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Measuring Bladder Health: Development and Cognitive Evaluation of Items for a Novel Bladder Health Instrument

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Abstract

Purpose: To describe the item development and cognitive evaluation process used in creating the Prevention of Lower Urinary Tract Symptoms Bladder Health Instrument (PLUS-BHI).

Materials and Methods: Questions assessing bladder health were developed using reviews of published items, expert opinion, and focus groups' transcript review. Candidate items were tested through cognitive interviews with community-dwelling women and an online panel survey. Items were assessed for comprehension, language, and response categories and modified iteratively to create the PLUS-BHI.

Results: Existing measures of bladder function (storage, emptying, sensation components) and bladder health impact required modification of time frame and response categories to capture a full range of bladder health. 167 women (18–80 years) completed individual interviews and 791 women (18–88 years) completed the online panel survey. The term "bladder health" was unfamiliar for most and was conceptualized primarily as absence of severe urinary symptoms, infection, or cancer. Coping mechanisms and self-management strategies were central to bladder

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health perceptions. The inclusion of prompts and response categories that captured infrequent symptoms increased endorsement of symptoms across bladder function components.

Conclusions: Bladder health measurement is challenged by a lack of awareness of normal function, use of self-management strategies to mitigate impact on activities, and a common tendency to overlook infrequent LUTS. The PLUS-BHI is designed to characterize the full spectrum of bladder health in women and will be validated for research use.

Keywords

Lower Urinary Tract Symptoms; Urinary Bladder; Health Surveys; Health Status Indicators; Interviews as Topic

Introduction

The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium conducts foundational research for LUTS prevention and promotion of bladder health (BH) in adolescent and adult women,[1] and a BH outcome measure is central to this work. Consistent with the World Health Organization’s definition of health, the PLUS Research Consortium defines BH as: “a complete state of physical, mental and social well-being related to bladder function, and not merely the absence of LUTS” with function that “permits daily activities, adapts to short term physical or environmental stressors, and allows optimal well-being (e.g., travel, exercise, social, occupational or other activities)”.[2] Measurement of health is strongly linked to the individual’s perception of the impact of health status on daily function, including physical, personal and social activities.[3] This perception may be affected by beliefs of “normal” as well as coping or self-management strategies.

Most instruments designed to assess women’s bladder function are condition-specific and were designed for use in clinical research. These instruments focus appropriately on LUTS severity, bother, impact, and quality of life in women presenting for evaluation or treatment.[4–15] A key challenge in BH measurement is the novelty of the measurement goal: quantification of the full BH spectrum ranging from very healthy to very unhealthy rather than a measure of LUTS severity and impact that captures the experience of the most affected women.

The conceptual model developed by PLUS includes four core dimensions of BH: Storage, Emptying, Bioregulatory and Functional/Psychosocial. Within each dimension, domains were defined and operationalized to inform a draft item pool. In order to develop a comprehensive and inclusive instrument that aligns with women’s perceptions of BH, the Clarification of Language, Evaluation And Refinement of questions (CLEAR) study was conducted. We describe our process to evaluate and refine the item pool for the PLUS-Bladder Health Instrument (BHI) as the first validation step leading to a final PLUS-Bladder Health Scale (BHS).

Methods

Figure 1 displays an overview of the PLUS-BHI development. Following the initial activities to establish the BH conceptual model and associated domains, phase II focused on development of an item pool that mapped to BH domains. Figure 2 displays the subsequent cognitive evaluation processes for item refinement in phases III and IV (CLEAR study), comprised of one-on-one cognitive interviews (CI) and an online panel. The goal of the CI was evaluation of the four steps of the cognitive response process to individual items: comprehension, retrieval, judgement and response.[16, 17] Complementing this, the online panel allowed randomized comparisons of language, multiple item structures and formats, and evaluation of response options. All procedures and study activities were IRB approved across the PLUS research centers.

Phase I: Domain Specifications

For the BH functional dimensions, domain specification was directed by existing clinical definitions of bladder dysfunction[18] and development of corollary healthy bladder functions,[19] including storage (capacity, continence, and sensation); emptying (initiation, stream flow, ease, efficacy and sensation); and bioregulatory (infection). The psychosocial dimension is related to various aspects of quality of life, behaviors and emotional impact and is independent of specific bladder functions.

Phase II: Item Development

Thirteen PLUS consortium members with experience in questionnaire development and/or LUTS clinical care and research (female pelvic medicine and reconstructive surgery, urology, obstetrics and gynecology, primary care) performed a comprehensive review of existing LUTS scales and quality of life measures (Supplemental Table 1). Items were evaluated for applicability across the full BH spectrum, and where gaps in coverage were noted, items were developed *de novo*. The group considered both item stems and response categories that would represent a continuum of BH with the goal of categorization into different states of BH from very healthy to very unhealthy.

Phase III: Cognitive Interviews

Community-dwelling women who were ≥18 years and fluent in written and spoken English were recruited across seven clinical research centers (CRC). There is a separate protocol to evaluate the BHI in Spanish-speaking Latinx populations. Sites leveraged various recruitment strategies including flyers, online/print ads, community presentations, and health fairs, and participants were compensated with $50 gift cards. Items were tested in two broad categories: 120 function-specific (storage, emptying, and bioregulatory) and 162 non-function-specific (global perception and functional impact). In order to ensure representation across BH states, women were screened by self-report of bladder problems using a modified version of the Patient Perception of Bladder Condition (PPBC) for the function-specific items.[20] Using "Which of the following statements best describes any problems you may have with peeing or your bladder?", women were categorized as none/mild (PPBC response=1 or 2), moderate (3 or 4), or severe bladder problems (5 or 6). Participants were further categorized relative to bladder function components: urinary frequency, urinary urgency, urinary incontinence, pain or discomfort, voiding, and urinary tract infections. For the non-function-specific items, recruitment was based on achieving representation across four age categories:18–24, 25–44, 45–64, and ≥65 years.

Interviewers at each CRC were trained to conduct CI by a measurement expert who participated in BH item development. A concurrent ‘think aloud’ process and structured probing questions were used to identify problems at each step along the question-response process. Following each round of CI, items were reviewed and revised as needed to improve participant processing of both item stem and response categories. Using this iterative process, items were progressively advanced through the CI rounds until a final item version was fully interpretable and answerable by all participants.

Following the first CI round, transcripts from 30 focus groups (FG) conducted with English speaking adult women were reviewed. The transcripts were generated from the PLUS Study of Habits, Attitudes, Realities, and Experiences of BH (SHARE), designed to explore adolescent and adult women’s experiences, perceptions, beliefs, knowledge, and behaviors related to BH and function.[21] Two measurement experts independently reviewed the transcripts for clarification of BH concepts and terminology, and findings were incorporated into item wording and structure for CI rounds 2–5.

Phase IV: Online panel

Refined items from phase III were administered to women enrolled in the Dynata™ proprietary national online panel who were ≥18 years and fluent in English. Online participants were compensated using a Dynata™-managed point system. Stratified quota sampling was used to obtain equal representation across four age categories, geography, and education. Participants were randomized to receive different versions of item wording and/or response options. Areas of testing included BH conceptualization, response formation (i.e., exceptions, recall accuracy, and deconstruction), item preference (comparison of words and phrases), and range of options impact. Survey responses were analyzed using ANOVA and t-test for numeric rating scales and chi-square for categorical outcomes. Analyses were conducted using R v3.5.1 and SAS v9.4.[22, 23]

Findings

Phase II: Item development—None of the existing LUTS questionnaires adequately aligned with the PLUS BH model with the exception of the Emotional Health subscale of the Incontinence Impact Questionnaire and elements of the Adaptation Behavior Index.[8, 24] Timeframe, language, and response categories from existing measures required extensive modification to capture the spectrum of bladder function and psychosocial elements related to perception of BH impact. Most instruments assume continuous ongoing LUTS, and we sought approaches to additionally capture less frequent, episodic or transient symptoms over longer time periods. Evidence suggests recall of salient events is poor even in symptomatic clinical populations,[25] thus we assumed recall of infrequent or minor events would be similarly affected. We included rarely occurring events in response categories and tested frequency categories that included vague quantifiers (never → often), time-based scales (none, once or twice a year → daily), and patterns of frequency (sporadic, intermittent, constant).

Each item or group of items was gauged for its ability to characterize the BH spectrum. Response items were developed to reflect frequencies that could be relevant to all women inclusive of any level of symptoms or impact. Finally, while BH items focus primarily on current status, we also wanted to capture a life-course perspective that acknowledges impact of transient symptoms at various life stages on current and future BH.

Item development to measure global perception of BH was challenging given that many women in the FG and CI did not have a strong awareness of bladder function or BH unless a significant symptom or problem was present. A variety of concepts and language were explored, including how often participants “think” about their bladder, whether they feel control over their bladder, and rating bladder function with non-traditional response categories such as grading “A-F” or “I have a good one (bladder)” versus “I wish I could return it.”

Phase III: Cognitive Interviews—Once item development was complete, CI were conducted among 167 women with a mean age of 45.2±17.2 years (Table 1 and Supplemental Table 2). After the first CI round and upon review of the FG transcripts, it was clear that the term “bladder health” was unfamiliar to participants.[26] Bladder health was frequently conceptualized as absence of disease (e.g. cancer) or symptoms (e.g. not having “accidents”).

Attempts to query women about BH changes demonstrated that recall was tied less to someone’s age but rather to seminal events, such as pregnancy or initiation of sexual activity. Most women expressed an inability to accurately recall bladder function and impact beyond the past year. As a result, “in the past year” time reference was used for current BH status. Recall for prior BH experience included any time prior to the last year instead of assigning a specific age or life stage (e.g., adolescent, midlife adult).

The PLUS BH definition includes the ability to perform usual activities and support optimal well-being (e.g. being able to “do what you want to do”). We developed a metric of impact on daily activities (e.g., no impact, diminishment of enjoyment, disruption, stopping activities), and terminology was iteratively refined to best capture women’s perceptions and vocabulary regarding BH impact. The word “interfere” garnered the most endorsement and global interpretation of any change in activity related to bladder function.

In both the FG and CI, coping mechanisms and self-management emerged as central to women’s BH perception and therefore likely to influence self-report of BH. While women refrained from saying they stopped or changed certain activities, they would “do something” or “take precautions” so bladder function would not affect their lives. The term “confidence” gained by invoking coping or self-management activities resonated with most women regardless of age or use of these strategies, potentially mediating perception of bladder function impact. We therefore included items to measure planning, level of interference, and adaptations made in order to continue certain activities.

Phase IV: Online panel—The online survey was completed by 791 women. Surveys with inappropriate completion times (e.g. <4 min or >28 minutes) (n=114) and >25% item non-response (n=23) were removed, leaving 654 for analysis. Prespecified sampling strata were relatively balanced with respect to age, education, and geography (Supplemental Table 3). The following examples illustrate selected online panel findings.

To categorize the full spectrum of leakage episodes and capture infrequent or minor episodes that may be underreported, item structure and response options were explored to maximize endorsement of any leakage experienced. Participants received one of three versions: "In the past year, have you ever {"leaked," "accidentally leaked," or "lost"} urine, even just a drop or two?" Additionally, respondents were given one of two response options using either a dichotomous yes/no or a 4-level qualified "yes" response format (Figure 3.A). The results demonstrated that usage of "accidentally leaked" urine had a higher level of endorsement than "leaked" or "lost" urine (p=0.003). When coupled with the 4-level quantified response categories, further endorsement of incontinence was observed compared to yes/no (81% vs 71%, p=0.0015).

Alternate response choices were tested that would optimally distribute women across global perception of BH categories (Figure 3.B). In this instance, panel participants were randomized to a Guttman type (qualitatively different categories)[27] or traditional Likert response scale to measure their perception of bladder status. In comparing the distributions, there is less differentiation of bladder status across response categories with Likert (p=0.01), illustrative of a "Likert Trap".[28]

A third example illustrates measurement of impact of BH on activities with a focus on capturing events that might otherwise go unnoticed and therefore unreported by women (Figure 3.C). A qualifying prompt in the stem (e.g "…even if just for a short period of time") was evaluated to ensure broad interpretation and increase endorsement where applicable. This prompt resulted in an 8% increase in report of having "stopped doing things you enjoy because of your bladder" compared to no prompt, though difference did not reach statistical significance (p=0.059).

Conclusion

This report reflects phases of developing a novel instrument for measurement of BH in women. Using primarily community-focused recruitment strategies, our findings highlight challenges in robustly measuring BH and differences in a clinical versus wellness focused approach to capturing experiences and language across the BH spectrum.[29] Measurement of BH is influenced by lack of knowledge about BH and women's tendency to ignore, accept, or self-manage changes in bladder function, affecting perception of BH impact.

For CLEAR and SHARE participants, the term "bladder health" was unfamiliar. While broad efforts have been made to understand risk and protective factors and provide public health messaging in other conditions (e.g. cardiovascular disease), this approach has not occurred with BH. Like many visceral functions, BH is generally taken for granted until symptoms raise awareness. Infrequent LUTS, subtle disruption of activity, and competing health issues may diminish awareness of BH changes. Additionally, self-management strategies as well as a normalization of LUTS may mitigate the effect of worsening BH on lifestyle, thus affecting how women report BH impact on quality of life or functional questionnaires. Therefore, a core function of any BH measure must effectively assess BH states that are not considered a problem by the respondent, yet do represent some variation or distinction on the BH spectrum. Similarly, simply asking about participation in physical, social, travel, and occupational activities does not fully capture BH status and impact; it is necessary to account for satisfaction with participation and adaptations made to maintain participation.

Cognitive evaluation helps establish content validity. Given that women were not familiar with the concept of BH, we felt this was a critical step to ensure the BH items were interpreted in the way intended and that the stems and response categories were relevant across the broad range of bladder function and impact we sought to capture. The process also informed refinement of items such that language was consistent with women's use of terminology. These findings may reduce response error in the final PLUS-BHS, which is currently undergoing validation in the Validation of Bladder Health Instrument for Evaluation of Women study (VIEW). Limitations of the study include use of an online panel that is restricted to women with internet access and sociodemographic characteristics that may not reflect the US population.

Although the BH range has not been codified, we expect to find a spectrum of BH states. While prior clinical research has refined measurement of LUTS, a BH measure should have similar precision across all BH states. A validated BHS will allow future prevention research and identification of at-risk populations with the goal of shifting the population towards a greater state of BH.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key of Definitions for Abbreviations

PLUS	Prevention of Lower Urinary Tract Symptoms Research Consortium
BHI	Bladder Health Instrument
BH	Bladder health

LUTS	lower urinary tract symptoms
CLEAR	Clarification of Language, Evaluation And Refinement of questions study
CI	cognitive interviews
FG	focus groups

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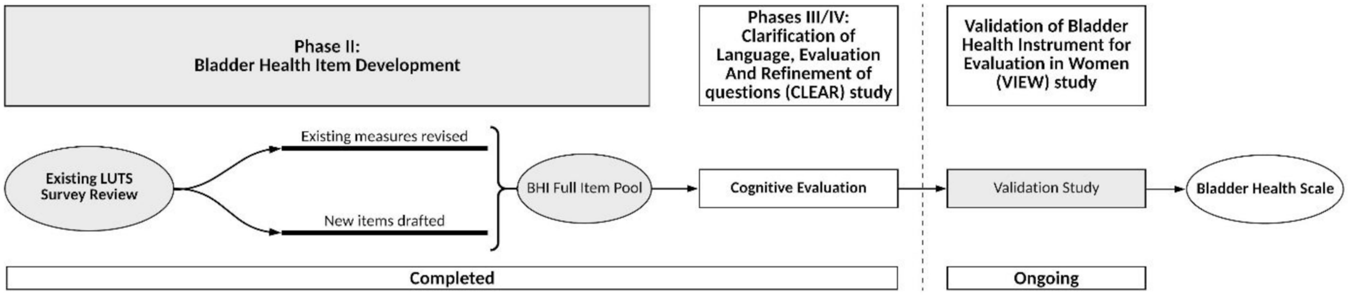
Phase II:
Bladder Health Item Development
Phases III/IV:
Clarification of Language, Evaluation And Refinement of questions (CLEAR) study
Validation of Bladder Health Instrument for Evaluation in Women (VIEW) study
Existing LUTS Survey Review
Existing measures revised
New items drafted
BHI Full Item Pool
Cognitive Evaluation
Validation Study
Bladder Health Scale
Completed
Ongoing

Figure 1.

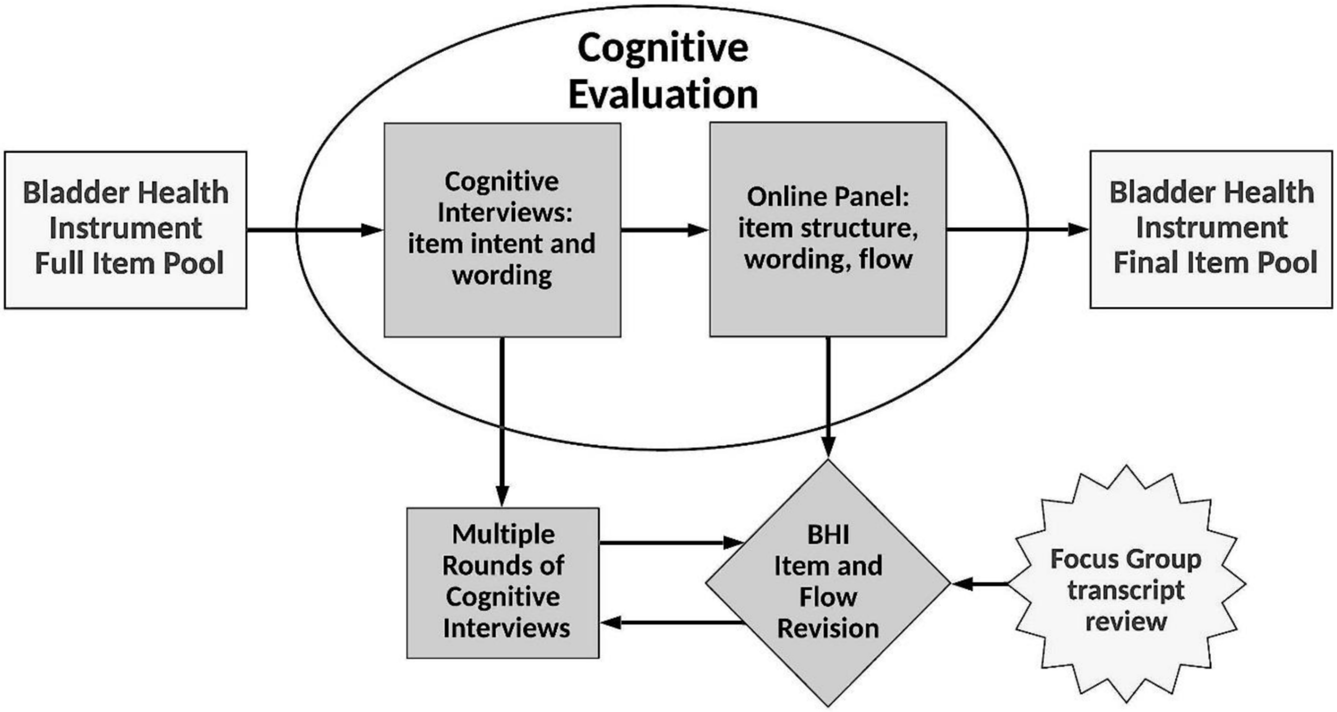
Cognitive Evaluation
Bladder Health Instrument Full Item Pool
Cognitive Interviews: item intent and wording
Online Panel: item structure, wording, flow
Bladder Health Instrument Final Item Pool
Multiple Rounds of Cognitive Interviews
BHI Item and Flow Revision
Focus Group transcript review

Figure 2.

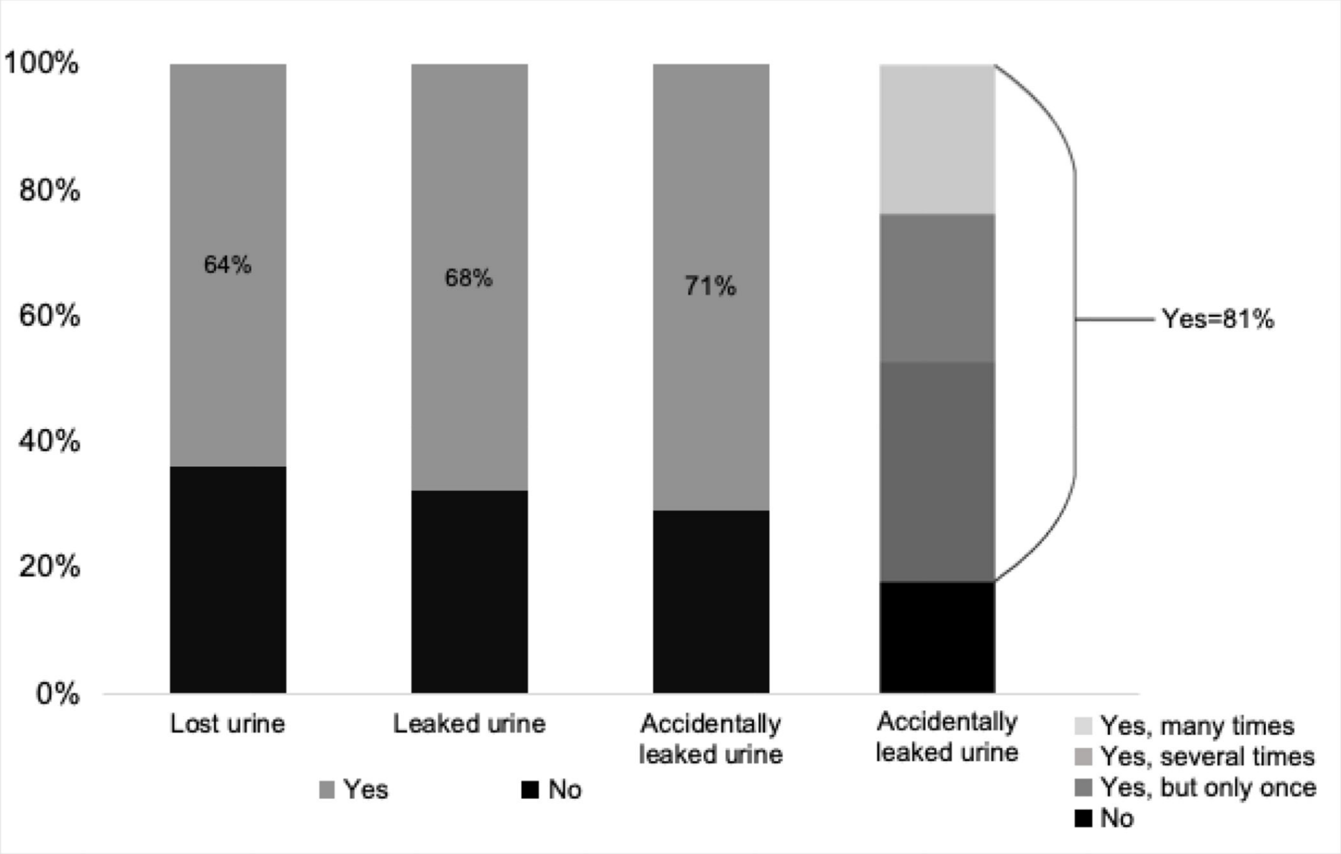

Figure 3.A.

Distribution of responses with dichotomous versus 4-level response categories

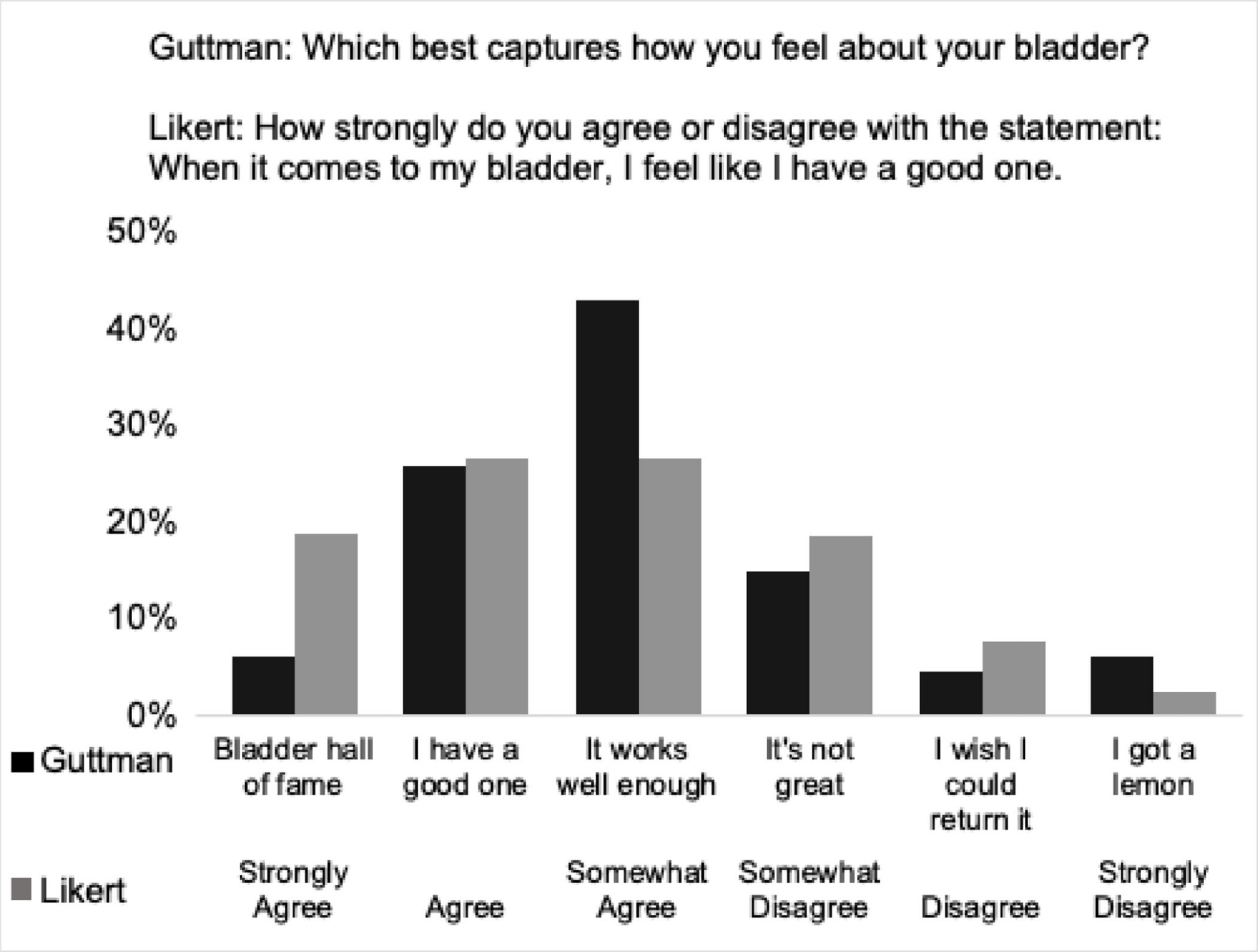

Figure 3.B.

Distribution of responses with Guttman versus Likert response structure

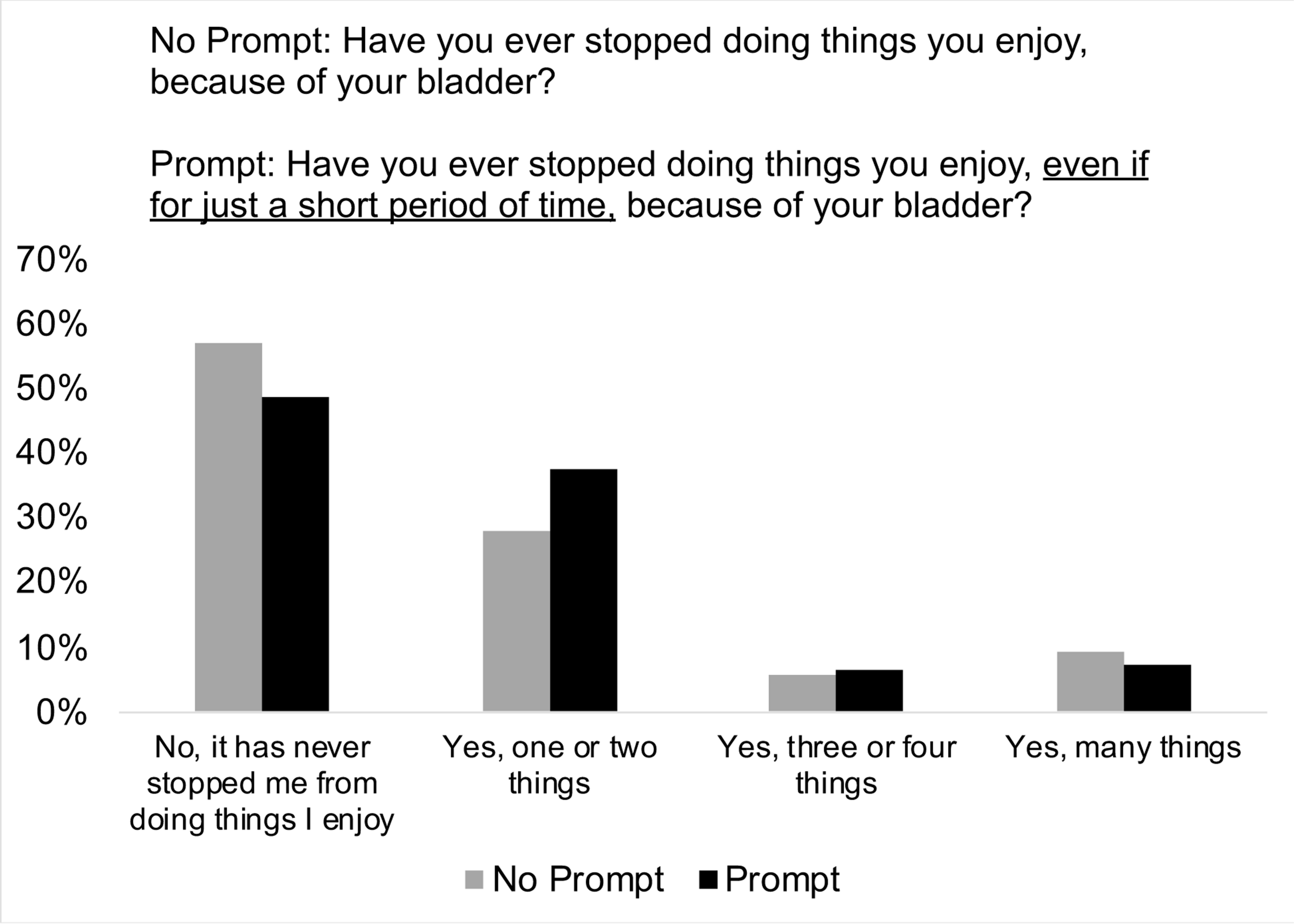

Figure 3.C.

Distribution of responses with and without prompt

Table 1:

Summary of demographics of cognitive interview participants

	N (%)
Total	**167**
Age: Mean (SD)	45.2 (17.2)
18–25 years	35 (21%)
26–44 years	44 (26.3%)
45–64 years	63 (37.7%)
65+ years	25 (15%)
Highest level of education	
High school/GED or less	26 (15.6%)
Undergraduate degree or some college credit	102 (61.1%)
Graduate degree	38 (22.8%)
Missing	1 (0.6%)
Hispanic or Latina	8 (4.8%)
Missing	3 (1.8%)
Race	
White or Caucasian	94 (56.3%)
Black or African-American	42 (25.1%)
Asian	13 (7.8%)
Some other race or origin	12 (7.2%)
Missing	6 (3.6%)
Income	
Less than $10K	21 (12.6%)
$10K – $24.9K	17 (10.2%)
$25K – $49.9K	48 (28.7%)
50K – 74.9K	28 (16.8%)
$75K or more	41 (24.6%)
Missing	12 (7.2%)

Which of the following statements best describes any problems you may have with peeing or your bladder?*	N (%)
Total	104
Does not cause me any problems at all	23 (22.1%)
Causes me some very minor problems	21 (20.2%)
Causes me some minor problems	30 (28.8%)
Causes me some moderate problems	13 (12.5%)
Causes me severe problems	14 (13.5%)
Causes me many severe problems	3 (2.9%)

[*] Asked during function-specific CI