Author's response to reviews

Title: Psychometric properties of the Osteoporosis Patient Assessment Questionnaire (OPAQ) 2.0: results from the Multiple Outcomes of Raloxifene Evaluation (MORE) study

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Diana Marshall
Senior Managing Editor
BMC Musculoskeletal Disorders

Dear Ms. Marshall:

We are electronically resubmitting our manuscript, “Psychometric Properties of the Osteoporosis Patient Assessment Questionnaire (OPAQ) 2.0: Results from the Multiple Outcomes of Raloxifene Evaluation (MORE) study,” for publication as a research article in BMC Musculoskeletal Disorders. We have added required language in the Methods section, as instructed below.

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Journal Editorial Office Comment: Editorial Requirements - Research involving human subjects, human material, or human data, must have been performed in accordance with the Declaration of Helsinki (http://www.wma.net/en/30publications/10policies/b3/index.html) and must have been approved by an appropriate ethics committee. Experimental research on vertebrates or any regulated invertebrates must comply with institutional, national, or international guidelines, and where available should have been approved by an appropriate ethics committee. A statement detailing what ethical approval has been obtained, including the name of the ethics committee and the reference number where appropriate, must appear in all manuscripts. If a study has been granted an exemption from requiring ethics approval or does not require approval, this should also be detailed in the manuscript (including the name of the ethics committee that granted the exemption). For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. Please refer to our Editorial Policies for full details of the ethical requirements for the journal: http://www.biomedcentral.com/about/editorialpolicies#Ethics.

Response: We have made the necessary requested changes to meet editorial requirements. We have included the required statement detailing ethical approval on page six of the manuscript.

The validity and clinical relevance of HRQoL instruments have come under increased scrutiny since the 2005 European Medical Agency and 2009 United States Food and Drug Administration guidelines related to the use of patient-reported outcomes in clinical medical product development. These guidelines clearly specify a need to develop and confirm the suitability of HRQoL instruments in the patient population for which the therapy will be indicated in order to support the validity of evaluation. The HRQoL data from the MORE trial remain a robust and rich source of HRQoL information in osteoporosis clinical trials. Therefore, in this manuscript, we explored the psychometric properties of the Osteoporosis Patient Assessment Questionnaire (OPAQ) version 2.0, in terms of reliability, validity, and responsiveness; we used generic, clinical, demographic, and preference-based data that were collected from a population of postmenopausal women with osteoporosis. This study included a subset of 1477 women from the MORE study population who completed the questionnaires. Psychometric properties of the 14 OPAQ 2.0 domains were evaluated by standard statistical techniques. Internal consistency was $> 0.7$ in 9 OPAQ 2.0 domains. Correlations were moderate and significant for similar OPAQ 2.0 domain scores, NHP domains, and HUI scores. All, but 3, OPAQ 2.0 domains were able to discriminate between patients with or without prevalent vertebral fractures and to detect a worsening trend with increased number of vertebral fractures. Women with $\geq 1$ incident
vertebral fracture(s) generally had a greater worsening in OPAQ 2.0 scores (excluding social activity and support of family and friend) from baseline to study endpoint, compared with women without incident vertebral fractures. Most domains in the OPAQ 2.0 demonstrated robust psychometric properties; however, several domains that did not show these criteria may need to be reassessed and removed for a potentially shorter and validated version of OPAQ.

The manuscript represents original material. The material in this manuscript has not been published previously nor is it under consideration for publication elsewhere. This manuscript has not had prior interactions with *BMC Musculoskeletal Disorders*. All authors have contributed to the conception and design or to the analysis and interpretation of data, have either drafted or critically revised the manuscript for intellectual content, and have approved the final version of the manuscript. All International Committee of Medical Journal Editors conditions have been met.

We would like to suggest the following reviewers: Christine de la Loge (cdelaloge@mapi.fr), and Paul Lips (p.lips@vumc.nl).

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We appreciate your review and consideration of this manuscript and look forward to hearing from you regarding possible publication. Please address correspondence to me at (317) 277-9530 (phone); (317) 651-8684 (fax); rburge@lilly.com (email).

Sincerely,

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