Consensus Survey by Vulvodynia Experts on Outcome Measures to use in Chronic Pain Multicenter Clinical Trials

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Objective

There are compelling reasons to use "universal" measures of self-reported health, including the ability to compare disease burden and treatment impact across various chronic conditions and to evaluate comorbid conditions in chronic pain multicenter clinical trials. To promote universally-relevant scales, the National Institutes of Health developed the Patient-Reported Outcome Measurement Information System (PROMIS©). We report results of a survey where "universally-relevant" and traditional (legacy) outcome measures were rated by internationally-recognized vulvodynia experts for future use in a multicenter clinical trial.

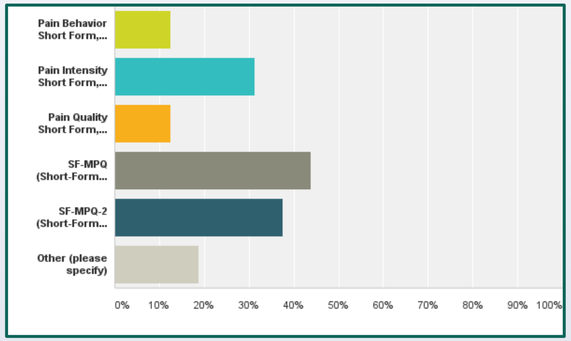
Methods

Using Survey Monkey, a panel of experts answered 6 questions measuring 6 domains, including pain intensity and quality, pain interference, depression, anxiety, sexual function and quality of life. PROMIS© measures and those used in previous vulvodynia trials were listed, including the Short-Form McGill Pain Questionnaire (MPQ), Brief Pain Inventory (BPI), Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI), Female Sexual Function Index (FSFI), and Moss Short Form Health Survey, (SF-36). Institutional review board approval was obtained from all research sites and all subjects signed an informed consent before participation.

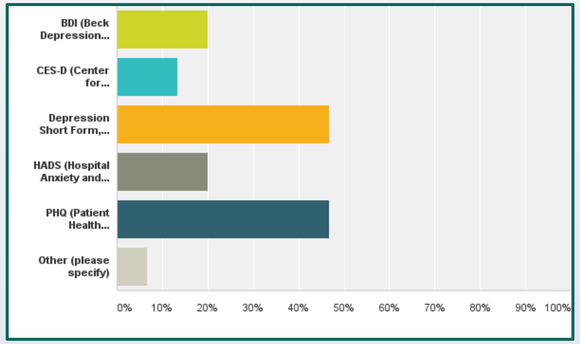
Results

From this small sample of respondents, 13/17 selected both PROMIS© and legacy measures, 3/17 selected traditional measures only, and 1/17 selected PROMIS© measures only. PROMIS© questionnaires were more frequently selected for pain interference, anxiety and quality of life whereas legacy measures were more commonly selected for pain intensity and quality, and sexual function. Selections were similar for depression scales.

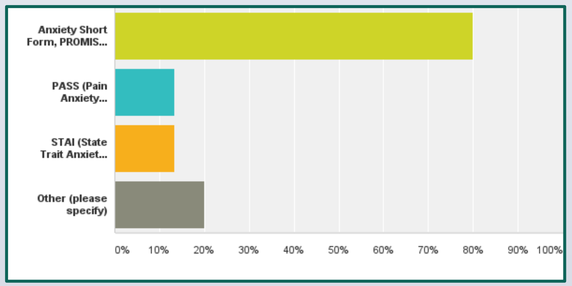
Q1: Which universally (widely relevant) outcome measure(s) do you recommend for assessing pain?



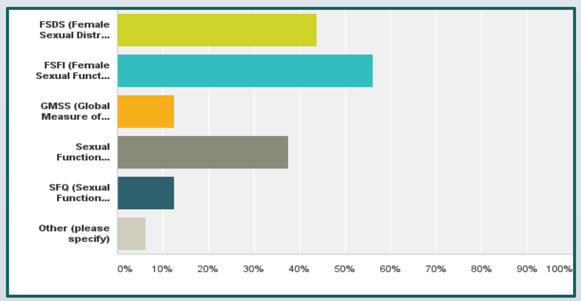
Q2: Which outcome measure(s) do you recommend for assessing depression?



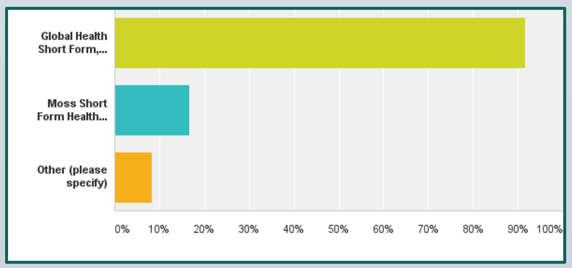
Q3: Which outcome measure(s) to you recommend for assessing anxiety?



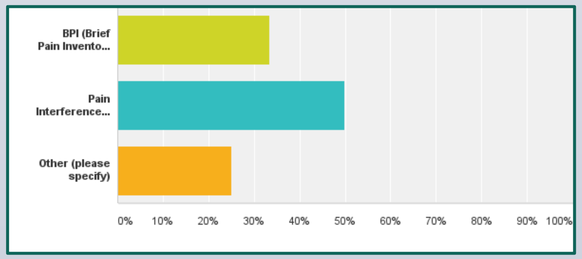
Q4: Which outcome measure(s) do you recommend for assessing sexual function and/or satisfaction?



Q5: Which outcome measure(s) do you recommend for assessing quality of life?



Q6: Which outcome measure(s) do you recommend for assessing physical function?



Conclusion

Incorporation of PROMIS© measures with previously published measures appear acceptable to a majority of the expert panel for future vulvodynia trials. PROMIS© measures should be validated against traditional measures in future clinical trials to determine treatment responsivity in women with vulvodynia.

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Conflict Disclosure

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