To the Editor: We read this article with great interest and congratulate the authors on their work. There has been a need for a disease specific health related quality of life (HRQoL) assessment tool in the field of urolithiasis for some time. Urinary tract calculi can be extremely painful and represent the second most costly disease in urology. The stone patient experience is something that has not been fully explored, and the authors have attempted to elucidate many important symptoms that clinicians may have ignored or not thought of in the past. There is wide variation in symptoms and HRQoL impact, with stones ranging from completely asymptomatic to those causing short-lived but acute colic. In addition, the various interventions to treat stones add a level of complexity to the measurement of HRQoL in this group of patients. Hence, it is important during the creation of any new HRQoL instrument that the most up-to-date techniques and methodologies be used, that the methodology be clear for all to examine so that it can be evaluated fully and its validity judged, and that it stand the test of time.

We believe that the item generation methodology needs further explanation. The authors state that they asked health care providers for their views during interviews and focus groups, and this approach surely influenced the study as a whole. This action moves the study away from a patient centric viewpoint, which is the cornerstone of qualitative research (it appears that the themes for the patient interviews were already generated based on the provider views). Similarly, were the patient groups inclusive enough to cover all stone groups, such as patients without calcium or metabolic disorders? Acute stone episodes and therapeutic interventions appear to be excluded. It would be useful to review the itinerary and transcripts of these interviews and examine direct quotes/excerpts used to develop the methodology. It is unclear which excerpts of the hierarchy of ideas were used and whether the correct content was captured. There is also no mention of whether the content of the interviews was analyzed manually or electronically, and if electronically (which is standard practice), which software platform was used.

While it is clear that there are 3 domains identified, it is unclear how each domain is weighted and, therefore, how they contribute to the final score. Is it possible that the item selection and reduction results were influenced by issues surrounding qualitative research? There is no clear evidence of reproducibility of the methods used to collect the data, for example test-retest reliability information. Content validity is not mentioned. Was the instrument validated by the target population or an expert panel? There is also no mention of the responsiveness of the instrument, eg responses in an asymptomatic stone population or comparison with patients undergoing interventions, and whether this was tested. Finally, the new generation of quality of life instruments should be designed to be capable of generating utility values for use in economic evaluations.

We have been unable to obtain a copy of the instrument anywhere in the article or in any other published source or contact the authors. We believe that to fully evaluate this instrument and, therefore, assess its clinical relevance and usefulness in practice, it would be useful if the data were freely available for interested researchers to review to further advance this important topic of scientific research.

Respectfully,

Aditya Raja, Claire O’Neill and Hrish B. Joshi
Department of Urology
University Hospital of Wales
Reply by Authors: Regarding the methodology for our development of the WSQ (Wisconsin Stone-QOL), we followed the 4 iterative steps outlined by the U.S. Food and Drug Administration for development of patient reported outcome measures. We included as much detail as space allowed in our initial published report. Table 2 in the article lists the 65 discrete items that emanated from patient only discussions, which were grouped within 6 general themes identified in our manual coding. Table 4 in the article actually lists all 28 items, although not in the specific wording of the final WSQ. While electronic analyses using specifically designed software platforms appear useful, they need not be used in all situations. Computer assisted analysis, which requires manual coding, does not in and of itself ensure that the correct content is captured, nor the validity of the approach and/or final product.

Content validity was appraised in step 2, after patients completed a reduced item pilot survey and provided general feedback about content as well as opinions about 2 different item response formats. With refinement based on these comments and those of the urologists, the final questionnaire was developed. As noted in our article, “Further testing is needed to assess test-retest reliability, concurrent validity ... and construct validity,” measurable instrument properties that are outlined in step 3 of the Food and Drug Administration guidelines. We are pleased to report that these tests, as well as others, are currently under way.

Finally, as to therapeutic interventions, an entire theme composed of 16 separate items (table 2 in article) was generated from patient comments and is represented on the final WSQ. Regarding economic impact, this issue did not emerge as a major theme in our patient discussions, perhaps owing to unique factors within our patient population. As our instrument is tested in alternate settings, this and other factors may emerge as important enough to be added as a modification to the WSQ.


Re: Are Osteotomies Necessary for Bladder Exstrophy Closure?

J. G. Borer


To the Editor: In this article Borer broaches the continuing debate of the importance of pelvic osteotomy for primary bladder exstrophy closure. The bulk of his argument supporting the notion that osteotomy is not important is derived from successful closure by Mushtaq et al of 95% of bladder exstrophy cases (70 of 74) without the use of osteotomy. It is noteworthy that Mushtaq et al omitted any description of the width of the pubic diastasis of the study population, an important variable. We agree that newborn closure is feasible and easily accomplished if the bladder template is of good quality, the pubic diastasis is not excessive (less than 4 cm) and the