

**TITLE:** Clinical and Demographic Factors Determining Patient Fracture Risk Decision Point (FRDP): The Improving Risk Communication in Osteoporosis (RICO) Project

**AUTHORS:** Sharma Mitali<sup>1</sup>, Beudart Charlotte<sup>2&3</sup>, Clark Patricia<sup>4</sup>, Fujiwara Saeko<sup>5</sup>, Adachi Jonathan D.<sup>6</sup>, Papaioannou Alexandra<sup>6</sup>, Messina Osvaldo D.<sup>7&8</sup>, Morin Suzanne N.<sup>9</sup>, Kohlmeier Lynn<sup>10</sup>, Nogues Xavier<sup>11</sup>, Leckie Carolyn<sup>6</sup>, Harvey Nicholas C.<sup>12</sup>, Kanis John A.<sup>13&14</sup>, Reginster Jean-Yves<sup>3&15</sup>, Hiligsmann Mickael<sup>‡</sup>, Silverman Stuart L.<sup>‡</sup><sup>1&16</sup>  
‡ co-last authors

**AFFILIATIONS:**

1. *The OMC Research Center, Beverly Hills, California, USA*
2. *Department of Health Services Research, CAPHRI Care & Public Health Research Institute, Maastricht University, The Netherlands*
3. *WHO Collaborating Center for Public Health Aspects of Musculoskeletal Health and Aging, Division of Public Health, Epidemiology and Health Economics, University of Liège, Belgium.*
4. *Clinical Epidemiology Unit, Children's Hospital of Mexico Federico Gomez-Faculty of Medicine UNAM, Mexico City, Mexico.*
5. *Department of Pharmacy, Yasuda Women's University, Hiroshima, Japan*
6. *McMaster University, Hamilton, Ontario, Canada*
7. *Investigaciones Reumatológicas y Osteológicas (IRO). Collaborating Centre WHO, Buenos Aires, Argentina*
8. *IRO Medical Center, Investigaciones Reumatológicas y Osteológicas SRL, Buenos Aires, Argentina*
9. *Department of Medicine, McGill University, Montreal, Canada.*
10. *Spokane Osteoporosis and Endocrinology, Spokane, WA, USA*
11. *Internal Medicine Department, Hospital del Mar Research Institute, Pompeu Fabra University, CIBERFES (ISCIII), Barcelona, Spain*
12. *MRC Lifecourse Epidemiology Centre, University of Southampton, Southampton, SO16 6YD, UK; NIHR Southampton Biomedical Research Centre, University of Southampton and University Hospital NHS Foundation Trust, Southampton, UK*
13. *Mary MacKillop Institute for Health Research, Australian Catholic University, Melbourne, Australia.*
14. *Centre for Metabolic Bone Diseases, University of Sheffield, Sheffield, UK.*
15. *Protein Research Chair, Biochemistry Dept, College of Science, King Saud University, Riyadh, Kingdom of Saudi Arabia.*
16. *Cedars-Sinai Medical Center, Los Angeles, California, USA*

**CORRESPONDING AUTHOR:**

Mitali Sharma

OMC Research Center

Beverly Hills, California, U.S.A.

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4 Email: [info@omcresearch.org](mailto:info@omcresearch.org)  
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9

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13  
14

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16 International; L.K. is an Amgen speaker; Radius consultant, speaker. Other authors declare that  
17 they have no conflict of interest with regard to the content of this manuscript.  
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20 **Human Subject Protection:** The whole study was subject to an initial central IRB (Advarra for  
21 sites in the United States and Canada) and then local IRB (country and institutional specific)  
22 review and approval (if and when required by applicable law). Informed consent was obtained  
23 for all phase of the project. All subjects either received a patient information sheet or informed  
24 consent depending on the local IRB of the site. Subjects were informed of their ability to  
25 withdraw at any time as stated by the coordinator as well as the patient information sheet or  
26 informed consent form.  
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34

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36 Royal Osteoporosis Society (ROS) in the U.K. for helping with patient recruitment. We also  
37 thank all participants involved in this study for the time they dedicated to this research. As  
38 compensation for their time, participants were paid an honorarium at the discretion of their site  
39 investigator.  
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4 **SUMMARY**

5 To understand how osteoporosis medication acceptance varies across countries with differing guidance on treatment  
6 threshold and influence of clinical and demographic factors. 79.2% accepted treatment at a fracture probability at or  
7 below treatment threshold. Fracture history and age did not strongly impact acceptance, suggesting need for  
8 improved fracture risk communication.  
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11 **ABSTRACT**

12 **PURPOSE**

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

19 In 2022-2023, 332 postmenopausal women at risk of fracture were interviewed from nine countries to determine  
20 participants' Fracture Risk Decision Point (FRDP), the lowest probability of major osteoporotic fracture at which  
21 they would accept an osteoporosis medication. Participants' FRDP was evaluated given eight hypothetical 10-year  
22 FRAX scores.  
23

24 **RESULTS**

25 In countries with FRAX-based treatment thresholds, over half of participants per country reported an FRDP that was  
26 below threshold. Collectively, 79.2% demonstrated FRDPs at or below their respective threshold. Age and fracture  
27 history did not have a strong influence on FRDP; however, those who demonstrated higher levels of numeric  
28 literacy reported a significantly higher median FRDP (10%) compared to those who showed lower levels (5%,  $p <$   
29 0.001).  
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31 **CONCLUSIONS**

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

37 Osteoporosis, fracture risk decision point (FRDP), FRAX® probability, treatment threshold, patient willingness to  
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## INTRODUCTION

Internationally, one of the leading methods for quantifying fracture risk is done in terms of the Fracture Risk Assessment Tool (FRAX<sup>®</sup>) 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) (Silverman, 2010). Although the use of BMD in calculation of FRAX score improves the sensitivity of this metric, the predictive value is comparable regardless of this additional data. Therefore, FRAX allows health care providers to predict fracture probability based on clinical risk factors, which is increasingly valuable in countries with poor access to densitometry (Kanis, 2016).

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 to healthcare, and the local epidemiology of fracture (Kanis, 2016). While countries such as the United States, 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 2 & 3**) (Kanis, 2016; Clark 2018). 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 use of a fixed 20.3% treatment threshold thereafter (**Appendix 4**) (Kanis, 2016; NOGG, 2021). 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) (Litwic, 2017).

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

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4 the lowest percentage risk of major osteoporotic fracture (MOF)—in terms of ten-year FRAX  
5 probability—at which participants chose to hypothetically initiate a medication with minor,  
6 transient side effects. FRDP and willingness were assumed to be inversely proportional, as those  
7 who were more willing to accept a treatment would likely choose to do so at a lower fracture risk  
8 threshold.

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10 This study is part of an initiative called the Improving Risk Communication in Osteoporosis  
11 (RICO) study, which examined a pertinent communication gap between physicians and patients  
12 with osteoporosis. With involvement from eleven sites in nine different countries across Europe,  
13 Asia, North and South America, the RICO survey aims to understand whether the  
14 implementation of a visual aid may improve communication of one’s individual FRAX  
15 probability (Beaudart, 2024).  
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## 26 **METHODS**

### 27 **Recruitment**

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29 332 women who had been diagnosed with either osteoporosis or who were postmenopausal at  
30 risk of fracture were recruited from eleven global sites in countries, such as the United States  
31 (n=64), Canada (n=61), Mexico (n=36), Japan (n=35), Argentina (n=30), Belgium (n=30), the  
32 United Kingdom (n=29), Spain (n=28), and the Netherlands (n=19). Participants in the United  
33 States were recruited from two different sites, one in California (n=35) and one in Washington  
34 (n=29), and those recruited in Canada were interviewed by sites in Ontario (n=31) and Quebec  
35 (n=30). Sites recruited participants from a number of sources, including the local community, the  
36 site investigator’s clinical rheumatology or endocrinology practice, or an osteoporosis patient  
37 network, such as the Canadian Osteoporosis Patient Network (COPN) or the Royal Osteoporosis  
38 Society, UK (ROS). Given that this study was observational and did not pose a specific  
39 hypothesis, a sample size calculation was not applicable. Our study suggested a pragmatic target  
40 sample of thirty participants per site.  
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53 Participants at risk of fracture were defined as women with elevated FRAX score, elevated bone  
54 mineral density, or for whom pharmacologic and/ or non-pharmacologic osteoporosis  
55 management were being considered by their site clinician. In order to ensure the diversity of  
56 participant perspectives, it was recommended that sites utilize a convenience sample of (1) at  
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4 least ten participants who had sustained a fracture since the age of forty, (2) at least ten  
5 participants who had completed at least some education at the university level, (3) at least ten  
6 participants who had decided to take a prescription osteoporosis medication, and (4) at least ten  
7 participants who did not meet each of these criteria (**Appendix 1**).

### 11 **Survey Administration**

13 At each site, a study coordinator guided participants through a structured survey either online via  
14 Zoom video conference or in-person, depending on participant preference and local COVID-19  
15 guidelines. In both settings, Microsoft PowerPoint was used to display questions and all visuals  
16 to each participant. An extensive scoping review was conducted by Beaudart et al. to inform  
17 design of this exercise, including the use of icon arrays as a visual aid to enhance patient  
18 understanding of fracture probability (Beaudart, 2022). Icon arrays have previously been found  
19 to yield a similar understanding of risk presentation among patients with various levels of  
20 numeric literacy and reduce the impact of denominator neglect when considering the relative  
21 benefit of treatment in a population (Galesic, 2009; Galesic, 2011).

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

25 At the beginning of each survey, participants took a short, five question assessment—extracted  
26 from an experimentally designed Graph Literacy Scale (Galesic, 2011)—with which  
27 investigators gained a rough understanding of their ability to interpret graphs or visual aids. Two  
28 of these questions were Likert type questions that were used to gauge the participant’s self-  
29 perception of numeric literacy and preference for numeric versus verbal presentation of  
30 information (Fagerlin, 2007). However, the remaining three questions were an objective  
31 assessment of numeric literacy and were used to stratify participants into high or low numeric  
32 literacy groups (Galesic, 2011) (**Appendix 5**).

33 Within the survey, participants were presented with a maximum of eight hypothetical scenarios  
34 and asked whether they would be willing to accept a prescription for osteoporosis medication  
35 with minimal, transient side effects. To promote simplicity and participant understanding, this  
36 referred to any class of antiresorptive therapy. Each hypothetical scenario utilized two icon  
37 arrays to depict various fracture risk levels; the first icon array demonstrated the participant’s  
38 hypothetical risk of MOF over ten years or FRAX probability, and the second showed how much  
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of that risk could be mitigated upon taking a medication (**Figure 1**). An optimistic 40% reduction in fracture risk was assumed with medication use given recent literature on antiresorptive osteoporosis therapies (Lorentzon, 2019).

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 a medication by the final scenario (40% risk of MOF), then their FRDP was considered to be >40%.

**Question 6.1. Determining 10-year fracture risk cut-off to initiate a medical treatment**

Scenario 6.1.1. Would you be willing to start a medical treatment?

<b>Without medical treatment</b>	<b>With medical treatment</b>
Your risk of breaking your spine, hip, forearm or shoulder in the next 10 years is of 5%	Your risk of breaking your spine, hip, forearm or shoulder in the next 10 years with treatment is of 3%
Would you be willing to start a medical treatment? Yes <input type="checkbox"/> No <input type="checkbox"/>	

**Figure 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 ten year period and that medication would reduce this to a 3% fracture risk over ten years.

### 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 United States 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 do not and

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4 thus were excluded from this analysis (Kanis, 2016). Secondary outcomes detailed the impact of  
5 numeric literacy level, age, and fracture history on participant FRDP.  
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### 7 **Data Entry & Statistical Analyses**

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9 Site coordinators uploaded source documents and recorded all data in an electronic data capture  
10 system called “Online Clinical Trials” ([www.essaionline.com](http://www.essaionline.com)), which allowed the lead study  
11 team to ensure sites’ adherence to study protocol and accuracy of data entry.  
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15 In order to validate the statistical significance of difference in median FRDP among those with  
16 variable levels of numeric literacy and those with or without fracture history, Mood’s analyses  
17 were conducted. The Pearson correlation coefficient was calculated to understand the  
18 significance of the relationship between age and FRDP. Chi squared tests were used to analyze  
19 preference for risk timeframe given fracture history and age. P-values were compared to an alpha  
20 level of 0.05 to determine statistical significance, and all data was analyzed with use of the  
21 statistical software, QI Macros.  
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### 29 **RESULTS**

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31 The mean and median ages of participants were 67.5 and 67.0 years, respectively, 48.2% of  
32 participants (n = 160) reported a history of fracture, and 50.3% (n = 167) were adherent to a  
33 prescription osteoporosis medication. Given the numeric literacy assessment, 64.8% (n = 215) of  
34 participants answered at least two of three questions correctly on the numeric literacy assessment  
35 and therefore demonstrated a high level of numeric literacy, whereas 35.2% (n = 117)  
36 demonstrated low numeric literacy on the assessment (Galesic, 2011).  
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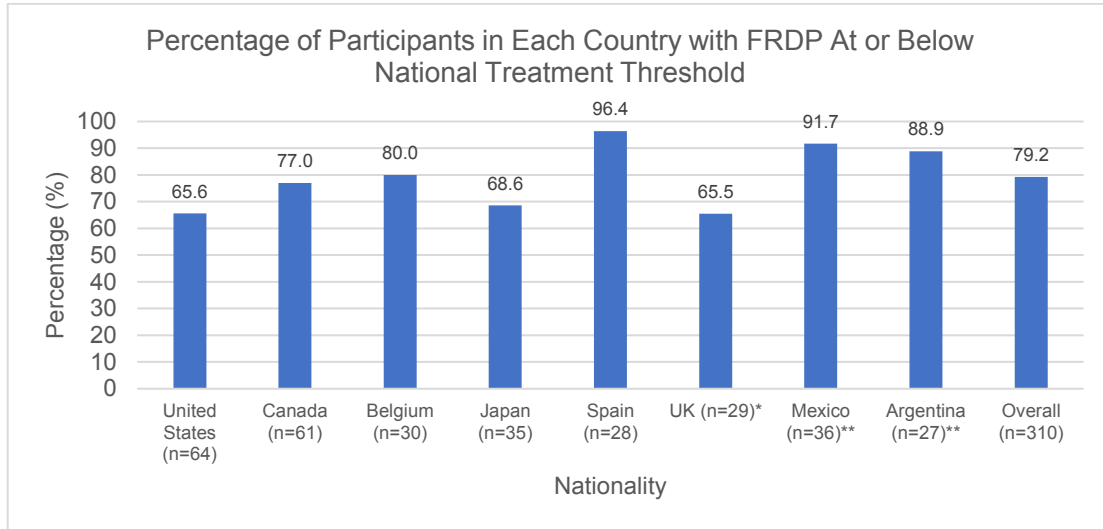
Country	Median FRDP
Belgium	5%
The Netherlands	5%
Spain	5%
Mexico	5%
Argentina	5%
Japan	10%
U.K.	10%
United States	15%
Canada	15%

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

56 Median FRDP in each country varied from 5% to 15% in all nine countries from which data was  
57 collected (**Table 1**). In the eight countries which employed FRAX-based treatment thresholds in  
58 a clinical setting, 79.2% of all participants reported an FRDP that was less than or equal to their  
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nationally recognized treatment threshold (**Figure 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 United States (65.6%), and Japan (68.6%) and the highest being in Spain (96.4%), Mexico (91.7%), and Argentina (88.9%).



**Figure 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 4**). \*\* = national treatment guidelines suggest an age dependent FRAX treatment threshold (**Appendix 3**).

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

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4 In the eight countries that utilize a nationally recommended FRAX treatment threshold, 79.2% of  
5 all participants and at least half of participants within each individual country indicated that they  
6 were willing to accept a prescription for osteoporosis medication at a fracture risk level that was  
7 at or below their respective national treatment threshold. This bodes well for medication  
8 acceptance if patients are given individualized care and explanation of fracture risk.  
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13 There was, however, a variable distribution among countries regarding percentage of participants  
14 who agreed to initiate a medication below the national treatment threshold. With the exception of  
15 Spain (96.4%), countries with age-dependent intervention thresholds, such as Mexico (91.7%),  
16 Argentina (88.9%) had the highest percentages of participants who were willing to accept a  
17 prescription medication given a FRAX probability that was less than or equal to their individual  
18 treatment threshold (**Appendix 3**) (Clark, 2018; NOGG, 2021). The lowest percentage of  
19 participants with FRDP below their respective treatment threshold was observed in the United  
20 Kingdom (65.5%), which employs a hybrid threshold.  
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### 28 **Secondary Outcomes**

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30 Surprisingly, history of fracture did not have a significant impact on participant FRDP, and age  
31 only showed a minor correlation to FRDP. The negative correlation between age and FRDP was  
32 weak ( $r=-0.153$ ) but significant ( $p = 0.007$ ), giving some indication that increased age was  
33 correlated with willingness to initiate medication at a lower fracture risk threshold. However, the  
34  $r^2$  value of 0.023 indicates that only 2.3% of the variability seen in FRDP may be impacted by  
35 age and that many other factors may also be influencing the decision. Although clinical risk  
36 factors, such as age or fracture history, are both used in calculation of one's FRAX score and  
37 may significantly increase one's risk of fracture, age showed only a weak influence on FRDP,  
38 and fracture history did not bear significant weight on participants' FRDP (Silverman, 2010).  
39 These findings are consistent with that of the GLOW study, which indicates that participants  
40 with comorbidities for future fracture tended to underestimate their fracture risk (Gregson, 2014).  
41 This points to a potential communication gap in discussions regarding fracture risk and a need  
42 for further patient education on how age and history of fracture may predispose one to future  
43 fracture.  
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### 55 **Limitations**

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57 A major source of potential bias includes limited overall sample size as well as  
58 overrepresentation of participants from Canada and the United States. Additionally, participants  
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4 were largely recruited from rheumatology or endocrinology practices—rather than internal or  
5 family medicine—and anecdotally, some investigators reported that women with a unique  
6 interest or concern regarding their fracture risk were more inclined to participate in this study.  
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8 Some participants may have had preexisting knowledge about fracture risk, as they had been  
9 recruited from patient networks, such as the Canadian Osteoporosis Patient Network (COPN) in  
10 Canada and The Royal Osteoporosis Society (ROS) in the U.K., where patients are frequently  
11 exposed to educational resources on osteoporosis and bone health. Participants who were  
12 recruited from these networks were therefore more likely to have a comprehensive understanding  
13 of local treatment thresholds and a more informed base perception of fracture risk (ROS; COPN,  
14 2019). However, to counterbalance this, during the initial RICO interview, all participants were  
15 indirectly informed that 20% FRAX probability or higher was largely considered to be high  
16 fracture risk (Kanis, 2016). Participants were not given any further education about osteoporosis  
17 or fracture risk prior to this study. The differences in FRDP observed in this study may have  
18 been partially influenced by these inter-site discrepancies in enrollment procedure.

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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 (Cauley, 2006). 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 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 & 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

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4 countries. Future iterations of this study will expand upon this research by representing Pan-  
5 Asian, African, and Middle Eastern patient populations as well.  
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8 Results of this study identify a clear gap in patient-provider communication regarding clinical  
9 risk factors and consequences of fracture, as those with a history of fracture were not  
10 significantly more motivated to initiate a prescription osteoporosis medication, and age was only  
11 a very minor predictor of FRDP. This calls for greater emphasis on the significance of clinical  
12 risk factors, such as advancing age or fracture history, when providing patient education on  
13 fracture risk. In hopes of making this important leap in patient awareness, proposed next steps  
14 for RICO will include a randomized control trial to compare the efficacy of a verbal presentation  
15 versus a visual aid in improving patient willingness to initiate a prescription osteoporosis  
16 medication.  
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## 24 **CONCLUSION**

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26 This study addressed the significant gap in patient-provider communication regarding the  
27 implications of one's FRAX probability and the important role of prescription osteoporosis  
28 medication in reducing one's risk of fracture. As part of the Improving Risk Communication in  
29 Osteoporosis (RICO) project, this study demonstrated how patient willingness to accept a  
30 prescription osteoporosis medication—or FRDP—may deviate from nationally prescribed  
31 treatment thresholds and highlighted a number of factors which may impact FRDP. Furthermore,  
32 in all countries in which FRAX was used in a clinical setting, 79.2% of participants were willing  
33 to initiate a prescription osteoporosis medication given a fracture risk that was below their  
34 nationally recommended treatment threshold. Participants with higher levels of numeric literacy  
35 were significantly less willing to initiate a prescription osteoporosis medication than those who  
36 had scored lower on the numeric literacy assessment. In addition, increased age showed only  
37 minimal correlation with FRDP, and history of fracture did not bear any significant weight on  
38 this decision—despite both of these being significant clinical risk factors for fragility fracture  
39 (Silverman, 2010). This study highlights several ways in which healthcare providers can try to  
40 improve their fracture risk communication in an effort to help patients make informed clinical  
41 decisions, reduce their fracture risk, and improve quality of life.  
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## Appendix 1. 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 <sup>3</sup>
Format of Interviews													
Online	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
Face to face	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)	
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

## Appendix 2. Nationally Recognized, Fixed FRAX Intervention Thresholds for Use of Prescription Osteoporosis Medication<sup>2</sup>

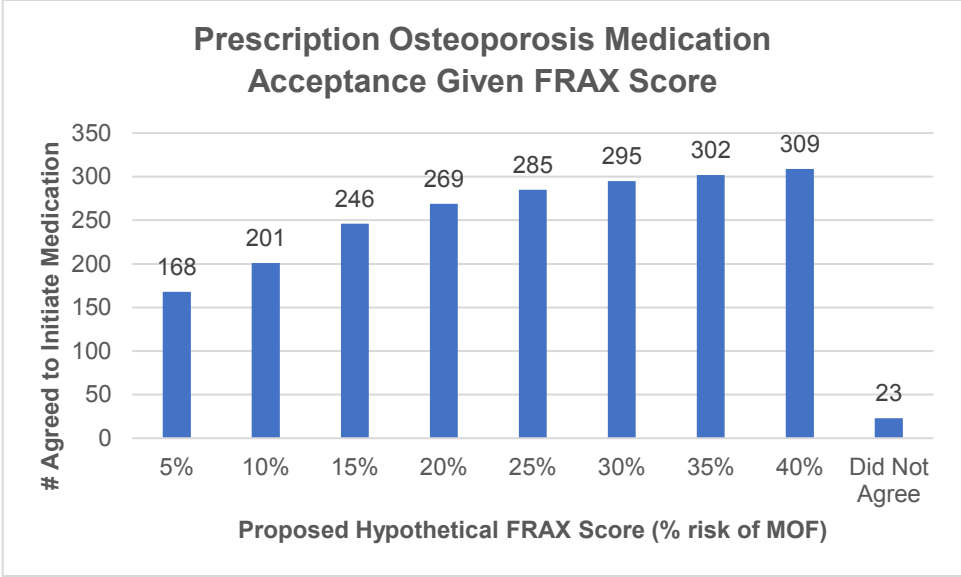
Country	National FRAX-Based Treatment Threshold (% risk of major osteoporotic fracture)
Japan	15%
Spain	20%
United Kingdom	20%
United States	20%
Canada	20%

## Appendix 3. Nationally recognized, age-dependent intervention thresholds for use of prescription osteoporosis medication in Argentina and Mexico<sup>3</sup>

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







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