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HEALTH-RELATED QUALITY OF LIFE IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AND AN INADEQUATE RESPONSE TO ANTI-OSTEOPOROSIS MEDICATION: BASELINE RESULTS OF THE FRENCH COHORT FROM THE**OBSERVATIONAL STUDY OF SEVERE OSTEOPOROSIS (OSSO)**Fardellone P¹, Liu-Leage S², Alfonsi A², Tcherny-Lessenot S²¹CHRU Amiens, Amiens, France; ²Lilly France, Suresnes, France

OBJECTIVES: To evaluate changes in health-related quality of life (HRQoL). **METHODS:** The OSSO study is a 12-month, European, prospective, observational study of postmenopausal women with osteoporosis and an inadequate response to anti-osteoporosis therapy, defined as: 1) presence of a new fragility fracture despite prescription of any approved anti-osteoporosis therapy for at least 12 months before the fracture, and/or 2) discontinuation of any approved anti-osteoporosis therapy due to compliance problems and/or side effects. **RESULTS:** A total of 418 women enrolled in France were included in the baseline analysis: 196 (46.90%) had a new fragility fracture and 222 (53.10%) had compliance problems/ side effects, a less severe patient group based upon baseline patients' characteristics. HRQoL was assessed using the osteoporosis disease-specific QUALEFFO questionnaire. At baseline, the mean (SD) total QUALEFFO score for the OSSO French population (n = 418) was 42.7 (18.8), and the mean (SD) scores for the five domains were: pain 46.2 (27.4), physical function 33.0 (23.0), social function 56.9 (25.9), general health 62.7 (20.7) and mental function 42.4 (19.2). The mean total QUALEFFO score was significantly higher in the fracture cohort than in the compliance/side effect cohort (47 vs. 38.8, P < 0.001). Similarly, the scores for each of the five domains were significantly higher in the fracture cohort. In the subgroup of index patients who sustained a vertebral fracture a few months before enrolment in the study, the mean total QUALEFFO score was higher and respectively 55.4 (17) in those with a lumbar vertebral fracture, 53.1 (15.8) with a thoracic vertebral fracture, 49.4 (15) with a lumbar and thoracic vertebral fracture. **CONCLUSIONS:** There is a clear impairment of quality of life at baseline in the French postmenopausal women with osteoporosis taking part in the OSSO study, more pronounced in the fracture group. The vertebral fracture worsens the quality of life.

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UNDERSTANDING AND ASSESSING TIBIA FRACTURE ON QUALITY OF LIFE; CONCEPTUAL MODEL AND NEW DISEASE SPECIFIC HR-QOL MEASUREBrod M¹, Lammert M², Rasmussen MH²¹The BROD GROUP, Mill Valley, CA, USA; ²Novo Nordisk, Bagsvaerd, Denmark

OBJECTIVE: Tibia fractures are the most common long bone fracture and are associated with significant morbidity ranging from infection and amputation to employment problems. Additionally, general health problems such as stiffness and ongoing pain are not uncommon. The purpose of this qualitative study was to examine QoL issues for tibia fracture, develop a conceptual model of the QoL impact of fractures and generate a preliminary version of the Fracture-QoL Measure. **METHODS:** Data were collected from the literature, orthopedic experts (N = 6) and patients, individually or in focus groups (N = 42), in 4 countries (US, Canada, UK, Germany) by interviews following a semi-structured interview guide. Transcripts were analyzed for common themes and the conceptual model and item generation was based on these themes. Items underwent cognitive debriefing. **RESULTS:** Tibia fractures have a significant negative impact across multiple aspects of QoL most notably health, relation-

ships and productivity. Contrary to physician beliefs, these impairments are still evident several years post injury for most patients. The short term impacts occur in the first 4–6 weeks post injury and include sleep disturbances and work loss. For patients who do not heal properly or develop infections, the severity of the impact on QoL midterm (6 weeks–3 months) is greater and impacts self image and feelings of helplessness. These patients are at greater risk for long-term consequences which include divorce and continued mental and physical health issues. The full conceptual model of the short, mid and long term QoL impacts, potential determinants and modifiers of the relationships along with the Fracture-QoL Measure will be presented. **CONCLUSIONS:** Improving the ability of orthopedic experts to recognize the significant QoL impacts will facilitate patient access to necessary support services and appropriate treatments. Discussion of these impacts with patients will help them to be better prepared for a realistic recovery.

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ELICITING AND QUANTIFYING PATIENT PREFERENCES FOR DOSING FREQUENCYWalker M¹, Carr AJ², Cowell W¹¹Roche Products Ltd, London, London, UK; ²Clinimatrix Limited, London, London, UK

OBJECTIVE: To develop a rating scale to elicit and quantify patient preferences for different dosing frequencies with bisphosphonate therapy in osteoporosis. **METHODS:** Expert interviews generated information for developing descriptions of an osteoporosis health state along with four different treatment scenarios for bisphosphonates: daily, weekly, monthly, and monthly plus a support programme. A rating scale questionnaire was used to elicit relative values for the health state and each scenario on a 0–100 scale. Face and content validity, acceptability and comprehension were tested with experts (n = 3) and osteoporosis patients (n = 22). Telephone administration of the rating scale was assessed in a pilot study of 50 bisphosphonate users. Construct validity was evaluated in 491 women with or at risk of osteoporosis who were: naïve to (n = 212), currently taking (n = 225) or lapsed (n = 54) bisphosphonate users. **RESULTS:** The questionnaire demonstrated good face and content validity, was acceptable to experts and patients, and suitable for telephone administration taking 5–10 minutes to complete. Construct validity was demonstrated by: (i) Lower valuation for health state compared with treatment scenarios (median values: health state = 20, daily = 40, weekly = 70, monthly = 80, and monthly with support programme = 85); (ii) Non-osteoporotic women gave lower valuations for health state than women with osteoporosis (median value = 10, one-way ANOVA, F = 4.80, p = 0.009); (iii) Lapsed weekly users gave lower valuations to weekly scenario (median value = 50) than naïve or current users, one-way ANOVA, F = 17.68, p < 0.0001; (iv) 94% of lapsed and 85% of current users who felt they had to take bisphosphonates too often, preferred monthly treatment; (v) monthly dosing with support programme was the most highly valued scenario by all patient groups (median value = 85). **CONCLUSIONS:** The preference questionnaire is a valid and acceptable method for quantifying patient preference for dosing frequency with bisphosphonate therapy. Overall, bisphosphonate treatment scenarios with lower dosing frequencies were valued more highly.