

## Content Validation of the Patient-Reported Outcomes Measurement Information System (PROMIS) Framework in Women With Urinary Incontinence

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**Aims:** To assess whether the existing National Institutes of Health (NIH) Patient Reported Outcomes Measurement Information System (PROMIS) conceptual framework and item banks sufficiently capture the concerns of women with urinary incontinence (UI). **Methods:** Thirty-five women with UI were recruited between February–April 2009 for 4 structured focus groups to develop and assess the content validity of a conceptual framework for the impact of UI. This framework included domains from the NIH PROMIS framework and item banks including broad domains of physical and social function and mental health. All sessions were transcribed, coded, and qualitatively and quantitatively analyzed using analytic induction and deductive analysis to identify new themes and domains relevant to women with UI. **Results:** The focus groups provided information that confirmed the relevance of existing PROMIS domains and identified new outcome domains that are important to this patient population. The groups confirmed the relevance of the physical and social functioning, and mental health domains. Additional themes that emerged included the distinction between ability versus participation and satisfaction, role functioning, external mediators, re-calibration/coping, cognitive function and new possibilities. Participants also felt strongly that not all domains and items apply to all women with UI and an option to tailor questionnaires and skip non-relevant items was important. **Conclusions:** The PROMIS framework domains are relevant to women with UI, but additional patient-important themes are identified that may improve the comprehensiveness of this assessment framework for measuring outcomes important to women with UI. These results will inform future item content development for UI. *NeuroUrol. Urodynam.* 30:503–509, 2011. © 2011 Wiley-Liss, Inc.

**Key words:** content validity; conceptual framework; incontinence; patient outcomes; quality of life; tailored outcomes

### INTRODUCTION

Patient-reported outcomes (PROs) in pelvic floor disorders (PFDs) are increasingly incorporated into clinical trials and practice and provide evidence for the benefits of treatment interventions. Inclusion of the patient's perspective is now mandated by research funding bodies, ethics committees, and regulatory agencies (e.g., Food and Drug Administration).<sup>1</sup> PROs measure patient perceptions at four levels of increasing complexity: symptoms, functioning, general health perceptions, and health-related quality of life (HRQOL). As one moves from constructs with relatively low complexity (e.g., symptoms) to constructs of higher complexity (e.g., HRQOL), correlations between PRO constructs can weaken.<sup>2</sup> Therefore, in addition to traditional objective measures, multidimensional PRO assessment has been emphasized across health disciplines.

Monitoring treatment outcomes across multiple dimensions imposes considerable burden upon patients. Many of the standard questionnaires in Urogynecology are validated in accordance with Classical Test Theory psychometrics where a valid test relies upon patients completing all items on the questionnaire. Because patients differ in symptoms and level of health, these standard questionnaires may include many

items that are irrelevant for a specific patient. Also, several questionnaires must be given in their entirety to assess multiple outcomes, increasing patient burden. Short forms can reduce patient burden, but the cost of brevity is often reduced precision and breadth.

The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) was developed to introduce a new approach for PRO collection, use and reporting across a variety of diseases.<sup>3,4</sup> The goal of

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PROMIS is to build and validate item banks that measure key health concepts using modern test theory, Item Response Theory (IRT) psychometrics. Item banks are content valid, cover all aspects of the construct being measured, and have enough items to attain high measurement precision.<sup>5</sup> Once items are calibrated using IRT, they can be administered either as a static short form or the calibrations can be used to guide computer adaptive testing (CAT). In CAT, a seed item is delivered to the patient and based upon her response, the most relevant items from the bank are selected for further administration. Two individuals taking a CAT may receive different items, but because items are all calibrated along a common dimension, the scores are comparable without patients needing to answer non-relevant questions. The overarching goal of our research is to develop item banks for women with PFDs that will allow CAT development.

The field of PFDs has made significant strides in the development of disease-specific PROs<sup>6</sup> including symptom,<sup>7–10</sup> HRQOL,<sup>7,9–11</sup> and sexual function<sup>12</sup> questionnaires. However, the majority of these questionnaires are based on Classical Test Theory, covering very specific domains that are not flexible. Furthermore, only a handful of validated questionnaires are driven by a patient-based conceptual framework.<sup>13</sup> Before we can further develop item banks, we need to have clearly defined constructs with careful specification of sub-domains that are comprehensive and important to women with PFDs. This current paper reports the initial steps of item bank development, including content validation and refinement of the NIH PROMIS framework for women with urinary incontinence (UI). Our primary objective was to develop a comprehensive conceptual framework for patient-important outcomes for UI for future UI CAT development.

## MATERIALS AND METHODS

We used focus groups to refine a working conceptual framework of patient-important outcomes and to evaluate the content validity of the PROMIS framework ([www.nihpromis.org](http://www.nihpromis.org)) in women with UI. Focus groups are often used to understand new phenomena, generate data about attitudes, perceptions and behaviors of targeted populations, and can combine the advantages of qualitative and quantitative methods into an integrated survey research methodology.<sup>14,15</sup>

For this project, we focused on the most prevalent PFD, UI. Women seeking care for UI were recruited from our institution between February–April 2009 following approval by the Institutional Review Board of Women and Infants Hospital. All participants gave written informed consent. Women who were pregnant, <21 years of age, reported painful bladder symptoms, or were unable to participate due to language or cognitive issues were excluded.

We conducted four semi-structured interactive focus groups: three groups of women seeking care who had not undergone treatment (pre-treatment) and one group of women who had

undergone treatment (post-treatment) at least 6 months prior. A priori, we planned to include a post-treatment group to confirm themes identified in pre-treatment groups and to explore themes that may be unique to post-treatment women. All women completed validated UI-specific questionnaires including the Urinary Distress Inventory (UDI-6),<sup>8</sup> the Urinary Impact Questionnaire (UIQ-7),<sup>8</sup> and the Medical, Epidemiological, and Social Aspects of Aging (MESA)<sup>16</sup> questionnaire. Participants were reimbursed \$25 and parking costs.

The content of the focus groups was built on a working conceptual framework developed based on three previous focus groups exploring decision-making needs of women with PFDs (unpublished data), the PROMIS framework, the World Health Organization International Classification of Functioning, Disability and Health (ICF),<sup>17</sup> and existing literature. Our overarching objective was to develop a comprehensive conceptual UI framework and the four specific sub-aims of our focus groups were: (1) to evaluate the content, appropriateness, and importance of each domain in the PROMIS framework; (2) to identify gaps in our framework (comprehensiveness); (3) to test PROMIS item wording and response format; and (4) to explore the comfort level with information technology. In our study, content validation, or logical validity, refers to the extent to which our framework represents all relevant dimensions and outcomes of the condition's (UI) impact on a woman's function and quality of life.

### Focus Group Materials and Procedure

A focus group manual was developed and refined prior to each focus group such that each subsequent session built on previous findings. Ranking cards for items within PROMIS domains and sub-domains of global health, physical and satisfaction with physical activities, sleep/wake, social activity and satisfaction with participation, fulfillment of social roles, emotional distress were prepared (see Table I also for PROMIS domains explored). We also included computer tablets for pilot testing of the PROMIS computerized-adaptive test demonstration by participants.

Content discussion was started with participants sharing their definitions and understanding of how UI affected their "functioning" and which outcomes were important. Participants were asked to organize the domain and item ranking cards in order of importance as "highly," "somewhat," or "not at all relevant." Outcomes missing from the PROMIS framework were discussed.

The next part of the discussion focused on the readability, response options, and time frame of reference of the PROMIS items. Finally, participants were asked to pilot a PROMIS CAT demonstration. Participants were then asked about their comfort level with completing CAT questionnaires compared to paper-pencil questionnaires.

Our goal was to conduct as many focus groups as needed to reach saturation (the point at which no new information is

TABLE I. Focus Group Content

Concept explored in focus groups	Examples
PROMIS domains explored	Physical Function (ability, satisfaction) Emotional Distress (anxiety, depression, anger) Sleep/Wake function Social Function (ability, satisfaction, social roles) Fatigue
Comfort level with electronic technology	Pilot testing of computers, Internet Preferences for types of data collection methods (i.e., computer, paper-pencil, handheld, tablet)

yielded). Each session lasted approximately 90 min and was moderated by an experienced, neutral moderator with expertise in qualitative methods (MAC). All sessions were audiotaped and transcribed. Transcripts were independently reviewed and coded by two coders using NVivo software (QSR International). The content of each transcript was examined based on an analytic induction method which is an iterative technique that ensures a thorough and systematic review of all thematic content in each transcription and generates a list of conceptual gaps in the framework.<sup>14</sup> We also used deductive analysis to confirm and expand on already known domains in our framework. Statements that did not fit in our original framework of domains were coded as “Other” and were re-reviewed to identify new themes to ensure comprehensiveness of the framework. Any disagreement was resolved through discussion and consensus. Multiple codes could be assigned in cases where more than one concept was measured in a statement. Key words, phrases, emergent themes, and language used by participants were identified, categorized, and quantified.

**RESULTS**

Thirty-five women (24 pre-treatment and 11 post-treatment) participated. The mean age was 59.7 years (range 34–87), 94% were Caucasian, 2% African-American, 10% Hispanic, 26% reported some high school, and 74% reported at least some college education. Twenty-nine percent of women were retired, 49% were employed at least part-time, and 23% reported an annual household income less than \$20,000. Fifty-four percent had a clinical diagnosis of stress UI, 11% had urge incontinence, and 35% had both stress and urge incontinence, confirmed by MESA responses. The mean UDI-6 score was 43 + 26 and the mean UIQ-7 score was 29 + 28.

**Sub-Aims 1–2: To Evaluate the Content, Appropriateness, and Comprehensiveness of the PROMIS Framework for UI**

Participants confirmed the importance of the broad PROMIS categories of physical, social, and emotional health domains. A refined conceptual framework incorporating our focus group findings is presented in Figure 1 (PROMIS domains are listed in the Materials and Methods Section, in Table I, and can be found at [www.nihpromis.org](http://www.nihpromis.org)). Table II presents the themes and abridged remarks from participants representing each theme. We did not explore in detail themes previously determined to be patient-relevant in the UI literature (e.g., symptoms), but focused on unique PROMIS domains and new themes.

**Physical function.** Universally in all groups a significant discussion centered on the importance of distinguishing between how UI impacted one’s ability to perform physical activities versus satisfaction with the activity or their participation in the activity. Women reported that they had the physical ability to perform most activities (walking, shopping, household chores), but UI mainly prevented their participation and/or satisfaction with that activity. The following statements characterize such discussions: “You have to do it, so it’s not really about ability but more about satisfaction” and “the word ability is not the right word-for example, I am able to get on the treadmill but I don’t push myself as hard so I won’t get soaked.” Thus, women still did their activities, but UI affected the type of activity and/or how much and how hard they did it (extent of participation). A similar prevalent theme was the distinction between responsibility and enjoyment: “We do it because we are women, but it is less enjoyable.” Many stated they often had to “weigh” the activity benefits with the risk of a UI

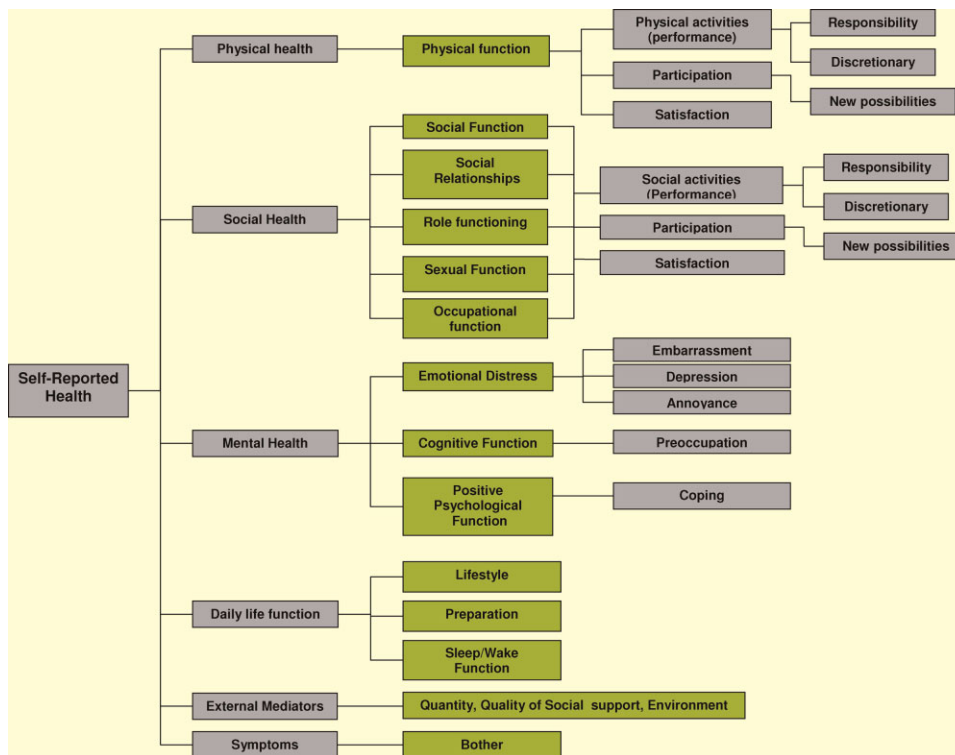


Fig. 1. Conceptual framework for patient-important outcomes in functioning for women with urinary incontinence.

TABLE II. Emerging themes and sample quotes from focus groups exploring UI patient-important outcomes

Theme	Frequency	Participant quotes
PROMIS domains		
Physical function	54	"Anything that's a strenuous activity. I still do it but not as much." "I refuse to change my lifestyle. I still run, but now I'm just soaked." "It affects how hard I work out."
Social function	81	"Going to the theater- how do you get past a thousand people to go to the ladies room? So forget that."
Mental health/emotional distress	71	"Helpless. One can become depressed, reclusive and spiral downward and it is hard to get up from that." "It is frustrating that my body does not work like it used to." "Annoying." "Sometimes it is hurtful because people just don't get it." "Sometimes even my close friends get put off by it when I have to look for a bathroom or stop the car." "You sneeze and you feel like everyone around you knows." "I feel like I am being victimized by my bladder."
New emerging themes from current focus groups		
Ability versus satisfaction	68	"You have to, so it's not really about ability. You are "able" to do whatever is put before you. But it is annoying and makes it less enjoyable." "I cannot even enjoy a good walk." "It is not about our "ability" to do something. It is about being limited in your satisfaction. You do it, but you don't like to do it." "You are constantly getting interrupted by it in anything you do." "Why would you be satisfied when it is always on your mind?" "Sometimes it's not even worth doing because I am dreading the activity." "Since treatment, I am so much more confident and can enjoy doing things."
Cognitive function/preoccupation with UI	35	"It's hard to focus on work or the kids when you are paranoid you're going to have an accident." "Everyday of your life. It's ALWAYS on your mind." "It is a burden."
External mediators, social support	79	"If you're doing things with people you enjoy, that decreases the stress." "We're more comfortable with friends/family or at home where you are close to a bathroom. Entertaining or being with colleagues is bad. The worst is when you are with your spouse's colleagues." "I'm a bus driver which makes it worse-I am always stopping to go to the bathroom." "Not all women have the same situation, so it is hard to ask the same questions." "It is annoying to always have to run to the bathroom in front of other people." "They don't understand and think it's all psychological." "They ask why would I put myself through surgery for only incontinence? They don't get it." "How much it bothers you depends on who you're with."
New Possibilities	42	"I am trying things I would have never tried before." "It (treatment) opens so many new doors."
Participation/Sacrifice	58	"You have to weigh whether something is worth doing. Is this activity worth preparing for and maybe having an accident?" "You always have to weigh the consequences." "If it's for a long time, I won't go." "You cope for so long you forget." "I had forgotten what it was like to live life and do things without it (incontinence)." "You adjust your "baseline" and your expectations. You just keep doing what you have to do for years and don't even realize what a burden it was until it is gone." "I never let it get in the way of doing things with family or friends to begin with, but now that I don't have it anymore, I realize what a burden it was." "I am still doing what I did before, but I feel so much more social and confident."
Re-calibration of standards and coping	40	"We do it because we are women." "I have to do the errands, but a lot of times I dread it. But who else is going to do it?" "I'm scared of intimacy and I'm too embarrassed to date." "Definitely affects being connected to friends and family. Worse meeting new people." "Even though I never let it get in the way of being there for my family, I feel so much more with them (since treatment) since I'm not always thinking about it." "My life is not balanced-I still do all the family responsibilities, but less fun and social things." "Getting up at night really affects my sleep." "Staying asleep is lousy and I feel less alert during the day."
Responsibility versus enjoyment	52	
Role functioning	40	
Sleep/wake function	30	
Other themes, already supported in literature		
Preparation	80	"Always be prepared like a boy scout. You plan your life around the scenario." "Even just to go for a walk, I have a ritual that I do to protect myself just in case . . ." "Bring a diaper bag like for a baby." "There could be a fire, but as long as you know where the bathroom is, you're OK." "I was packing for a trip and was mortified by how much room my diapers took up. That's when I decided to get help."
Sexual function	15	"No sex." "Have to plan around it." "It's embarrassing to leak during sex. At least my husband is used to it."
Stigma/disclosure	15	"Our women's problems have been shoved under the rug for so many years. And that's what I did for a long time too." "I don't know how to explain it to other people so I just hide it." "A lot of people don't want to admit it." "When I first got the nerve to tell my doctor, he told me it was not life threatening and to just live with it. It was a long time before I told my other doctor and got help." "We deserve equal treatment for our problems."
Symptoms	42	"The smell is the worst. Can everyone smell it? Bring wet wipes everywhere." "You never feel clean and always feel there is an odor." "Depending on what is going on in their life, it affects everyone differently."

accident. Women strongly emphasized the importance of these distinctions (ability vs. satisfaction versus participation) and considered them separate outcomes that were highly important. In the post-treatment group, many women stated that improvement in their UI improved their “comfort level” and “confidence” in doing activities rather than actually improving their “ability.”

**Social function.** The impact of UI on social functioning was characterized by interpersonal interactions. The impact of UI on a woman’s family role varied by age (doing chores around house, playing with children or grandchildren, caregiver). Other aspects included occupational, social, and community roles. Although family roles were frequently discussed, women agreed that social roles were most often sacrificed: “I still have to do certain things because I’m mom, but sometimes even my good friends get annoyed when they have to keep stopping the car.” Sacrificing social roles results in an “imbalance” between family, work and leisure activities: “You end up spending more time with people you have to, like your family and work, but stop doing other things.” Within the theme of social function, many participants again discussed the need to distinguish between ability and satisfaction. A majority of women in the post-treatment group reported improvement in fulfilling their social and family roles, feeling more “connected” with friends and family after treatment.

**External mediators.** The impact of external mediators that could exacerbate or decrease the impact of UI was often discussed. In three of the sessions, women discussed specific social scenarios that worsened the impact of UI. Being outside the home or with outside people (not family or close friends) exacerbated the impact. Knowing an activity would take a long time or may restrict toilet access increased “dread” and decreased the likelihood of participation. Women also reported frustration and lack of social support stating “They don’t understand it-it’s not like a heart attack where you could die” and “They don’t understand why I would go through the risks of surgery just to fix UI.” This in turn would negatively impact participation in social activities, roles, and disclosure.

**Re-calibration, coping and new possibilities.** Another emerging theme was “re-calibration” and “coping” with UI. In discussion of domains that improved after treatment, women commented that it was not until after treatment that they realized how they had adjusted their own standards or expectations to continue functioning with UI. Many women stated they had lived with UI for so long, they had forgotten what it was like to enjoy life and be a “normal person.” Even women who “refused to let UI affect their activities” commented that their “confidence” in these activities significantly improved after treatment. In line with this, treated women also discussed “New possibilities or opportunities” which became available (or at least they would now consider) after their UI had been treated. The opportunities described fell within the Physical and Social Health domains.

**Other themes.** The need for preparation, behavioral adaptation, and effects on sleep/wake and cognitive function were additional themes that arose in the groups.

**Relative importance of themes.** Ranking results revealed that physical function, social function, and daily life function were rated more highly than mental and emotional health

and sexual function, but within all domains and PROMIS item banks, there were subjects who rated specific items as highly relevant. All groups discussed that not all items within a domain apply to everyone with UI, and much is dependent on baseline function, roles and activities. Women commented there should be an option of skipping items if they did not apply.

### Sub-Aim 3: To Test PROMIS Item Wording and Response Format

Overall, participants found the PROMIS items to be clearly worded, easy to read, understand and answer, but considered the 7-day recall for PROMIS items to be somewhat short for capturing the impact of UI on their functioning. An example of a PROMIS item from the Physical Function domain: “Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?” and an example from the Satisfaction with Participation in Discretionary Social Activities domain: “I am satisfied with my current level of social activity” (see [www.nihpromis.org](http://www.nihpromis.org) for additional items).

### Sub-Aim 4: To Explore The Comfort Level With Information Technology in this Population

Despite the majority of women not being highly experienced in using electronic devices, women reported that the PROMIS CAT demonstration was easy to use and were enthusiastic about its possible future use. Most women were able to complete the CAT demonstration with little training, including several older women.

## DISCUSSION

We describe the first steps in the development of item banks and computerized adaptive testing to assess the impact of female UI on functioning. Within the broad domains of physical and social function and mental health, women identified additional important themes including the distinction between ability versus satisfaction versus participation, role functioning, external mediators, re-calibration/coping, cognitive function and sleep/wake function resulting in a more comprehensive framework for UI. Our study confirmed the relevance of other known important domains including symptoms,<sup>18</sup> preparation,<sup>19</sup> and sexual function.

The most prevalent theme was the distinction between “ability” versus “satisfaction” versus “participation” in women’s experiences with physical and social activities (e.g., UI typically did not affect one’s “ability” to do an activity, but may have impacted on whether she would participate and if she participated, whether she was satisfied with that experience). This is consistent with PROMIS investigator findings for both physical and social function domains also.<sup>20</sup> Many existing UI and PFD measures emphasize ability and performance, but have focused less on the distinction between ability and satisfaction or enjoyment of specific physical or social activities. In addition, many existing questionnaires assess UI “bother,” which is likely a multi-dimensional construct incorporating aspects of ability, satisfaction, and participation in social and physical activities as well as many other constructs within our framework.

We gained additional insight into how everyday coping or re-calibration around UI can help minimize UI impact. This phenomena called “response shift” occurs when individuals experience changes in health states, causing them to alter

their internal standards (i.e., “recalibration”), values (i.e., “reprioritization”), or conceptualization (i.e., “reconceptualization”) of key quality of life domains.<sup>21,22</sup> There is growing evidence that response-shift effects vary in magnitude depending on the domain and disease, and can substantially impact both the detected direction and effect size of treatment interventions. Response shifts have been shown to distort subjective PRO measurement in orthopedic, cancer, and pain populations.<sup>23</sup> Because many women with UI will delay seeking care, this population may be particularly sensitive to response shifts and this issue warrants further investigation.

Our participants expressed concern that the PROMIS 7-day recall period was not an ideal timeframe to assess UI impact. Beyond 7 days, recall of symptoms and function can become degraded and biased as patients may simply forget experiences or unintentionally distort them. This is the basis of why PROMIS investigators chose a 7-day recall period. Female UI symptoms can be dynamic<sup>24</sup> with “good days” and “bad days,” which may lead to variable effects and reporting on function and HRQOL in the short-term. The effects of measuring symptoms as they occur (ecological momentary assessment) compared to measuring them based on a shorter or longer recall period is relatively unexplored in PFDs.

Our finding that women did not believe all items within a domain are universally applicable to women with UI supports the need for a measure that can be individually tailored. The modern PROs developed through PROMIS and a future UI CAT would provide a means for tailored assessment that is precise and efficient. It is encouraging that women were able to complete a sample CAT without difficulty. We intentionally recruited groups to include a wide age range and a minimum of 10% of minority women. Even older women not well experienced with electronic devices were able to complete the CAT without difficulty and felt positive about the experience.

There are few studies in the UI literature aimed at establishing a framework for the impact of UI on functioning, incorporating patient-important outcomes and the patient perspective. Coyne et al. conducted focus groups on both men and women with lower urinary tract symptoms, focusing primarily on symptom assessment. The authors also explored patient perspectives on treatment outcomes and expectations. However, to our knowledge our study is the first to develop a framework, and confirm the content validity of the PROMIS framework, for functioning in women with UI.

Some of the limitations of this study are inherent to the use of a qualitative focus group approach as we will discuss; however, the benefit of obtaining feedback directly from UI patients is invaluable for establishing a relevant framework. One limitation is potential selection bias since we only included women seeking care or who had treatment for UI. Therefore, our framework may not apply to all women with UI, including women who do not seek care for UI. Because our initial goal is to develop a measure to assess treatment outcomes, we felt it was most appropriate to focus on women seeking care for UI. In addition, we believe the domains identified are relevant to most women with UI and the possibility of a tailored assessment (the goal of our research), would overcome some of these limitations. In other words, if a particular domain is not relevant to a patient (or subpopulation), then a tailored assessment would allow that individual to move on to the next relevant domain and minimize the number of non-relevant questions asked. Also, although we focused our recruitment to include a wide age range of women and diversity in race and ethnicity, our study was conducted at a single site which may limit the external validity of our findings. We included women with urge, stress, or mixed

incontinence in our groups and although some themes were more common in certain UI types (e.g., sleep-wake function themes more common for urge incontinence), we did not develop separate frameworks based on type of condition or severity. Again, a tailored measure that can be individualized to patients will help to overcome many of these limitations, preventing the need for the daunting task of developing entirely separate frameworks. A final limitation may be the number of sessions conducted; however, based on our iterative coding, no new themes were identified in our last session.

The main strength of our study was that the information gained helped make substantive improvements in our framework, making it more comprehensive. These efforts will further contribute to the development of UI item banks and inform the development of a CAT measure. PROMIS efforts have included a combination of qualitative and quantitative methods integrating previous literature, extant measures, and most importantly patient perspective. Thus, our methods are consistent with the PROMIS methodology and are an important step in the modernization and enhancement of our current PRO measures for UI and PFDs.

## CONCLUSION

Women with UI confirmed the relevance of PROMIS domains and identified key concepts that improve the comprehensiveness of a conceptual framework for functioning and current assessment measures. These results will inform future UI item bank and computerized adaptive testing development.

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