## Abstract

**Aims:** To develop and assess structure, test-retest reliability and discriminative validity of a self-report questionnaire (University of South Australia Urinary Sensation Assessment: USA$^2$) to assess multiple dimensions of urgency sensation.

**Methods:** The USA$^2$ was designed and tested over two prospective, observational studies (2013-14). Participants were English speaking Australians aged 50 or more with and without overactive bladder (determined by OAB awareness tool), recruited via health and recreation centres. In Study 1, exploratory factor analysis determined USA$^2$ structure and subscales. In Study 2, confirmatory factor analysis reassessed structure; Mann-Whitney U tests determined discriminative validity (OAB vs. non-OAB for subscale and total scores) with Cohen's d effect sizes. Thirty-three individuals completed the USA$^2$ twice; intra-class correlation coefficients (ICCs) and Wilcoxon signed rank tests assessed test-retest reliability.

**Results:** Questionaries were returned by 189 eligible participants in Study 1 and 211 in Study 2. Exploratory factor analysis revealed 3 subscales: 'urgency', 'affective', 'fullness'. Confirmatory factor analysis supported these subscales. Subscale and total scores were significantly different between groups with and without OAB ($p<0.001$). Cohen's d effect sizes (95% CI) were total score 1.8 (0.5-3.1), 'Urgency' subscale 1.8 (1.3-2.3), 'Affective' 1.7 (0.95-2.4), and 'Fullness' 0.75 (0.42-1.09). Total and subscales scores demonstrated test-retest reliability; ICCs (95% CIs) of 0.95 (0.9-0.98), 0.96 (0.92-0.98), 0.94 (0.88-0.97) and 0.78 (0.56-0.89).

**Conclusions:** The USA$^2$ assesses multiple dimensions of urgency sensation, is reliable over a two week period and discriminates between older adults with and without overactive bladder. Further validation is required in conditions other than overactive bladder.

## Introduction

Urinary urgency is a common, troubling symptom of uncertain aetiology. Current instruments assess the sensation of urgency as a unidimensional construct with a focus on behavioural or affective responses (1). In other fields of medicine, the multidimensional assessment of adverse sensations such as pain and dyspnoea has revealed that different qualities of sensation can reflect different underlying mechanisms and that dimensions such as intensity and unpleasantness can be manipulated separately (2). Multidimensional assessment of urgency may promote a more sophisticated understanding of underlying mechanisms and treatment approaches. Our group has previously reported a process of categorising verbatim descriptors of desire-to-void sensation and demonstrated that this sensation differs in multiple dimensions between people with and without overactive bladder (3, 4). The purpose of the current study was to develop and assess the structure, test-retest reliability and discriminative validity of a self-report questionnaire to assess the multidimensional sensation of urgency.

## Materials and Methods

The University of South Australia Urinary Sensation Assessment ($USA^2$) prototype was developed with 16 descriptors based on dimensions and sensory qualities that we identified in our previous studies, where participants with and without OAB described their sensation of 'desire-to-void' (3, 4). The $USA^2$ prototype permitted respondents to rate how well each descriptor (randomly listed) reflected their average sensation of desire-to-void over the past month, using a six-point rating scale. Table 1 outlines the items (descriptors) and response options (rating scale) for the prototype and final version of the $USA^2$. The prototype items 'breathless' and 'freezing' were irrelevant items, included to check any tendency to rate all items equally. An additional item allowed respondents to provide another descriptor if existing options were not comprehensive.

Content and user-friendliness of the prototype questionnaire were confirmed via a prospectively designed iterative feedback process involving interviews with eight people who had been involved in the earlier studies, (2 men, 6 women, aged ≥50, all with symptoms of overactive bladder). Invitations (by letter) ceased when three consecutive participants had not suggested changes to the questionnaire. Feedback prompted minor changes to questionnaire layout and instructions and the prototype version of the $USA^2$ took between 2-7 minutes to complete.

The prototype version of the $USA^2$ was assessed for structure, validity and reliability using two prospective, observational studies with independent samples and specific aims as follows:

- **Study 1:** assess $USA^2$ internal structure and removal of redundant items.
- **Study 2:** confirm $USA^2$ structure and assess test-retest reliability and discriminative validity.

Both studies were approved by the Human Research Ethics Committee of the University of South Australia and were completed in 2013-2014.

### Participant recruitment

For both studies, independent samples of English speaking men and women aged 50 or more, with and without OAB were recruited for each phase from health-care facilities and recreation clubs which targeted the over 50s demographic. Participants were excluded if they self-reported the following conditions via a demographic questionnaire: urinary tract infection (UTI) in the past month, prior diagnosis of bladder cancer, urethral stricture or kidney/ureteral stones, neurological conditions which may affect the bladder, or a short term memory disorder. Recruitment for Study 2 began after Study 1 data analysis was completed.

## Study 1 Method

A prospective sample estimate was based upon requirements of factor analysis, where at least five participants per questionnaire item were recommended (5, 6). The minimum

sample estimate was 170 participants (17 items in the USA$^2$ prototype, five participants per item, per participant group (with or without OAB).

The lead researcher attended and distributed survey materials (USA$^2$, Overactive Bladder Awareness Tool (OAB-V8) (7) and a demographic questionnaire) at each health-care facility and recreation club, where participants independently completed questionnaires and returned them via post. Items for which more than 75% of participants chose the 'zero' option were excluded prior to analysis.

Data were analysed using SPSS version 20 (SPSS Inc., Chicago, IL, USA). OAB status was determined using the OAB-V8 which assesses bother associated with symptoms of overactive bladder; participants with a score of 8 or greater were classified as having overactive bladder(7). Exploratory factor analysis assessed questionnaire structure by determining whether items could form logical groupings or subscales. Factor analysis was completed using data sets with complete USA$^2$ data. The technique employed was principal axis factoring with oblique (promax) rotation. Cronbach's alpha assessed the internal consistency of sub-scales and the total score. Further item reduction was considered for items which displayed poor factor loadings or had a lowering effect on Cronbach's alpha. Subscale items were examined for unifying themes and named accordingly.

**Study 1 Results**

Of 295 returned questionnaires, 230 were eligible for inclusion in the analysis (Table 2). Surveys were excluded from analysis based on respondents' report of being less than 50 years of age (n=2), having a UTI (n=12), neurological condition (n=5), kidney/bladder disease (n=33), or short term memory disorder (n=8). Participants' average age was 67 years (SD = 9, range 50 – 93 years) and 69% (n= 159) were female. Questionnaire data are summarised in Table 3. Six questionnaire items were removed as more than 75% of participants chose the 'zero' option (freezing, breathless, pain, tickle/tingle, heavy, other). Exploratory factor analysis was completed with 189 full data-sets and revealed a simple 3-factor structure which formed three subscales (Urgency', 'Affective' and 'Fullness'), explaining 62% of the shared variance in the data-set. The pattern matrix is presented in Table 4. One item ('Normal') was removed based on a failure to load onto any factor and a lowering effect on Cronbach's alpha. Cronbach's alpha values were Urgency, 0.93, Affective, 0.88, Fullness, 0.72 and Total Score, 0.91. Based on these findings, the USA$^2$ was modified to a 10-item final version (Table 1) for further evaluation in Study 2.

**Study 2 Method**

A prospective sample estimate was determined by the requirements of structural equation modelling; with expected multivariate non-normality and allowing for exclusions, a minimum sample of 180 was estimated (6). The final version of the USA$^2$ (Table 1) was distributed at different health-care facilities and recreation clubs from those approached in Study 1, along with the OAB-V8 and demographic questionnaires. Participants independently completed questionnaires and posted materials to the researchers. The lead

investigator attended a selection of recruitment sites, to invite volunteers to complete a repeat USA$^2$ after a week's interval; volunteers who agreed wrote their address on the envelope in which they returned their first questionnaire and were subsequently sent a second questionnaire. Data were analysed using SPSS version 20 (SPSS Inc., Chicago, IL, USA).

Questionnaire structure was re-assessed using confirmatory factor analysis, where path diagrams representing the 3-factor structure (identified in Study 1) were assessed with structural equation modelling. Only complete USA$^2$ data-sets were included in the analysis (all 10 items completed). Path loading estimates were expected to be greater than 0.7 and goodness-of-fit indices assessed were the root mean square error of approximation (RMSEA) (expected value < 0.1) and the comparative fit index (CFI) (expected value >0.95)(6). Discriminative validity was determined using Mann-Whitney U tests to assess for significant differences in USA$^2$ total and subscale scores between individuals with and without OAB (OAB status determined by OAB-V8 scores of 8 or more(7)). Cohen's-d effect sizes for between group differences were calculated. For the subset of individuals who completed the questionnaire twice, intra-class correlation coefficients (ICCs) and Wilcoxon signed rank tests assessed test-retest reliability.

**Study 2 Results**

Of 258 volunteers who returned the 10-item USA$^2$, 211 (Table 5) were eligible for inclusion. Participants were excluded for UTI (n=6), neurological conditions (n=13), kidney/bladder diseases (n=20) or short term memory disorder (n=8). Participants' average age was 69 years (SD = 10, range 50 – 92 years) and 66% (n= 140) were females. Confirmatory factor analysis was completed on data-sets with complete USA$^2$ data (n=200) and upheld the 3-Factor solution with loading estimates for the path diagrams all > 0.7, indicating good model construct validity(6). With a model adjustment to allow for correlation between items within the 'affective' domain, model fit indices were acceptable with the RMSEA < 0.1 (0.097) and the CFI >0.95 (0.97)(6).

The USA$^2$ demonstrated discriminative validity with significant subscale and total score differences between groups with (n=106) and without (n=101) OAB ($p<0.001$). Cohen's-d effect sizes (95% CI) for the between group differences were total score 1.8 (0.5-3.1), 'Urgency' subscale 1.8 (1.3-2.3), 'Affective' subscale 1.7 (0.95-2.4), and 'Fullness subscale 0.75 (0.42-1.09). Figure 1 presents the median scores for each item in groups with and without OAB, demonstrating a multidimensional profile of sensation for each group.

Thirty-three participants returned repeated questionnaires. The total and subscales scores all demonstrated acceptable test-retest reliability with ICCs (95% CIs) of 0.95 (0.9-0.98), 0.96 (0.92-0.98), 0.94 (0.88-0.97) and 0.78 (0.56-0.89) respectively. Neither total nor subscale scores were significantly different between occasions of testing.

## Discussion

The USA$^2$ is a user-friendly, self-report questionnaire assessing multiple dimensions of the sensation 'desire-to-void'. Two independent data-sets confirmed that three subscales make up the total score, representing 'Urgency', 'Affective' and 'Fullness' domains. In this group of community dwelling volunteers, the USA$^2$ was reliable over a week, and discriminated between people with and without OAB as determined by the OAB-V8. Scores for all sub-scales were significantly higher in people with OAB, with the smallest between group difference in the 'Fullness' subscale.

A key strength of the USA$^2$ design was that it included descriptors of sensation originally derived from people with and without OAB (3) and each descriptor was separately assessed, allowing each to potentially differ between people with and without OAB. This represented a paradigm shift in the assessment of urgency which traditionally has been assessed in single dimensions or with multiple dimensions combined within single items so that dimensions cannot be separately assessed (1). Consequently the USA$^2$ permits the creation of a multidimensional profile of sensation for people with and without OAB. Aside from the tendency for greater scores in all domains in people with OAB, the key between-group differences were the relative absence of an affective domain in people without OAB and prominence of 'pressure' or 'fullness' over other descriptors in this group. Thus, 'pressure' and 'fullness' may describe 'normal' bladder sensation.

Both exploratory and confirmatory factor analysis supported three factors (subscales) for the USA$^2$, which were theoretically sound; one factor represented physical descriptors of urgency (Urgency subscale), another represented affective descriptors (Affective subscale) and the final factor represented physical descriptors of 'normal' desire to void sensation (Fullness subscale). Interestingly, a division between affective and physical descriptors has been shown in questionnaires assessing other sensations such as dyspnoea (Multidimensional Dyspnoea Profile (8), Dyspnea-12 (9)), pain (McGill Pain Questionnaire short-form (10)) and pruritus (11). This may reflect that the physical nature of sensation (urgency or other sensations) and the affective dimension may each be discrete and processed in different areas of the brain (12). The affective dimension of urgency may explain why change in 'bother' scores in traditional assessments of overactive bladder better predict treatment satisfaction than changes in the frequency with which symptoms are experienced (13).

The descriptors 'tickle/tingle' and 'pain' were removed from the USA$^2$ during Study 2 as these items were rated 'zero' by 78% and 87% of participants respectively. Both had been mentioned in previous research reporting the quality of urgency sensation in small numbers of people (n = 11-19) with and without OAB (14-16). However, in this large sample of community dwelling older Australians (n= 230 in Study 2), both were rarely chosen by people with or without OAB.

In addition to age and culturally influenced language choice, there are a number of reasons why the terms 'tickle/tingle' may not have been commonly selected in the current study whilst having been reported in previous research (14). In the current study, participants recalled their average sensation of 'wanting to wee' over the previous month. In contrast, participants in a study by Heeringa (14) reported sensation induced by forced diuresis (focal period 'right now'). It is possible that sensation generated by rapid bladder filling differs from usual sensation (17). Furthermore, participants in the study by Heeringa were required to wait until their bladders were full before voiding and 'tingling' described sensation experienced in the perineal region when the bladder was very full (14). Participants in the current study were requested to rate their average sensation over a month. In daily life, it is likely that people choose to void for a variety of reasons, with different bladder volumes and levels of sensation (18). It is possible that if 'tingling' is associated with a full bladder, it may be rarely experienced in a day-to-day context. In a study by Coyne, only participants without urgency reported 'tingling', associated with fullness (16).

The descriptor 'pain', as it relates to urgency, may be relevant to various patient groups. However, symptom questionnaires for painful bladder syndrome (PBS) tend to assess pain and urgency as separate symptoms (19-21). Focus groups of patients with PBS have confirmed that pain and urgency are experienced as separate symptoms (22). Further research will be required to determine whether the item 'pain' should be reconsidered for inclusion in the assessment of 'desire-to-void' sensation in patient groups who experience pain associated with their bladders (e.g. PBS, prostatitis, enlarged prostate) or whether pain should be assessed as a symptom separate from urgency.

A number of limitations apply to this study. Firstly, the USA$^2$ was validated in English speaking Australian adults aged 50 years or more with or without symptoms of OAB. Objective assessments of bladder function were not undertaken and people with recent urinary tract infections, neurological conditions and kidney/bladder diseases were excluded. It is possible that the perception of urgency in different between sexes, cultures or pathologies and the current study was not designed or powered to allow meaningful subgroup analysis. To allow use of the USA$^2$ to potentially discriminate between subtypes of urgency in different pathologies, this instrument would need to be validated in different patient groups, in whom the sensory quality of urgency may differ.

In the current research, the number of participants reporting symptoms of stress urinary incontinence was relatively high (68% and 66% of females in studies 1 and 2 and 19% and 13% of males). It is possible that urgency experienced in conjunction with stress urinary incontinence may have different underpinning mechanisms (such as urethral hypermobility in females) and be perceived differently to urgency related to other causes of overactive bladder. Further research may elucidate whether the profile of urgency sensation generated in the current research is skewed towards urgency as experienced in conjunction with stress urinary incontinence.

Furthermore, without a gold standard method for the diagnosis of OAB, the USA$^2$ was validated against another questionnaire (OAB-V8). Determining the discriminative validity of the USA$^2$ against groups with and without OAB may be limited by the accuracy of the OAB-V8 in making this group division. However, as the OAB-V8 assesses all four symptoms of the OAB symptom complex (urgency, incontinence, frequency and nocturia), it is more likely that the incidence of OAB may have been over rather than under-estimated in this study, as higher scores may be contributed to by symptoms other than urgency. It is possible that the large between group differences found in the current study may under-represent the true difference between groups if diagnosis of OAB were to be confirmed in a clinical context where patients with high OAB-V8 symptom scores for symptoms other than urgency may have been differently diagnosed. A urodynamic diagnosis of overactive bladder was not requested in this study. It is not know whether the urgency experienced in the context of urodynamics is comparable with urgency experienced in every-day life. Further studies are required to confirm the external validity of the USA$^2$ for assessing sensation of urgency in a variety of contexts (urodynamic testing, daily life, situations associated with expectation of urgency). The USA$^2$ provides a means by which the perceptual experience of urgency in different contexts can be compared.

The within-participant stability over a short time period (test-retest reliability) of the USA$^2$ makes it a potentially useful instrument for assessing pre-and post-treatment change in sensory perceptions related to the desire to void. If future studies can demonstrate responsiveness to change in the USA$^2$, it could prove useful in addressing a widely recognised limitation of clinical trials assessing treatments for urinary urgency; namely, the inability to assess change in the sensation itself (23, 24). In particular, as each subscale of the USA$^2$ has demonstrated test-retest reliability, it may be possible to investigate whether each subscale demonstrates responsiveness to change, as subscales of the USA$^2$ may respond differentially to various treatment options for urgency.

## Conclusion

The USA$^2$ is a self-report questionnaire which assesses multiple dimensions of urgency sensation. It differs from available instruments for overactive bladder which typically assess the frequency or bother associated with overactive bladder symptoms**;** instead the USA$^2$ assesses the sensory-perceptual experience of the sensation of urgency. This instrument is reliable over a two week period and discriminates between older adults with and without OAB. Further research is required to validate this questionnaire in contexts such as urodynamic testing and daily life as well as in conditions other than OAB. Potential clinical benefits include investigating sensory profiles according to gender, age and differing underlying mechanisms of urgency, profiling induced versus recalled urgency sensation and investigating how urgency perception might change in response to various treatment modalities.

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## References


1. Das RN, Buckley JD, Williams MT. Dimensions of Sensation Assessed in Urinary Urgency: A Systematic Review. J Urol. 2013;190(4):1165-72.
2. Lansing RW, Gracely RH, Banzett RB. The multiple dimensions of dyspnea: Review and hypotheses. Respiratory Physiology and Neurobiology. 2009;167(1):53-60.
3. Das R, Buckley JD, Williams MT. Descriptors of sensation confirm the multidimensional nature of desire to void. Neurourol Urodyn. 2015;34(2):161-6.
4. Das R, Buckley JD, Williams MT. The multidimensional sensation of desire to void differs between people with and without overactive bladder. Neurourol Urodyn. 2015;34(5):444-9.
5. Pallant J. SPSS Survival Manual. 4th ed. Crows Nest NSW: Allen & Unwin; 2011.
6. Hair JF. Multivariate data analysis. 7th ed. Hair JF, editor. London: Pearson; 2010.
7. Coyne KS, Zyczynski T, Margolis MK, Elinoff V, Roberts RG. Validation of an overactive bladder awareness tool for use in primary care settings. Adv Ther. 2005;22(4):381-94.
8. Meek PM, Banzett RB, Parschall MB, Gracely RH, Schwartzstein RM, Lansing RW. Reliability and validity of the Multidimensional Dyspnea Profile. Chest. 2012;141(6):1546-53.
9. Yorke J, Russell A, Swigris J, Shuldham C, Haigh C, Rochnia N, et al. Assessment of dyspnea in asthma: validation of the Dyspnea-12. J Asthma. 2011;48(6):602-8.
10. Wright KD, Asmundson GJG, McCreary DR. Factorial validity of the short-form McGill pain questionnaire (SF-MPQ). European Journal of Pain. 2001;5(3):279-84.
11. Yosipovitch G, Zucker I, Boner G, Gafter U, Shapira Y, David M. A questionnaire for the assessment of pruritus: validation in uremic patients. Acta Dermato Venereologica. 2001;81(2):108-11.
12. Tadic SD, Griffiths D, Schaefer W, Cheng CI, Resnick NM. Brain activity measured by functional magnetic resonance imaging is related to patient reported urgency urinary incontinence severity. J Urol. 2010;183(1):221-8.
13. Michel MC, Oelke M, Goepel M, Beck E, Burkart M. Relationships among symptoms, bother, and treatment satisfaction in overactive bladder patients. Neurourol Urodyn. 2007;26(2):190-5.
14. Heeringa R, De Wachter S, van Kerrebroeck P, van Koeveringe GA. Normal bladder sensations in healthy volunteers: A focus group investigation. Neurourol Urodyn. 2011;30(7):1350-5.
15. Heeringa R, van Koeveringe GA, Winkens B, van Kerrebroeck PEV, De Wachter S. Do patients with OAB experience bladder sensations in the same way as healthy volunteers? A focus group investigation. Neurourol Urodyn. 2012;31(4):521-5.
16. Coyne KS, Harding G, Jumadilova Z, Weiss JP. Defining urinary urgency: Patient descriptions of “gotta go”. Neurourol Urodyn. 2012;31(4):455-9.
17. De Wachter S, Smith P, Tannenbaum C, Van Koeveringe G, Drake M, Wyndaele JJ, et al. How should bladder sensation be measured?: ICI-RS 2011. Neurourol Urodyn. 2012;31(3):370-4.
18. Harvey J, Finney S, Stewart L, Gillespie J. The relationship between cognition and sensation in determining when and where to void: the concept of cognitive voiding. BJU Int. 2012;110(11):1756-61.
19. Parsons CL, Dell J, Stanford EJ, Bullen M, Kahn BS, Waxell T, et al. Increased prevalence of interstitial cystitis: Previously unrecognized urologic and gynecologic cases identified using a new symptom questionnaire and intravesical potassium sensitivity. Urology. 2002;60(4):573-8.
20. Goin JE, Olaleye D, Peters KM, Steinert B, Habicht K, Wynant G. Psychometric analysis of the University of Wisconsin interstitial cystitis scale: implications for use in randomized clinical trials. J Urol. 1998;159(3):1085-90.
21. O'Leary MP, Sant GR, Fowler Jr FJ, Whitmore KE, Spolarich-Kroll J. The interstitial cystitis symptom index and problem index. Urology. 1997;49(5, Supplement 1):58-63.
22. Payne C, Allee T. Goal achievement provides new insights into interstitial cystitis/painful bladder syndrome symptoms and outcomes. Neurourol Urodyn. 2009;28(1):13-7.
23. Brubaker L, Chapple C, Coyne KS, Kopp Z. Patient-reported outcomes in overactive bladder: Importance for determining clinical effectiveness of treatment. Urology. 2006;68(2A):3-8.

24. Starkman JS, Dmochowski R. Urgency assessment in the evaluation of overactive bladder (OAB). Neurourol Urodyn. 2008;27(1):13-21.

**Figure legend**

Study 2, median item scores within USA[2] subscales for people with (OAB**,** n=106) and without overactive bladder (non-OAB**,** n=101).