# Correlations Among Measures of Bladder Function and Comfort

Thérèse Dowd Katherine Kolcaba Richard Steiner

The University of Akron Akron, OH

There is a need for standard functional and psychosocial measurements of compromised urinary bladder syndrome (CUBS). Utilizing Kolcaba's Comfort Theory, the purpose of this study was to assess the psychometric properties and relationships among 8 measures of comfort, status of urinary frequency and incontinence, and quality of life. A convenience sample of 47 persons (45 women, 2 men) ages 25 to 92, who had UI for more than 6 months, was recruited. Data were collected twice with a 2-week interval. We examined (a) 1 measure of the immediate outcome of comfort related to CUBS, (b) 5 measures of UI status, and (c) 2 measures of quality of life. Reliabilities were adequate for all measures. Relationships among variables are presented and discussed. Recommendations are made for measures that detect improvement over time related to first line interventions.

ompromised urinary bladder syndrome (CUBS), defined as urinary frequency and/or leakage sufficient to be a problem (Dowd, Kolcaba, & Steiner, 2000) is prevalent in men and women of all ages. Although informational, behavioral, medical, and surgical interventions have been reported to be helpful and even curative, comparison of treatments is difficult because measures of outcomes are not standardized or universally accepted (Blaivas, 1998; Elser, Fantl, & McClish, 1995). There is thus a need for standard functional and psychosocial measurements of CUBS status to evaluate the holistic and specific benefits of low tech, cognitive behavioral interventions for early stages of CUBS. In particular, it is essential to have convenient, accurate, socially acceptable, and affordable measures of early urinary frequency (UF) and urinary incontinence (UI), in order to institute early treatment and possible reversal of symptoms.

Unfortunately, accurate measurement of CUBS among community dwelling persons is challenging. Verbal reports of improvement in CUBS are not sufficiently reliable (Dowd, Campbell, & Jones, 1996; Elser, Fantl, & McClish, 1995), and a purely objective approach such as urodynamic testing is expensive, invasive, time consuming, may not be sensitive to all bladder conditions, and may not be necessary for early CUBs. Psychosocial indicators specific to CUBS may be too long or inappropriate and they are only indirect measures of actual changes in function.

Pad weights, done under laboratory conditions, are considered to be the gold standard of UI status because they actually quantify the amount of urine loss in a given time (Mouritsen, Berlid, & Hertz, 1989; Siltberg, Larsson, & Victor, 1997). However, when done at home, this measure is inconvenient and embarrassing, so much so that potential

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research participants either refuse to join studies using the measure or drop out. Because home pad tests cannot be standardized, their scientific utility is limited (Jakobsen, Vedel, & Andersen, 1987).

The most important tool in the primary evaluation of lower urinary tract symptoms is the voiding diary, a record of each voiding and incontinence event over a designated period of time. This is usually considered an objective and valid measure of change (Dowd, Kolcaba, & Steiner, 2000; Hansen & Klarskov, 1998; Mathewson-Chapman, 1997). It is considered the best tool for assessing the results of treatment especially for those with urgency (Siltberg, Larsson, & Victor, 1997). The voiding diary is even considered by some to be a more valid measure of functional bladder capacity than cystometric capacity (Hellstrom, Ekelund, Larsson, & Misom, 1991). Pfister (1999) noted that mental acuity, ambulatory ability, and motivation are essential ingredients for reliable voiding diaries. As yet there is no agreement about the number of days for the diary keeping. Three-day diaries have been found as accurate as 7-day diaries for assessing voiding patterns in community dwelling women (Lentz & Stanton, 1992) but a 7-day time period has also been recommended (Sasso & Gallo, 1996).

Visual analog scales (VASs) are single item indicators that are appropriate to quantify perceptions of a state or complaint, and also to describe symptom intensity (Frazer, Sutherst, & Holland, 1987; Youngblut & Casper, 1993). Generally, reliability and validity estimates are adequate, regardless of the response format selected, and VASs can be used as a second measure of an important concept to help establish concurrent validity (Youngblut & Casper, 19993). VASs are useful as global indicators of individuals' perspectives about how and to what degree CUBS affects their lifestyle. Positive correlations were found between a VAS for interference with daily activities and UI and pad weights (Wyman, 1997).

Measures to assess psychosocial and physical factors associated with UI are available, but measures of treatment outcomes related to lifestyle are few (Joseph & Lantz, 1996; Talbot & Cox, 1995; Vinsnes & Hunskaar, 1991). One measure, the Incontinence Impact Scale (IIQ), measures the impact of UI on quality of life (Uebersax, Wyman, Shumaker, McClish, & Fantl, 1995). Significant correlations have been found between IIQ and the type of incontinence (Wyman, Harkins, Choi, Taylor, & Fantl, 1987), and symptom distress (Dugan et al., 1998; Gallagher, 1998; Robinson, Pearce, Preisser, Dugan, Suggs, & Cohen, 1998). Detrusor instability, amount of loss of urine with each event, and CUBS were all associated with higher impact or lower quality of life. The primary purpose of this study was to assess the psychometric properties and relationships among several well known measures and four new holistic measures of CUBS.

#### CONCEPTUAL FRAMEWORK

The study was based on Kolcaba's Theory of Comfort (Kolcaba, 1994), which posits that there are three types of comfort (relief, ease, and transcendence) perceived in a holistic context (physical, psychospiritual, sociocultural, and environmental). Comfort acts as a motivating and strengthening force for the performance of health seeking behaviors (HSBs). Comfort is the immediate outcome or the first response to an intervention, preceding and readying patients for engagement in durable HSBs. HSBs are defined as behaviors in which patients engage consciously or subconsciously that move them toward well-being. HSBs can be internal or external (Schlotfeldt, 1975).

Comfort related to CUBS readies patients for engagement in HSBs of interest in this study. The HSBs that we examined were urinary frequency/urinary incontinence (UF/UI) status, and quality of life. The study looked specifically at the reliability for each measure and the correlations among new measures (comfort related to CUBS, UI amount, CUBS limit, bladder function) and established measures (voiding diaries (UF/UI counts), pad weights, quality of life).

The established measures were included because a review of the literature suggested that voiding diaries (Abrams & Klevmark, 1996; Robinson, McClish, Wyman, Bump, & Fanti, 1996), visual analog scales (Frazer, Sutherist, & Holland, 1987), and pad weights (Jakobsen, Vedel, & Andersen, 1987) were accurate measures of UF/UI. While the existing instruments had adequate validity and reliability, we developed the additional instruments specifically to measure change over time in community dwelling persons. We wanted to measure change over time because our program of research was focused on interventions for early CUBS.

#### **METHODS**

#### Site

The study was conducted with community-dwelling persons in Northeast Ohio. Participants responded to ads placed in local newspapers, church and community newsletters, and flyers distributed at libraries, senior centers and high rises, and churches. A feature newspaper article about CUBS, with mention of the authors' ongoing research, greatly boosted recruitment. Presentations about bladder health given by the principal investigator at senior centers also resulted in several volunteers. Data were collected at participants' homes or apartments over three visits. Protection of human subjects was assured through approval of the appropriate institutional review board.

# Sample

The sample included adult men and women. Eligibility criteria were functional independence, history of CUBS lasting more than 6 months, and ability to read and write English. Exclusion criteria were: severe neurological dysfunction and inability to care for personal needs. Specific efforts were made to recruit African American participants. An African American colleague who gave health promotion presentations to selected populations invited the researchers to present with her at several of her sessions. Information about the research and an invitation to participate were given at the end of the presentation.

## **Incentives**

To facilitate data collection, both informational and monetary incentives were offered (Wineman & Durand, 1992). The informational incentive was a pamphlet specially designed for this population. The content, synthesized from the literature and clinical experience, was reviewed with subjects and given to them at the second data collection visit. This content included voluntary and autonomic physiology of the urinary elimination system and standard techniques to enhance bladder function such as self-monitoring, scheduled voiding, urge management, pelvic muscle exercises, and fluid and dietary adjustments. A financial incentive of \$20 was given to all participants who successfully completed the study.

# **MEASURES**

Comfort Related to CUBS. Comfort is measured by the Urinary Incontinence and Frequency Comfort Questionnaire (UIFCQ), which consists of 28 items about comfort in regard to the condition of CUBS. The UIFCQ was adapted by Kolcaba and Dowd from the General Comfort Questionnaire (Kolcaba, 1992) and is currently published in a study by Dowd, Kolcaba, and Steiner, 2000). The UIFCQ items (examples as given in parentheses) are related to the four contexts of comfort, for example, physical (I drink very little fluids), social (I enjoy having people over to my house), psychospiritual (I feel good about myself), and environmental (My home smells clean); together they yield a measure of holistic comfort. Respondents rate their comfort with regard to the four contexts as a person living with CUBS. It has a six-response, Likert-type format with anchors ranging from strongly agree to strongly disagree. Higher scores indicate more comfort. In a previous sample of persons with CUBS (N = 40), Cronbach's alpha was .82 (Dowd, Kolcaba, & Steiner, 2000).

UF/UI Status. UF/UI status is defined as the physiological and management aspects of CUBS. It includes the processes by which urine is collected and released and the extent of and limitations caused by CUBS. It is operationalized by the BFQ, UI Amount, void-

ing diary (number of toilet trips and UI events), and pad weights.

Bladder Function Questionnaire (BFQ). This 20-item questionnaire was developed by the authors to measure change in bladder function and management over time (see Appendix A). The researchers developed the BFQ based on clinical and research evidence. Questions (examples in parentheses) relate to emptying (I can empty my bladder completely), urine flow control (I cannot stop the leakage), perception of bladder function (My bladder is functioning well), and management strategies (Using some form of protection is necessary). Each item has the same response format and scoring as the UIFCQ. Higher scores indicate better bladder function. In a previous study (N = 100), Cronbach's alpha for the BFQ was .86 (Dowd & Kolcaba, unpublished).

UI Amount. This VAS asks subjects to estimate the amount of leakage daily by placing a mark on a line with the anchors from "no leakage" to "a very large amount." Testretest Reliability with VAS scales in general has ranged from 0.70 at 1 hour to 0.45 - 0.65

for periods up to 18 months apart (Youngblut & Casper, 1993).

Voiding Diaries. Grids for 3-day collecting periods were provided to participants and they were asked to mark each toilet trip (as a measure of frequency) and UI event. Reproducibility of diaries as measures of frequency in two 24-hour tests was 0.60 to 1.67 (Siltberg, Larsson, & Victor, 1997).

Pad Weights. Participants wore the provided pre-weighed pads 24 hours a day for 3 days. They changed pads as often as they wished. Each used pad was placed in a ziplock bag and then placed in a larger collection bag. Shortly after the first and last collection period, pads and diaries were picked up by data collectors and weighed on a scale calibrated to measure grams. Reproducibility of pad weights over two 24-hour periods was 0.66, and over two 48-hour periods was 0.90 (Victor, Larsson, & Asbrink, 1987).

Quality of Life. Quality of life, defined as feelings, limitations in daily living, and selfconcept associated with chronic CUBS, is operationalized by the Impact of Incontinence

Questionnaire (IIQ), and the CUBS Limit.

IIQ. The IIQ consists of 26 items grouped into activities of daily living, social interactions, and self-perception categories (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994). Factor analysis of the IIQ revealed three activity subscales: domestic, social/relationship, and travel/physical. Internal consistency reliabilities were 0.88, 0.83, and 0.77 respectively. Test retest reliability was r = 0.71, p = .0001 at 1-week and r = 0.65, p = .001

at 6 weeks. Respondents rate the extent of impact of CUBS on a 5-point scale ranging from not at all to greatly, and include a not applicable. Higher scores denote higher distress (Shumaker et al., 1994). Low scores indicate less impact.

CUBS Limit. This VAS asks subjects to estimate the extent to which the CUBS limits their activities by placing a mark on a line with the anchors from "not at all" to "most of the time." As noted above, test-retest reliability with VAS scales in general has ranged from 0.70 at 1-hour to 0.45 to 0.65 for periods up to 18 months apart for measures of quality of life (Youngblut & Casper, 1993).

# **Procedures**

In this study, three visits were made to collect data for two time points. A 2-week time period for test retest was selected because minimal variation would be expected in CUBS lasting more than 6 months. At the first data collection visit, the study was explained and informed consent obtained. Participants completed a demographic questionnaire that included the UI Index and a perception of CUBS severity question, the BFQ, UIFCQ, IIQ, and the two VASs. They were then instructed to wear and collect pads in individual ziplock bags for 3 days and nights (Lentz & Stanton, 1992). They were also instructed to record each toilet trip and UI event in the voiding diary for the same 3 days and nights, a time period sufficient for accuracy (Lentz & Stanton, 1992). After baseline data were collected, a second visit was made to review an information pamphlet about basic bladder health self-care. For participants recruited through presentations, there was some overlap of information. Pads were collected at this time and diaries discussed. Diaries were then left with participants. When appointments were made by telephone for the 2-week data collection, participants were reminded to collect the pads and complete the second voiding diary. At the third and last visit, questionnaires were again completed and pads and voiding diaries were collected. Informal opinions about the diaries and pad collection protocols were solicited for use in future studies. Participants were thanked for their participation in the study and given \$20.

#### RESULTS

# **Demographic Characteristics**

The demographic characteristics of the participants are presented in Table 1. All persons who enrolled completed the study. The 70% (N=33) Caucasian and 19% (N=9) African-American representation is consistent with proportions in the geographic region of the study and demonstrated the success of special efforts to recruit minorities. Because the number of men (N=2) in this study was so small, meaningful gender comparisons could not be made. Sixty percent of the sample had CUBS for less than 1 year. Severity of CUBS was rated as mild or moderate by 78% by both the question on how severe it was and the UI Severity Index (Sanduik, Hunskaar, Hermstad, Vanvik, & Bratt, 1998; see Table 1). Three persons (6.4%) had incomplete pad weight data.

# **Data Analysis**

Both internal consistency and stability measures of reliability were conducted. Cronbach's alpha computations for the BFQ, UIFCQ, and IIQ are presented in Table 2. The three instruments demonstrated adequate reliabilities at both measurement points, with the BFQ and UICQ reliabilities ranging from .72 to .83 across both measurement points and the

TABLE	1.	<b>Demographics</b>
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Gender	45
Women	45
Men	2
Age	25-92
Range	70.00
Median	
Mean	68.20
SD	13.81
Ethnicity	33
Caucasian	
African American	9
Other	4
	1.0 Over 2 years

CUBS Duration	Under 1 year	1-2 years		Over 2 years
CODO DUILLOS.	60%	21%		19%
Severity Indicators	Mild	Moderate	Severe	Very Severe
Rating of Severity UI Severity Index	27% 28%	51% 50%	17% 12%	5% 10%

established IIQ reliability ranging from .96 to .97. Intraclass test-retest reliabilities were computed for all the instruments (see Table 3). The BFQ and UIFCQ demonstrated test-retest reliabilities of .72 and .71, respectively. Three persons had incomplete pad weight data. Test-retest reliabilities ranged in the .80s for pad weights and diaries. The test-retest reliability for the IIQ was lower at .64.

One method for assessing validity of a measure is to examine its correlation with established criteria. To this end, correlations among new and established measures of CUBS were examined to evaluate the validity of the newer instruments. Since the variables were not normally distributed (for example pad weights were highly skewed) an appropriate statistic to examine the correlations among the instruments was the Spearman Rank-Order correlation (Burns & Grove, 2001). See Table 4 for results.

Many relationships were evident among the established bladder function measures. At Times 1 and 2, pad weights were correlated with toilet trips (-.45 & ns), UI Events (.67 & .78), and UI Amount (.33 & .40). Toilet trips were also correlated with UI Events (-.30 & -.35). One measure, UI Amount, was related to all measures but one, confirming that amount of urine loss is a significant indicator of the impact and severity of CUBS.

The new measures, UIFCQ and BFQ, were correlated with each other at Time 1 and 2 (.51 & .59) and both were correlated with the established IIQ (.54, .69, & .51, .66 respectively), indicating the validity of both the UIFCQ and the BFQ. The UIFCQ and BFQ were variably correlated with the two new VASs (UI Amount *ns*, -.32, & -.53, -.47, respectively, (CUBS Limit NS, -.48, & -42, -.47, respectively). The BFQ was also correlated with UI Events at Time 1 (-.30).

UI Amount and CUBS Limit were correlated with the established IIQ (-.34, -.60, & -.42, -.57, respectively). UI Amount was positively correlated with both pad weight (.33 & .40), and UI Events (.49 & .61) but not with toilet trips or UI Limit (-.38 & -.68). At Time 2, the IIQ was correlated with UI Events (-.30), UI Amount (-.34 & -.60), and UI Limit (-.42 & -.57).

TABLE 2. Internal Consistency Reliability (Cronbach's Alpha)

Scale	Time 1	Time 2
	0.72	0.83
BFQ UICQ IIQ	0.74 0.96	0.83 0.97

Table 3. Test-Retest Reliabilities

Variable	ICC <sup>a</sup>
UI Amount	0.50
CUBS Limit	0.35
Toilet Trips	0.86
UI Events	0.81
Pad Weights	0.78
BFQ mean	0.72
UICQ mean	0.71
IIQ mean	0.64

<sup>&</sup>lt;sup>a</sup>Intraclass Correlation Coefficients.

As expected, Cronbach reliability values for the instruments tested here were strong. The IIQ had very strong reliability with this population indicating that this older instrument has been well developed and refined. The two newer instruments, the UIFCQ and BFQ, had adequate reliabilities for instruments at this stage of development and should be sensitive measures of change over time.

# DISCUSSION

Intraclass correlations computed to calculate test-retest reliabilities were moderately strong or better for all measures but the UI Amount and the CUBS Limit. The recruitment presentations on bladder health and the pamphlet about bladder health presented after baseline data were collected, may have had unanticipated effects on our results, especially on the VASs. For example, Cronbach's alpha increased about 10 points between Time 1 and Time 2 for the UIFCQ and BFQ. This could reflect instability of the instruments or the beneficial effects of the bladder health information, or a combination of the two. The study would have been stronger had the information not been presented until the end; it was presented earlier to gain the cooperation and interest of our participants, and our low attrition rate attests to the investment that participants made in the study.

Correlations among the variables yielded both expected and unexpected findings. Pad weights correlated with number of UI Events (p < .001) and UI Amount (p < .01) at both time points, but with number of voids at Time 1 only (p < .01). These findings suggest that when it is imperative to know the actual amount of urine loss, for example, to determine the need for invasive measures, pad weights may be a useful measure.

Toilet trips correlated inversely with two bladder function measures: UI Events at both time points and pad weights at Time 1. This may indicate that the sample used toileting as a strategy to manage incontinence; that is, as the toilet trips increased, the UI Events decreased. The fact that pad weights were highly skewed may have accounted for the lack of association with pad weights at Time 2. Toilet trips were not associated with the other

TABLE 4. Spearman Rho Correlations of Measures at Time 1 and Time 2

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		Pad	Toilet	II		IU	f	CUBS	
		Weight	Trips	Events	BFQ	Amount	UIFCQ	Limit	ΙίΟ
Pad Weight	Time 1	1.00	-0.45**	0.67***	su	0.33*	ns	su	su
)	Time 2	1.00	ns	0.78***	ns	0.40*	ns	su	su
Toilet Trips	Time 1	-0.45**	1.00	-0.30*	su	ns	su	su	su
•	Time 2	ns	1.00	-0.35*	ns	SU	ns	su	su
UI Events	Time 1	0.67***	-0.30*	1.00	-0.30*	0.49	su	ns	su
	Time 2	0.78***	-0.34*	1.00	ns	0.61***	su	su	-0.30*
BFO	Time 1	ns	ns	-0.30*	1.00	-0.53***	0.51***	-0.42**	0.51***
Y	Time 2	ns	ns	ns	1.00	-0.47***	0.59***	-0.47***	0.66***
UI Amount	Time 1	0.33*	ns	0.49***	-0.53***	1.0	ns	0.38**	-0.34*
	Time 2	0.40*	ns	0.61	-0.47***	1.0	-0.32*	***89.0	***09.0-
UIFCO	Time 1	ns	ns	ns	0.51***	su	1.0	su	0.54***
	Time 2	ns	su	su	0.59***	-0.32*	1.0	-0.48***	0.69***
CUBS Limit	Time 1	ns	su.	ns	-0.42**	0.38	ns	1.0	-0.42**
	Time 2	Su	su	su	-0.47***	0.68***	-0.48***	1.0	-0.57***
OII	Time 1	Su	ns	su	0.51***	-0.34*	0.54***	-0.42**	1.0
,	Time 2	ns	su	-0.30*	0.66***	***09.0-	0.69***	-0.57***	1.0

p < .05. \*p < .01. \*\*p < .001.

measures. It seems that these women were not concerned about the amount of time they spent trying to prevent leakage as long as their toileting strategy succeeded. The inverse relationship suggests that UF may be an indicator of impending problems with UI. Interventions for early UF may prevent the onset of UI.

The BFQ was strongly correlated with the VAS for Amount, reflecting the fact that it includes questions about urine flow control and bladder management. It was, however, only modestly associated at Time 1 with number of UI Events and not at all at Time 2. This would seem to indicate that other factors such as physiology and function are implicated in loss of urine along with the ability to manage bladder function. The BFQ was strongly correlated with the measures of comfort and lifestyle, supporting the validity of the management aspect of this instrument. This focused instrument is a useful measure to reveal bladder function and ability to manage it.

The measures of comfort and lifestyle were clearly correlated to each other and only minimally correlated with the bladder function measures. The UIFCQ was correlated with the IIQ at both time points, confirming that it is a valid measure of CUBS. Its correlation with both the IIQ and the BFQ suggests that although the UIFCQ is related to quality of life/management of CUBS, comfort is also unique and separate from these measures. The correlation of the UIFCQ with the two VASs at Time 2 only may suggest that persons living with CUBS need information about this condition before they fully realize its impact on their lives.

Both the IIQ and BFQ correlated strongly with UI Amount but the UIFCQ had either a weak association or none. The IIQ is about quality of life issues that would be affected by amount of loss, such as social activities and travel. The BFQ reflects the actual condition of bladder function and its management, which also would be affected by the amount of loss. On the other hand, the UIFCQ is about the inner feelings generated by one's physical, social, psychospiritual, and environmental context and amount of loss does not appear to impact these feelings as much as it impacts interactions and other activities. Feelings are related to self-esteem, transcendence of problems associated with CUBS, determination and motivation to continue with modifications, and being in charge although not in control of the status of CUBS.

## **CONCLUSIONS**

For first line and non-invasive interventions, counting UI events and rating the amount of urine loss provide information similar to pad weights and are far more user friendly. In our study, informal opinions indicated that many participants did not like collecting the pads. One person misunderstood the directions and voided directly into the pads for the entire 3 days. However, she did the data collection over and remained in the study. Another person lost the data because her dog chewed the bags with the pads in them. She too collected them again for another 3-day period. Pads were also awkward to collect and weigh, since they had to be brought to a central location where the special scale was located. These results suggest that pad weights are impractical in community settings. Number of UI Events, as recorded in logs, was a reliable indicator of change in UI status, which is consistent with reports that demonstrate the accuracy of voiding logs for community research on CUBS.

We noted that the relationships between the objective status of CUBS and subjective perceptions of CUBS were inconsistent. In rating the severity of CUBS, the discrepancy emphasized that women rate their CUBS less severe than objective measures would indicate.

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Both types of measures, however, are important and change should be evaluated in several ways. Changes in CUBS can be more clearly and candidly reported with use of both objective and subjective measures of CUBS status. How an individual perceives their CUBS status influences their CUBS management behaviors.

This study indicated that the UIFCQ measures something different from the other measures. Comfort related to CUBS is unique and it responds positively to interventions for CUBS. Further, it can be measured and it is a valuable predictor of improvement in persons receiving treatment for CUBS. If aspects of comfort such as relief and ease can be enhanced for persons with CUBS, their quality of life can improve. Interventions for transcendence, such as empowerment messages, enable persons to have a higher quality of life even if the cure for CUBS is only partial.

# **Limitations and Suggestions for Future Studies**

We found that simple bladder health information seemed to cause changes in the measures between Time 1 and Time 2 that we did not anticipate. While we were able to control for these effects in our analysis, the correlations probably would have been stronger had there been no information given between data collection points. However, we felt compelled to give our participants help because they had so many questions and concerns and were relieved to be able to speak frankly. They also were going to great lengths to collect pads. For future use we do not believe that pad weights are justified for research in community settings.

Based on our findings, two new instruments, BFQ and UIFCQ are appropriate to detect changes in CUBS status in first-line intervention studies with individuals living in the community. These measures, along with UI Events recorded in logs and the IIQ, provide reliable indicators of the outcomes of interventions for CUBS. Therefore, we recommend that a comprehensive but not redundant assessment of change in status related to first-line interventions for CUBS in community dwelling persons include the following measures: UIFCQ, BFQ, voiding diary, and IIQ.

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Offprints. Requests for offprints should be directed to Thérèse Dowd, PhD, RN, College of Nursing, University of Akron, Mary Gladwin Hall, 209 Carroll Street, Akron, OH 44325-3701. E-mail: dowd@uakron.edu