the treatment threshold. Fracture history and age did not strongly impact acceptance, suggesting a need for improved fracture risk communication.

Purpose This part of the Improving Risk Communication in Osteoporosis (RICO) study aims to understand patients' willingness to initiate osteoporosis treatment given a hypothetical fracture probability—derived from the FRAX® Risk Assessment Tool—and how age, fracture history, and numeric literacy may influence this.

Methods In 2022–2023, 332 postmenopausal women at risk of fracture were interviewed from nine countries to determine participants' Fracture Risk Decision Point (FRDP), the lowest probability of major osteoporotic fracture at which they would accept an osteoporosis medication. Participants' FRDP was evaluated given eight hypothetical 10-year FRAX scores.

Results In countries with FRAX-based treatment thresholds, over half of the participants per country reported an FRDP that was below the threshold. Collectively, 79.2% demonstrated FRDPs at or below their respective threshold. Age and fracture history did not have a strong influence on FRDP; however, those who demonstrated higher levels of numeric literacy reported a significantly higher median FRDP (10%) compared to those who showed lower levels (5%, $p < 0.001$).

Conclusions Most patients were willing to accept an osteoporosis medication prescription at a hypothetical FRAX probability that was even lower than that of their nationally recommended treatment threshold. Literacy scores had a significant influence on FRDP whereas age and fracture history did not.

Keywords Fracture Risk Decision Point (FRDP) · FRAX® probability · Osteoporosis · Patient willingness to accept treatment · Treatment threshold

Introduction

Internationally, one of the leading methods for quantifying fracture risk is done in terms of the Fracture Risk Assessment Tool (FRAX®) score, which calculates 10-year fracture probability based on a number of factors, including but not limited to age, history of fracture, body mass index, and optionally, femoral neck bone mineral density (BMD) [1]. Although the use of BMD in the calculation of the FRAX score improves the sensitivity of this metric, the predictive value is comparable regardless of this additional data. Therefore, FRAX allows healthcare providers to predict fracture probability based on clinical risk factors, which is increasingly valuable in countries with poor access to densitometry [2].

Furthermore, many healthcare systems across the world utilize variable FRAX intervention thresholds to determine whether a patient's fracture probability is high enough to justify medication. These intervention thresholds may be fixed, age-dependent, or a hybrid of the two and vary between countries given factors such as cost-effectiveness, access

Mickael Hiligsmann and Stuart L. Silverman are co-last authors.

Extended author information available on the last page of the article

to healthcare, and the local epidemiology of fracture [2]. While countries such as the USA, Canada, Spain, and Belgium adhere to a fixed 20% treatment threshold and Japan to a 15% treatment threshold for major osteoporotic fracture, countries such as Argentina and Mexico utilize age-dependent thresholds (Appendix Tables 3 and 4) [2, 3]. Originally, age-dependent treatment thresholds were debuted by the National Osteoporosis Guideline Group (NOGG) to estimate a more clinically relevant FRAX cut-off. However, in order to address subsequent inequalities in access to treatment among those over 70 years old, a hybrid model is now used in the UK with age-dependent intervention thresholds between the ages of 50 and 70 years and the use of a fixed 20.3% treatment threshold thereafter (Appendix Table 5) ([2, 14]). In addition to local treatment guidance, participants' "self-perceived fracture risk" may impact their likelihood of osteoporosis medication acceptance, as shown by results of the Global Longitudinal Study of Osteoporosis in Women (GLOW) [4].

The objective of this study was to better understand how medication acceptance varies across fracture risk levels and how it compares to national guidance on treatment threshold. A secondary objective was to understand how certain demographic and clinical risk factors—such as age, fracture history, and numeric literacy—may impact the decision to accept a prescription osteoporosis medication. Participants' willingness to accept a prescription osteoporosis medication was quantified in terms of Fracture Risk Decision Point (FRDP), which is defined as the lowest percentage risk of major osteoporotic fracture (MOF)—in terms of 10-year FRAX probability—at which participants chose to hypothetically initiate a medication with minor, transient side effects. FRDP and willingness were assumed to be inversely proportional, as those who were more willing to accept a treatment would likely choose to do so at a lower fracture risk threshold.

This study is part of an initiative called the Improving Risk Communication in Osteoporosis (RICO) study, which examined a pertinent communication gap between physicians and patients with osteoporosis. With involvement from eleven sites in nine different countries across Europe, Asia, and North and South America, the RICO survey aims to understand whether the implementation of a visual aid may improve communication of one's individual FRAX probability [5].

Methods

Recruitment

A total of 332 women who had been diagnosed with either osteoporosis or who were postmenopausal at risk of fracture were recruited from eleven global sites in countries, such as the USA ($n=64$), Canada ($n=61$), Mexico ($n=36$), Japan ($n=35$), Argentina ($n=30$), Belgium ($n=30$), the UK ($n=29$), Spain ($n=28$), and the Netherlands ($n=19$). Participants in the USA were recruited from two different sites, one in California ($n=35$) and one in Washington ($n=29$), and those recruited in Canada were interviewed by sites in Ontario ($n=31$) and Quebec ($n=30$). Sites recruited participants from a number of sources, including the local community, the site investigator's clinical rheumatology or endocrinology practice, or an osteoporosis patient network, such as the Canadian Osteoporosis Patient Network (COPN) or the Royal Osteoporosis Society, UK (ROS). Given that this study was observational and did not pose a specific hypothesis, a sample size calculation was not applicable. Our study suggested a pragmatic target sample of 30 participants per site.

Participants at risk of fracture were defined as women with elevated FRAX score, elevated bone mineral density, or for whom pharmacologic and/or non-pharmacologic osteoporosis management was being considered by their site clinician. In order to ensure the diversity of participant perspectives, it was recommended that sites utilize a convenience sample of (1) at least ten participants who had sustained a fracture since the age of 40, (2) at least ten participants who had completed at least some education at the university level, (3) at least ten participants who had decided to take a prescription osteoporosis medication, and (4) at least ten participants who did not meet each of these criteria (Appendix Table 2).

Survey administration

At each site, a study coordinator guided participants through a structured survey either online via Zoom video conference or in-person, depending on participant preference and local COVID-19 guidelines. In both settings, Microsoft PowerPoint was used to display questions and all visuals to each participant. An extensive scoping review was conducted by Beaudart et al. to inform the design of this exercise, including the use of icon arrays as a visual aid to enhance patient understanding of fracture probability [6]. Icon arrays have previously been found to yield a similar understanding of risk presentation among patients with various levels of numeric literacy and reduce the impact of denominator neglect when considering the relative benefit of treatment in a population [7, 8].

Although the survey was originally developed in English, site investigators were able to request translation of participant-facing materials into locally spoken languages by certified professionals.

At the beginning of each survey, participants took a short, five-question assessment—extracted from an experimentally designed Graph Literacy Scale [7]—with which

investigators gained a rough understanding of their ability to interpret graphs or visual aids. Two of these questions were Likert-type questions that were used to gauge the participant's self-perception of numeric literacy and preference for numeric versus verbal presentation of information [9]. However, the remaining three questions were an objective assessment of numeric literacy and were used to stratify participants into high- or low-numeric literacy groups [7] (Appendix Fig. 3).

Within the survey, participants were presented with a maximum of eight hypothetical scenarios and asked whether they would be willing to accept a prescription for osteoporosis medication with minimal, transient side effects. To promote simplicity and participant understanding, this referred to any class of antiresorptive therapy. Each hypothetical scenario utilized two icon arrays to depict various fracture risk levels; the first icon array demonstrated the participant's hypothetical risk of MOF over 10 years or FRAX probability, and the second showed how much of that risk could be mitigated upon taking a medication (Fig. 1). An optimistic 40% reduction in fracture risk was assumed with medication use given recent literature on antiresorptive osteoporosis therapies [10].

The eight hypothetical risk scenarios presented 10-year FRAX probabilities ranging from 5 to 40%, increasing in increments of 5%. The lowest fracture probability at which the participant agreed to accept a prescription osteoporosis medication was determined to be their FRDP. If they did not agree to medication by the final scenario (40% risk of MOF), then their FRDP was considered to be > 40%.

Ethical considerations

Institutional Review Board (IRB) approval was obtained on a site-by-site basis given local or university-wide requirements. Advarra, a central IRB, provided approval for all sites in the USA and Canada.

Outcomes

The primary outcome measured medication acceptance by the percentage of participants in each country who reported that they would hypothetically accept a prescription osteoporosis medication given a fracture probability less than or equal to their national FRAX-based treatment threshold. This threshold varied between countries as well as within countries in those that use an age-dependent or hybrid threshold. This outcome was measured specifically in countries where FRAX intervention thresholds are widely used in a clinical setting. The Netherlands does not and thus was excluded from this analysis [2]. Secondary outcomes detailed the impact of numeric literacy level, age, and fracture history on participant FRDP.

Data entry and statistical analyses

Site coordinators uploaded source documents and recorded all data in an electronic data capture system called "Online Clinical Trials" (http://www.essaionline.com), which allowed the lead study team to ensure sites' adherence to study protocol and accuracy of data entry.

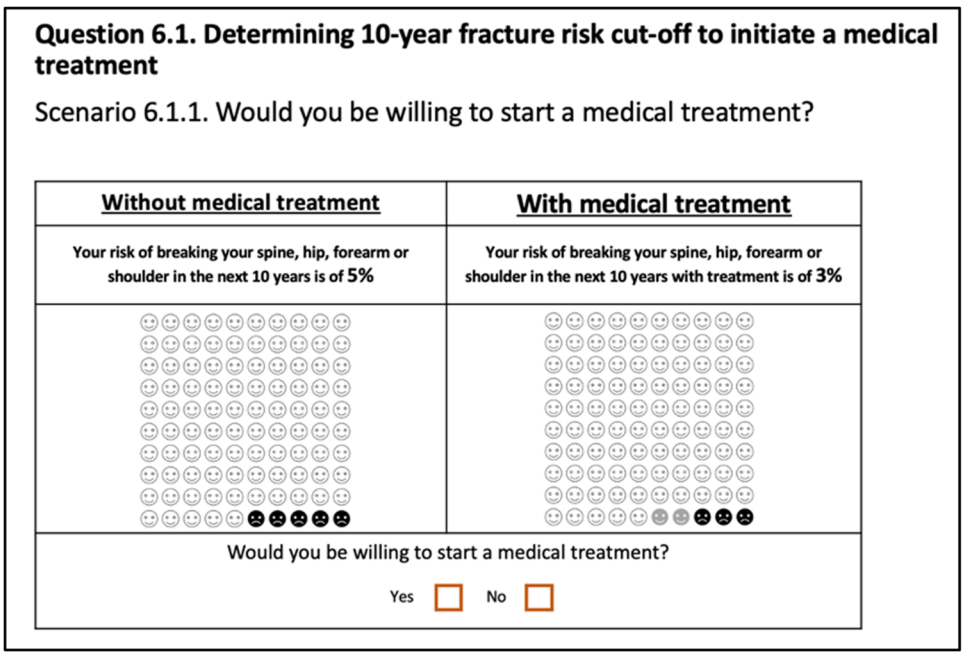

Fig. 1 The first of eight hypothetical scenarios, in which participants were asked whether they would willing to accept a prescription of osteoporosis medication with minor, transient side effects given that their risk of MOF was 5% over a 10-year period and that medication would reduce this to a 3% fracture risk over 10 years

In order to validate the statistical significance of the difference in median FRDP among those with variable levels of numeric literacy and those with or without fracture history, Mood's analyses were conducted. The Pearson correlation coefficient was calculated to understand the significance of the relationship between age and FRDP. Chi-squared tests were used to analyze preference for risk timeframe given fracture history and age. *p*-values were compared to an alpha level of 0.05 to determine statistical significance, and all data was analyzed with use of the statistical software, QI Macros.

Table 1 The median reported Fracture Risk Decision Point (FRDP) in each country

Country	Median FRDP
Belgium	5%
The Netherlands	5%
Spain	5%
Mexico	5%
Argentina	5%
Japan	10%
UK	10%
USA	15%
Canada	15%

Results

The mean and median ages of participants were 67.5 and 67.0 years, respectively, 48.2% of participants ($n = 160$) reported a history of fracture, and 50.3% ($n = 167$) were adherent to a prescription osteoporosis medication. Given the numeric literacy assessment, 64.8% ($n = 215$) of participants answered at least two of three questions correctly on the numeric literacy assessment and therefore demonstrated a high level of numeric literacy, whereas 35.2% ($n = 117$) demonstrated low numeric literacy on the assessment [7].

Median FRDP in each country varied from 5 to 15% in all nine countries from which data was collected (Table 1). In the eight countries which employed FRAX-based treatment thresholds in a clinical setting, 79.2% of all participants reported an FRDP that was less than or equal to their nationally recognized treatment threshold (Fig. 2). However, countries varied in terms of how many participants agreed to accept a prescription osteoporosis medication below this threshold—with the lowest percentages being in the UK (65.5%), the USA (65.6%), and Japan (68.6%) and the

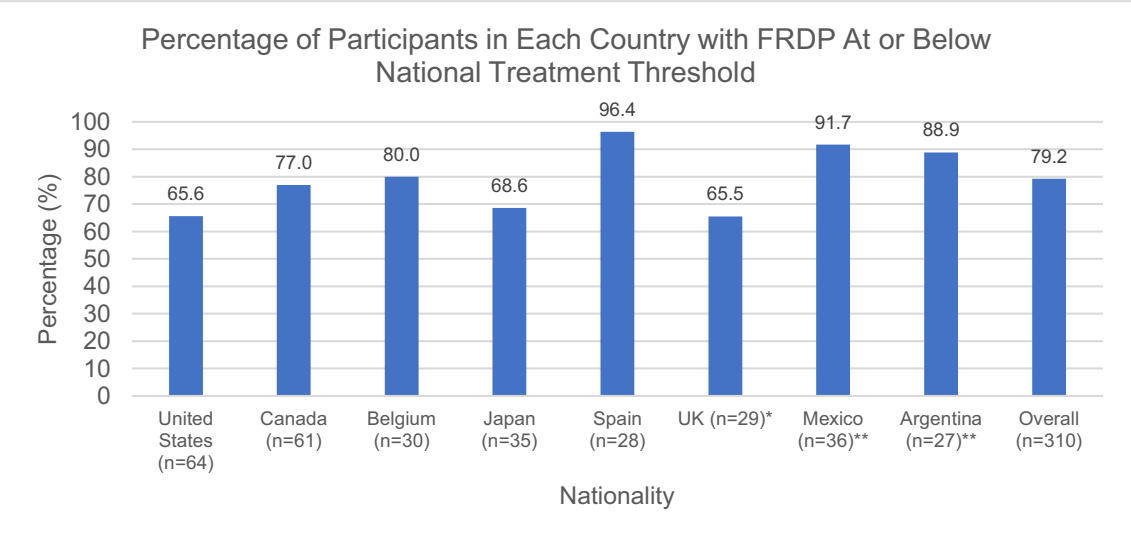

Fig. 2 Percentage of participants in each country who reported a Fracture Risk Decision Point (FRDP) that was at or below their nationally recognized treatment threshold, accounting for fixed versus age-dependent versus hybrid intervention thresholds in various countries. National treatment guidelines suggest a hybrid model, in which an age-dependent FRAX treatment threshold is utilized for those between the ages of 50 and 70 years and a fixed threshold is used thereafter 70 years of age (Appendix Table 5). **National treatment guidelines suggest an age-dependent FRAX treatment threshold (Appendix Table 4)

highest being in Spain (96.4%), Mexico (91.7%), and Argentina (88.9%).

With regard to secondary outcomes, participants with high numeric literacy scores demonstrated a significantly higher median FRDP of 10% fracture risk than those with low scores—who had a median FRDP of 5% fracture risk ($p < 0.001$). However, the median FRDP among participants with a history of fracture since the age of 40 years (5%) was not significantly different from the median FRDP of those who had not fractured (10%) ($p = 0.789$).

Participants who did not agree to accept a prescription osteoporosis medication in response to any of the eight hypothetical scenarios were excluded from the analysis correlating age and FRDP given that their FRDP could not be calculated. Among the 311 remaining participants, the negative correlation between age and FRDP was weak but significant ($p = 0.007$). The r value was -0.153 and the r^2 value was 0.023.

Discussion

Primary outcome

In the eight countries that utilize a nationally recommended FRAX treatment threshold, 79.2% of all participants and at least half of participants within each individual country indicated that they were willing to accept a prescription for osteoporosis medication at a fracture risk level that was at or below their respective national treatment threshold. This bodes well for medication acceptance if patients are given individualized care and explanation of fracture risk.

There was, however, a variable distribution among countries regarding the percentage of participants who agreed to initiate a medication below the national treatment threshold. With the exception of Spain (96.4%), countries with age-dependent intervention thresholds, such as Mexico (91.7%) and Argentina (88.9%), had the highest percentages of participants who were willing to accept a prescription medication given a FRAX probability that was less than or equal to their individual treatment threshold (Appendix Table 4) ([3, [14]). The lowest percentage of participants with FRDP below their respective treatment threshold was observed in the UK (65.5%), which employs a hybrid threshold.

Secondary outcomes

Surprisingly, a history of fracture did not have a significant impact on participant FRDP, and age only showed a minor correlation to FRDP. The negative correlation between age and FRDP was weak ($r = -0.153$) but significant ($p = 0.007$), giving some indication that increased age was correlated with willingness to initiate medication at a lower fracture risk threshold. However, the r^2 value of 0.023 indicates that only 2.3% of the variability seen in FRDP may be impacted by age and that many other factors may also be influencing the decision. Although clinical risk factors, such as age or fracture history, are both used in the calculation of one's FRAX score and may significantly increase one's risk of fracture, age showed only a weak influence on FRDP, and fracture history did not bear significant weight on participants' FRDP [1]. These findings are consistent with that of the GLOW study, which indicates that participants with comorbidities for future fracture tended to underestimate their fracture risk [11]. This points to a potential communication gap in discussions regarding fracture risk and a need for further patient education on how age and history of fracture may predispose one to future fracture.

Limitations

A major source of potential bias includes limited overall sample size as well as overrepresentation of participants from Canada and the USA. Additionally, participants were largely recruited from rheumatology or endocrinology practices—rather than internal or family medicine—and anecdotally, some investigators reported that women with a unique interest or concern regarding their fracture risk were more inclined to participate in this study.

Some participants may have had preexisting knowledge about fracture risk, as they had been recruited from patient networks, such as the Canadian Osteoporosis Patient Network (COPN) in Canada and The Royal Osteoporosis Society (ROS) in the UK, where patients are frequently exposed to educational resources on osteoporosis and bone health. Participants who were recruited from these networks were therefore more

likely to have a comprehensive understanding of local treatment thresholds and a more informed base perception of fracture risk ([15]; [12]). However, to counterbalance this, during the initial RICO interview, all participants were indirectly informed that 20% FRAX probability or higher was largely considered to be a high fracture risk [2]. Participants were not given any further education about osteoporosis or fracture risk prior to this study. The differences in FRDP observed in this study may have been partially influenced by these inter-site discrepancies in enrollment procedure. Consequently, caution must be exercised when interpreting preference results, especially regarding differences in FRDP between countries.

Other limitations of this study design include the absence of the male osteoporosis patient perspective in these findings and the use of hypothetical scenarios rather than each patient's true fracture risk [13]. Equally important is the notion that the proposed medication would only have minor, transient side effects—not accounting for how the risk of these more serious but rare adverse events may impact treatment decisions. Lastly, to maximize the simplicity of these scenarios, there was no discussion of the cost or convenience of initiating an osteoporosis medication.

A larger, more inclusive study would be needed to address all of these limitations. Additionally, in order to confirm the validity of participants' answers beyond a hypothetical willingness to initiate medication, additional data would be needed on actual prescription fulfillment—with acknowledgement of medication cost, convenience, and potential adverse events.

Strengths and future research

The external validity of this study is bolstered by its multinational scope and commitment to acknowledging a diverse range of perspectives, surveying participants from nine different countries. Future iterations of this study will expand upon this research by representing Pan-Asian, African, and Middle Eastern patient populations as well.

Results of this study identify a clear gap in patient-provider communication regarding clinical risk factors and consequences of fracture, as those with a history of fracture were not significantly more motivated to initiate a prescription osteoporosis medication, and age was only a very minor predictor of FRDP. This calls for greater emphasis on the significance of clinical risk factors, such as advancing age or fracture history, when providing patient education on fracture risk. In hopes of making this important leap in patient awareness, proposed next steps for RICO will include a randomized control trial to compare the efficacy of a verbal presentation versus a visual aid in improving patient willingness to initiate a prescription osteoporosis medication.

Conclusion

This study addressed the significant gap in patient-provider communication regarding the implications of one's FRAX probability and the important role of prescription osteoporosis medication in reducing one's risk of fracture. As part of the Improving Risk Communication in Osteoporosis (RICO) project, this study demonstrated how patient willingness to accept a prescription osteoporosis medication—or FRDP—may deviate from nationally prescribed treatment thresholds and highlighted a number of factors which may impact FRDP. Furthermore, in all countries in which FRAX was used in a clinical setting, 79.2% of participants were willing to initiate a prescription osteoporosis medication given a fracture risk that was below their nationally recommended treatment threshold. Participants with higher levels of numeric literacy were significantly less willing to initiate a prescription osteoporosis medication than those who had scored lower on the numeric literacy assessment. In addition, increased age showed only minimal correlation with FRDP, and a history of fracture did not bear any significant weight on this decision—despite both of these being significant clinical risk factors for fragility fracture [1]. This study highlights several ways in which healthcare providers can try to improve their fracture risk communication in an effort to help patients make informed clinical decisions, reduce their fracture risk, and improve quality of life.

Appendix

Table 2 Participant demographics

	All ($n=332$)	Canada, Hamilton ($n=31$)	Canada, Montreal ($n=30$)	US, Los Angeles ($n=35$)	US, Spokane ($n=29$)	Mexico ($n=36$)	Argentina ($n=30$)	The NL ($n=19$)	Belgium ($n=30$)	UK ($n=29$)	Spain ($n=28$)	Japan ($n=35$)	p-value[3]
Format of interviews	173 (52.1)	6 (19.4)	30 (100.0)	35 (100.0)	29 (100.0)	26 (72.2)	0 (0.00)	19 (100.0)	14 (46.7)	29 (100.0)	1 (3.6)	3 (8.6)	< 0.001
Online	159 (47.9)	25 (80.6)	0 (0.00)	0 (0.00)	0 (0.00)	10 (27.8)	30 (100.0)	0 (0.00)	16 (53.3)	0 (0.00)	27 (96.4)	32 (91.4)	
Face to face													
Age (years)	67.5 ± 8.02	68.9 ± 8.18	67.9 ± 5.33	63.9 ± 7.1	65.4 ± 7.79	66.5 ± 7.36	68.2 ± 8.55	67.0 ± 10.5	67.1 ± 7.62	65.8 ± 8.28	69.4 ± 8.69	71.8 ± 7.47	0.007
Prescription osteoporosis medication use	167 (50.3)	13 (41.9)	14 (46.7)	8 (22.9)	14 (48.3)	14 (38.9)	15 (50.0)	18 (94.7)	8 (26.7)	21 (72.4)	21 (75.0)	21 (60.0)	< 0.001
Positive history of fracture	160 (48.2)	15 (48.4)	15 (50.0)	14 (40.0)	11 (37.9)	15 (41.7)	9 (30.0)	18 (94.7)	12 (40.0)	21 (72.4)	14 (50.0)	17 (48.6)	0.001

Table 3 Nationally recognized, fixed FRAX intervention thresholds for use of prescription osteoporosis medication [2]

Country	National FRAX-based treatment threshold (% risk of major osteoporotic fracture)
Japan	15%
Spain	20%
Belgium	20%
USA	20%
Canada	20%

Table 4 Nationally recognized, age-dependent intervention thresholds for use of prescription osteoporosis medication in Argentina and Mexico [3]

Age (years)	Age-dependent, FRAX-based treatment threshold (% risk of major osteoporotic fracture)	
	Argentina	Mexico
40	1.5	2.6
45	2.2	3.5
50	2.3	4.5
55	3.3	5.8
60	6.6	7.7
65	12	10
70	15	14
75	16	17
80	19	19
85	25	20
90	27	20

Table 5 Nationally recognized, hybrid (fixed and age-dependent) intervention thresholds for use of prescription osteoporosis medication in the UK [14]

Age (years)	Hybrid, FRAX-based treatment threshold (% risk of major osteoporotic fracture)
	UK
50	7.3
55	9.5
60	12.2
65	16.5
70+	20.3

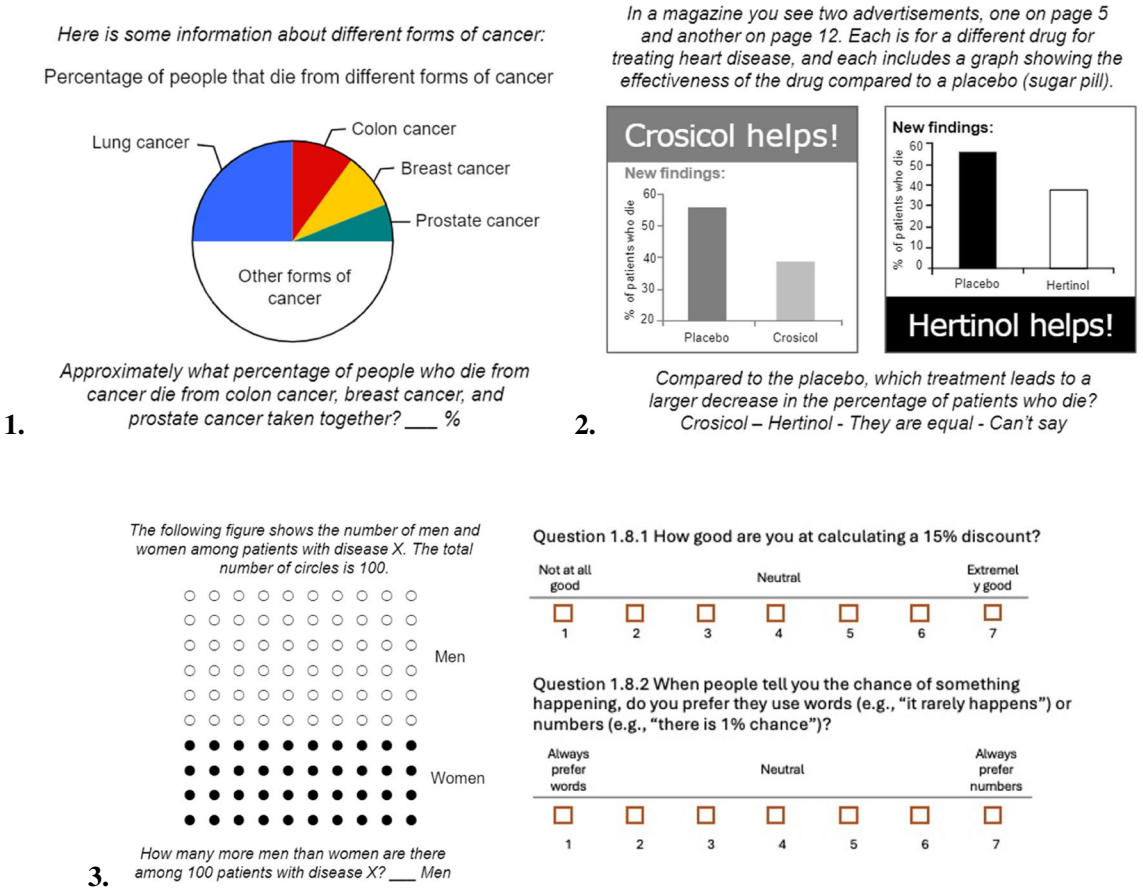

Fig. 3 Numeric literacy assessment questions[11]

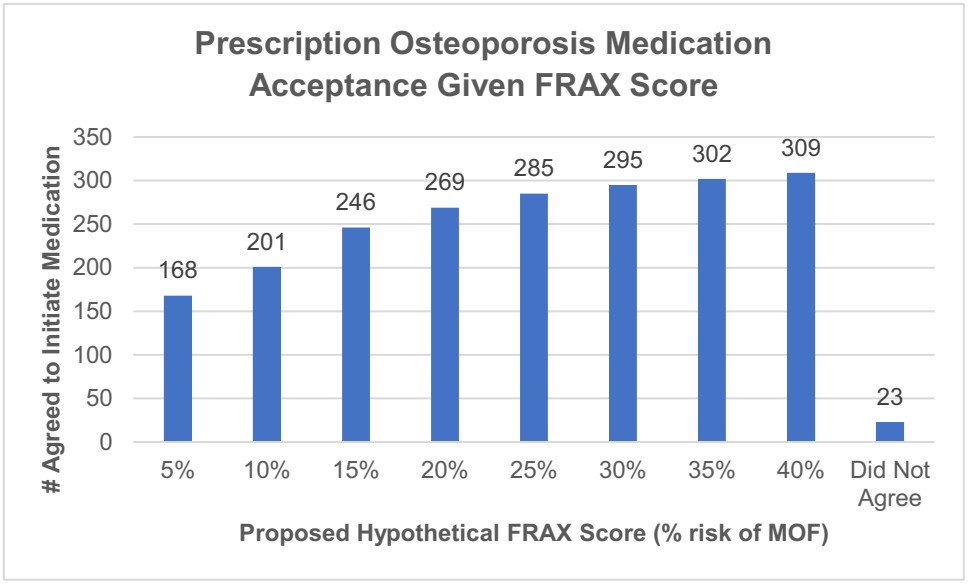

Fig. 4 Trends in medication acceptance across the eight hypothetical FRAX scenarios [9]

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Data availability Under request.

Code availability N/A.

Declarations

Human subject protection The whole study was subject to an initial central IRB (Advarra for sites in the USA and Canada) and then local IRB (country and institutional specific) review and approval (if and when required by applicable law). Informed consent was obtained for all phases of the project. All subjects either received a patient information sheet or informed consent depending on the local IRB of the site. Subjects were informed of their ability to withdraw at any time as stated by the coordinator as well as the patient information sheet or informed consent form.

Conflict of interest J.A.K is the founder of FRAX® and Editor-in-Chief of Osteoporosis International; L.K. is an Amgen speaker, Radius consultant, and speaker. Other authors declare that they have no conflict of interest with regard to the content of this manuscript.

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Authors and Affiliations

Mitali Sharma[1] · Charlotte Beaudart[2,3] · Patricia Clark[4] · Saeko Fujiwara[5] · Jonathan D. Adachi[6] · Alexandra Papaioannou[6] · Osvaldo D. Messina[7,8] · Suzanne N. Morin[9] · Lynn Kohlmeier[10] · Xavier Nogues[11] · Carolyn Leckie[6] · Nicholas C. Harvey[12,13] · John A. Kanis[14,15] · Jean-Yves Reginster[3,16] · Mickael Hiligsmann[2] · Stuart L. Silverman[1,17]

✉ Mitali Sharma
mxs2067@case.edu

[1] The OMC Research Center, Beverly Hills, CA, USA

[2] Department of Health Services Research, CAPHRI Care & Public Health Research Institute, Maastricht University, Maastricht, The Netherlands

[3] Division of Public Health, Epidemiology and Health Economics, WHO Collaborating Center for Public Health Aspects of Musculoskeletal Health and Aging, University of Liège, Liège, Belgium

[4] Clinical Epidemiology Unit, Faculty of Medicine UNAM, Children's Hospital of Mexico Federico Gomez, Mexico City, Mexico

[5] Department of Pharmacy, Yasuda Women's University, Hiroshima, Japan

[6] McMaster University, Hamilton, ON, Canada

[7] Investigaciones Reumatológicas y Osteológicas (IRO). Collaborating Centre WHO, Buenos Aires, Argentina

[8] IRO Medical Center, Investigaciones Reumatologicas y Osteologicas SRL, Buenos Aires, Argentina

[9] Department of Medicine, McGill University, Montreal, Canada

[10] Spokane Osteoporosis and Endocrinology, Spokane, WA, USA

[11] Internal Medicine Department, CIBERFES (ISCIII), Hospital del Mar Research Institute, Pompeu Fabra University, Barcelona, Spain

[12] MRC Lifecourse Epidemiology Centre, University of Southampton, Southampton SO16 6YD, UK

[13] NIHR Southampton Biomedical Research Centre, University of Southampton and University Hospital NHS Foundation Trust, Southampton, UK

[14] Mary MacKillop Institute for Health Research, Australian Catholic University, Melbourne, Australia

[15] Centre for Metabolic Bone Diseases, University of Sheffield, Sheffield, UK

[16] Protein Research Chair, Biochemistry Dept, College of Science, King Saud University, Riyadh, Kingdom of Saudi Arabia

[17] Cedars-Sinai Medical Center, Los Angeles, CA, USA