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PROTOCOL

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Prevention of Lower Urinary Tract Symptoms Research Consortium focus group Study of Habits, Attitudes, Realities, and Experiences of Bladder health

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Abstract

Aim: The study purpose is to explore adolescent and adult women's experiences, perceptions, beliefs, knowledge and behaviours related to bladder health across the life course using a socioecological perspective. Lower urinary tract symptoms affect between 20–40% of young adult to middle-aged women, with symptoms increasing in incidence and severity with aging. There is limited evidence to address bladder health promotion and prevention of dysfunction. This first study of the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium is designed to address gaps in existing qualitative research in this area.

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Design: This focus group study will be implemented across seven geographically diverse United States research centres using a semi-structured focus group guide informed by a conceptual framework based on the socioecological model.

Methods: The study was approved in July 2017. A total of 44 focus groups composed of 6–8 participants representing six different age categories (ranging from 11 to over 65 years) will be completed. We aim to recruit participants with diverse demographic and personal characteristics including race, ethnicity, education, socioeconomic status, urban/rural residence, physical/health conditions, and urinary symptom experience. Six of the focus groups will be conducted in Spanish and translated into English. Focus group transcripts will undergo content analysis and data interpretation to identify and classify themes and articulate emerging themes.

Discussion: This foundational qualitative study seeks to develop an evidence base to inform future research on bladder health promotion in adolescent and adult women.

Impact: This study has the potential to provide new insights and understanding into adolescent and adult women's lived experience of bladder health, the experience of lower urinary symptoms and knowledge and beliefs across the life course.

KEYWORDS

bladder health, focus groups, lower urinary tract symptoms, nursing, primary prevention, qualitative research, socioecological model, urinary symptoms, urologic nursing, women's health

1 | INTRODUCTION

Although extensive research has been conducted on bladder function and dysfunction, research is limited on healthy bladder habits, what it means to have a healthy bladder and primary prevention of lower urinary tract symptoms (LUTS). Important gaps in the literature include an operational definition of bladder health and how normal bladder function contributes to bladder health. To address these and other gaps in knowledge about bladder health, the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium is engaging in transdisciplinary research to conceptualize and define bladder health, with the goal of developing evidence for the primary prevention of LUTS and promotion of bladder health across the life course (Harlow et al., 2018).

The PLUS Consortium defines women's bladder health in terms of bladder 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)' and is 'not merely the absence of LUTS (Lukacz et al., 2018).' These characteristics are consistent with World Health Organization guidelines, which affirm that health is more than an absence of dysfunction or disease and includes physical, mental, and social well-being (Preamble to the Constitution of the International Health Conference, 2002).

Little is known about how adolescent and adult women view bladder health and the socioecological factors that shape bladder habits. To inform primary prevention efforts, it is important to understand the experience of a healthy bladder and to explore how individuals make meaning of bladder experiences. This includes characterizing the social processes shaping the individual's lived experience of bladder health and identifying language used by adolescent and adult women to describe bladder function (Digesu et al., 2008). These research efforts are critical in helping construct explanatory frameworks for understanding what makes or keeps the bladder healthy.

To foster understanding of bladder health from adolescent and adult women's perspectives, the PLUS Consortium will conduct the Study of Habits, Attitudes, Realities and Experiences (SHARE). The aim of this qualitative study is to explore adolescent and adult women's experiences, perceptions, beliefs, knowledge and behaviours related to bladder health and function. It will use focus group methodology to gain insight from people in a shared social context (Kamberelis & Dimitriadis, 2014; Ulin, Robinson, & Tolley, 2005). This paper outlines the transdisciplinary research protocol used for this multi-site qualitative focus group investigation. The protocol describes how a life course perspective is applied to engage adolescent and adult women in describing their lived experiences of bladder health. To characterize and contextualize focus group participants, information about participants' history of LUTS and typical toileting practices will be collected through quantitative measures administered after the focus group sessions.

2 | BACKGROUND

The SHARE study aims to address gaps in existing qualitative and quantitative bladder health research in adolescent and adult women. Limitations of the existing literature include paradigms emphasizing

biological and disease-focused thinking and limited attention to diversity of race and ethnicity, geographic and socioeconomic characteristics. For example, in a recent systematic review of qualitative evidence, Mendes et al. identified 28 studies that explored urinary incontinence in women aged ≥18 and showed that many of them described how adult women generally do not perceive urinary incontinence as a preventable condition, but rather see it as an inevitable process of aging (Mendes, Hoga, Goncalves, Silva, & Pereira, 2017). Similarly, at least one qualitative study showed a gap in information on pelvic floor disorders among African American and Latin American women, despite a demand for health education. Other studies have explored adult women's experiences of bladder sensations (Heeringa, de Wachter, van Kerrebroeck, & van Koeveringe, 2011; De Wachter, Heeringa, van Koeveringe, & Gillespie, 2011; Zhou, Newman, & Palmer, 2018) associated with LUTS, such as urinary tract infections (Baerheim, Digranes, Jureen, & Malterud, 2003), recurrent cystitis (Alraek & Baerheim, 2001) and overactive bladder (OAB) (Heeringa, van Koeveringe, Winkens, van Kerrebroeck, & de Wachter, 2012).

The few studies that have examined experiences among non-symptomatic populations (Coyne, Harding, Jumadilova, & Weiss, 2012; Heeringa et al., 2011) suggest that the experiences and terminology used by healthy women can differ from those with LUTS, indicating a need for healthcare providers and researchers to better understand experiences of women without LUTS. Additionally, existing qualitative studies generally have not explored a life course perspective and instead have examined discrete groups such as older adults (Andersson, Johansson, Nilsson, & Sahlberg-Blom, 2008; Dowd, 1991; Horrocks, Somerset, Stoddart, & Peters, 2004; Park, Yeoum, Kim, & Kwon, 2017; Smith et al., 2011; Teunissen, van Weel, & Lagro-Janssen, 2005) or postpartum women (Buurman & Lagro-Janssen, 2013; Wagg, Kendall, & Bunn, 2017). Further, the existing literature has minimal integration of theoretical or conceptual models and rarely includes a socioecological perspective (Fultz & Herzog, 2001; Hagglund & Wadensten, 2007). SHARE addresses this limitation by being one of the first studies to purposefully employ a life course perspective and socioecological conceptual framework to formulate novel insights about bladder health.

2.1 | Theoretical/conceptual framework

The PLUS Consortium developed a conceptual framework to guide its initial prevention research agenda (Brady et al., 2018). This framework acknowledges that individuals are embedded within social ecologies. Socioecological models are based on theories of individual behaviour and interpersonal relations, which may be thought of as *proximal* influences on health, and sociological structures, such as institutions, communities, cultures and policy landscapes, which may be thought of as *distal* social influences (Sallis & Owen, 2015). The PLUS conceptual framework informed the development of the SHARE focus group interview guide. Questions are designed to encourage participants to reflect on their current and past experiences in different socioecological and life course contexts.

3 | THE STUDY

3.1 | Study aim

The purpose of the study is to explore adolescent and adult women's experiences, perceptions, beliefs, knowledge and behaviours related to bladder health and function across the life course.

3.2 | Design

The PLUS Consortium identified a need for a qualitative research study to explore how adolescent and adult women perceive and experience bladder health and function across the life course. Qualitative methods facilitate the description of complex phenomena. Focus groups were selected as the qualitative research methodology because they provide an interactive forum for the expression of a wide range of responses and common/divergent opinions and beliefs. Focus groups are well-suited for the exploration of social norms and processes, cultural influences and institutional influences, and the language people use when talking to peers. Focus groups are particularly appropriate for our population, which ranges from young adolescents to older adult women who may have widely varying levels of experience with LUTS, with some participants having little or no experience. Group discussion may help participants generate ideas between each other, activate and uncover memories of experiences and serve to generate or formulate opinions. In the health sciences, focus groups are becoming the method of choice for eliciting input from a broad range of constituencies, including key stakeholders and marginalized groups of individuals whose voices often are not heard.

3.3 | Organization of study team

Consistent with the transdisciplinary composition of the PLUS Consortium, the SHARE study team is comprised of scientists, clinicians, and advocates with expertise in a range of disciplines, including social and behavioural science (social psychology, medical sociology, health education); medicine (paediatrics, geriatrics, urogynaecology, midwifery, behavioural medicine); public health (health disparities, community-based participatory research); and a community-based advocate. To support the level of study activities essential for the development and implementation of our multi-site focus group study, the transdisciplinary study team is organized into five cores for specific study-related tasks: administrative project management; recruitment; moderator training and data collection; data analysis; and data interpretation and dissemination (Figure 1). Each core consists of 2–4 members who developed initial protocols for their component. Protocols were reviewed and amended as needed by the full study team. As each component of the study unfolds, the aligned core will take leadership in operationalizing and monitoring

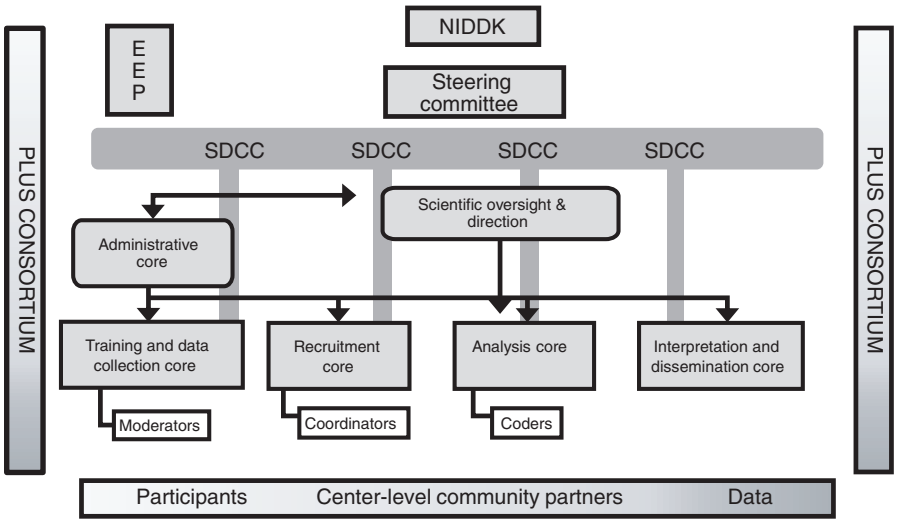

FIGURE 1 Organizational chart for the Study of Habits, Attitudes, Realities, and Experiences (SHARE); EEP, External Expert Group; SDCC, Scientific Data Coordinating Center; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; PLUS, The Prevention of Lower Urinary Tract Symptoms

the process as outlined in the manual of procedures (MOP). This approach allows us to capitalize on individual expertise and efficiency while continuing to support a transdisciplinary approach to the overall study process.

3.4 | Study setting and participants

This multi-site study will be conducted across seven geographically diverse U.S. research centres using a study-specific semi-structured focus group guide. All PLUS research centres will participate in recruiting participants and conducting focus groups.

3.4.1 | Participants

Participants will be recruited in 6 age groups:

- Early adolescents: 11–14 years
- Adolescent girls: 15–17 years
- Young adult women: 18–25 years
- Adult women: 26–44 years
- Middle-aged women: 45–64 years
- Older women: 65+ years

3.4.2 | Inclusion/Exclusion criteria

Eligibility criteria include cisgender women and adolescents who are English-speaking (for English language focus groups); Spanish-speaking (for Spanish language focus groups); able to read and provide written informed consent (or assent and parental consent for minors); and have an absence of any physical or mental condition that would impede participation. Pregnant women will be excluded due to the known effects of pregnancy on LUTS, but prior pregnancy is not an exclusion or inclusion criterion.

Although we will not recruit based on parity, we will periodically examine the distribution of parity within and across focus groups. If our observations suggest an issue with combining parous and non-parous women, we could further delineate groups by parous and non-parous status, retaining the age categories previously noted.

While our focus is on understanding adolescent and adult women's experiences of a healthy bladder, to ensure we have a full conceptualization of this experience, we will include participants without respect to LUTS status. This strategy contributes to a representative sample of adolescent and adult women with a wide range of experiences, which may or may not be defined by women as abnormal. In a previous study that purposefully recruited based on continence status, women's discussion of the experience of leakage changed over time after a screening process during which new terminology and concepts of leaking were introduced by the investigative team (Thomas et al., 2010). To avoid this risk, we will not pre-screen potential participants, but will collect individual written information about LUTS and toileting behaviour at the end of each focus group session. This will allow us to monitor the distribution of adolescent and adult women with respect to past and present experience of LUTS. If needed, we will adjust recruitment strategies or inclusion/exclusion criteria to ensure a range of experience. We aim to recruit a sample that is diverse with respect to race, ethnicity, education, socioeconomic status, physical/health conditions, LUTS status, and urban/rural residence—including up to 10 focus groups conducted in Spanish.

3.4.3 | Sample size

In each of the six age group categories, we will conduct 3–5 focus groups, consistent with best practice recommendations, (e.g., (Morgan, 1997). The unit of analysis is the focus group itself, regardless of the number of participants comprising each group session. We therefore proposed a sample size of 40–44 focus groups, with an average of 6–8 participants per focus group, necessitating the recruitment of 240–352 participants.

3.5 | Recruitment methods

Recruitment will be conducted across all seven PLUS research centres, leveraging the recruitment method(s) most suited for success at each centre. In preparation for this study, the PLUS Community Engagement Subcommittee conducted a survey of centres to identify centre-specific recruitment expertise and research populations (Table 1). Trained Research Coordinators (RCs) at each PLUS centre will conduct recruitment to saturate the planned age groups and ensure variability and comparability across sites and samples.

We will use a matrix outlining major: (a) socioecological considerations of each age group; (b) ideal recruitment groups relevant to bladder health; (c) age-related issues relevant to recruitment in each age group; (d) optimal recruitment portals by age group; and (e) optimal recruitment methods (Table 2). Whenever possible, we will reach out through existing community partnerships to optimize recruitment efforts. Community partners, community-based organizations, faith-based organizations and/or community health centres that are trusted community resources will serve as recruitment portals and advisors to facilitate the recruitment of racial and ethnic minority populations, rural populations and women whose primary language is Spanish. Community engagement partners will also advise on locations for hosting focus group sessions to accommodate potential participants' preferences and optimize attendance.

Focus groups will be conducted in four phases to allow for monitoring the composition of the recruited focus groups for diversity and to identify gaps in recruitment (Table 3). This recruitment plan allows us to leverage age-appropriate best practices with centre-specific strengths, allowing for an adaptive approach to recruitment.

3.6 | Study implementation

The overall study flow for this qualitative project is provided in Figure 2. A MOP developed by the research team is in place to guide the study process.

3.6.1 | Focus group moderator training

Moderators trained in qualitative research principles and focus group methodology will conduct each session. In focus group methodology, the moderators serve as the primary data collection instruments guided by a well-designed focus group guide. Focus group moderators will be female. Given significant geographic and disciplinary differences in qualitative research training and practice, it is important that moderators be grounded in the PLUS conceptual framework and the value of a community-informed approach, which are central tenets of the SHARE study. Therefore, all focus group moderators will receive training in the qualitative research principles adopted by the PLUS Consortium, best practices for focus group research and the focus group study protocol. Training will be both online and in-person; use action learning, community engagement and didactic sessions; and continue through focus group data collection.

3.6.2 | Focus group procedures

Each focus group session will be guided by a semi-structured focus group guide and will last approximately 90 min. The focus group guide is derived from the PLUS conceptual framework. The guide has five sections and 16 core questions with accompanying probes (Table 4). Each section and accompanying questions correspond to categories of the conceptual framework. For each focus group, a site-specific designated member of the research team will take written field notes using a standardized format to record methodological, contextual, and reflective observations. Sessions will be audio-recorded for later transcription.

At the conclusion of the focus group, participants will be asked to complete self-administered measures (Table 5) to characterize demographics, medical history (focusing on OB/Gyn/Urologic history), LUTS status and toileting behaviours. Completion is expected to take about 30 min. Each participant will receive a gift card valued at $50.

TABLE 1 Potential populations for recruitment by age group and special populations

	Age Group						Special Populations					Geography	
	Early Adolescents (11–14)	Adolescents (15–17)	Young women (18–25)	Adult women (26–44)	Middle-aged women (45–64)	Older women (65+)	LGBTQ	People who speak a language other than English	Racial and/or ethnic minority groups	People who are uninsured or have low SES	Occupations of interest to PLUS	Urban	Rural
Site													
Site 1	x	x	x	x	x		x	x	x	x	x	x	
Site 2					x	x			x	x		x	x
Site 3		x	x	x				x	x	x			
Site 4		x	x	x	x	x	x		x	x		x	
Site 5		x	x	x	x	x	x		x	x	x	x	x
Site 6		x	x	x		x			x	x			
Site 7	x	x	x	x		x		x	x	x			

Abbreviation: SES, socioeconomic status.

TABLE 2 Priority populations by age group, socioecological context, and recruitment considerations

	Adolescence		Adulthood			Older Adulthood
	Early	Adolescent	Emerging Adulthood	Young Adult	Mid/Late	
Chronological Age	11–14	15–17	18–25	26–44	45–64	65+
Major Social Ecological Considerations	• Onset of menarche • Puberty • Onset of sexual activity • School/ peers • Sports	• Puberty • School • Sports • Dating/Peers • Onset of sexual activity	• Sexual activity • Pregnancy • Childbirth • Work • School • Childrearing	• Sexual activity • Pregnancy • Childbirth • Work • School • Childrearing	• Work • Aging parents • Child/grandchild rearing • College planning • Planning for retirement	• Transitioning roles–parent, partner, caregiver • Issues of retirement
Ideal Recruitment Groups[a]	• Girl-focused after school programs	• Running clubs • School clubs	• College athletes • Workers in restricted context	• Workers in restricted context • Mothers groups	• Caregivers • Workers in restricted context	• Senior clubs, activity groups
Age-Related Issues Relevant to Recruitment	• Parental consent • Highly engaged in social media	• Parental consent • Highly engaged in social media	• Busy • Multitasking	• Busy • Multitasking	• Busy • Multitasking	• Mobility • Computer literacy • Larger font material • Trust-building
Optimal Recruitment Portals	• Schools • Sports teams • Online • Girls Scouts	• Schools • Sports teams- community • Sports teams–school • School clubs • Online	• School • Work • Community resources • Health/ community centres • OB/GYN practices	• Work • Community resources • Health/ community centres • OB/GYN practices • Elementary schools	• Worksites • High schools/college • Community sites • Grocery stores • Health/wellness centres • Healthcare settings	• Community senior centres • YMCAs • Faith-based groups • Area Agencies on Aging • Healthcare settings
Optimal Recruitment Methods	• Social Media • Text	• Social Media • Text • Flyer (trusted coffee shop, store)	• Email • Social Media • Text • Flyer	• Email • Social Media • Text • Flyer	• Email • Flyer • Mail	• Word of mouth • Flyer • Phone call

[a]Ideal recruitment groups are based on the recruitment goal of identifying groups of participants with a shared social context suitable to engage in facilitated dialogue, while also finding adequate diversity by sociodemographic characteristics for which there is a known association to health (e.g., race/ethnicity, socioeconomic status, education), both within and across groups.

TABLE 3 Phases and planned distribution of focus groups by age and population across sites[a]

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7
Phase 1	45–64 years, English	65 + years	26–44 years, English	18–25 years	15–17 years	18–25 years	11–14 years
Phase 2	26–44 years, English 45–64 years Spanish	45–64 years, African American 65 + years, African American	26–44 years, Spanish 45–64 years, English	18–25 years 26–44 years	18–25 years, rural 65 + years, rural	26–44 years 45–65 years	11–14 years 15–17 years
Phase 3	26–44 years, Spanish 65 + years English	45–64 years, rural 65 + years, rural	45–64 years, Spanish 65 + years, English	26–44 years 45–64 years	26–44 years, urban 45–64 years, urban	26–44 years 45–64 years	15–17 years 18–25 years
Phase 4	65 + years Spanish	45–64 years	65 + years, Spanish	15–17 years	11–14 years 11–14 years, African American	65 + years	18–25 years

[a]Additional attention to diversity of participants by socioeconomic status, which was also considered in recruitment outreach.

3.7 | Quantitative measures

The Lower Urinary Tract Symptom Tool (LUTS Tool) will be used to assess LUTS in adult women. A separate instrument, the International Consultation on Incontinence Questionnaire Pediatric Lower Urinary Tract Symptoms, will be used to measure LUTS in participants between the ages of 11–17 years. Toileting behaviours will be assessed using the Toileting Behaviors- Women's Elimination Behaviors, which elicits information about behaviours women use in public and private environments to empty their bladders (Palmer & Newman, 2015; Wang & Palmer, 2010, 2011). These measures will be used to summarize participant characteristics using descriptive statistics.

4 | QUALITATIVE DATA MANAGEMENT, ANALYSIS, AND INTERPRETATION

4.1 | Data management

The steps for data management are iterative (Figure 2). Audio recordings will be uploaded to the PLUS Scientific Data Coordinating Center. Audio recordings will be professionally transcribed verbatim and checked for accuracy by the site-specific RC. Names of specific places or individuals will be redacted. Each participant in the focus groups will be identified by their pseudonym throughout recording and transcription to protect confidentiality and to facilitate tracking responses and linking them to survey and demographic variables, if needed during analysis.

The Spanish language focus groups will be transcribed in Spanish and then translated into English using best practices to assure accuracy in translation (Clark, Birkhead, Fernandez, & Egger, 2017). Briefly, a native Spanish-speaking moderator and the translator will review all original and translated transcripts. All significant inconsistencies will be discussed and resolved by a team of three native Spanish speakers, including a co-investigator, moderator, and translator.

A glossary of terms will be maintained to inventory shared terminology. Data analysis will be conducted with de-identified written transcripts. Field notes will be appended to the transcription and used in data analysis and interpretation. Field notes also will serve as a tool for assessing fidelity of the interview guide and determining ongoing moderator training needs.

4.2 | Data analysis

The analysis will be guided by the socioecological model and the life course approach. For identifying themes and concepts associated with the experience of healthy bladders, we will perform a directed content analysis (DCA). DCA is a systematic process for making context-based inferences from the data (Elo & Kyngas, 2008). It begins with a conceptual framework for structuring the analysis and uses a deductive approach to explore textual data for insights relevant to the research question, with the goal of validating and extending knowledge in the area of interest. This analytic approach has particular utility in research areas where current theory or previous evidence needs further elucidation and description (Hsieh & Shannon, 2005). This analysis will assist researchers in identifying emergent insights related to (a) the lived experience of bladder health across the life course; (b) socioecological contextual factors shaping bladder behaviour; and (c) knowledge, assumptions, beliefs, values, and understandings about a healthy bladder. Participants' dialogue may also inform the Consortium's understanding of specific risk and protective factors potentially linked to bladder health and LUTS.

Our main subgroup analysis will focus on age. For coding, each focus group will be identified by its participants' age group and language used (Spanish or English). The general demographic descriptors for the composition of the groups will also be available for use during analysis. There will be the opportunity to conduct analyses within age group, and across age categories, to identify similarities and differences.

Standard qualitative data analysis techniques will be used, beginning with coding and memoing (Corbin & Strauss, 2008; Saldaña,

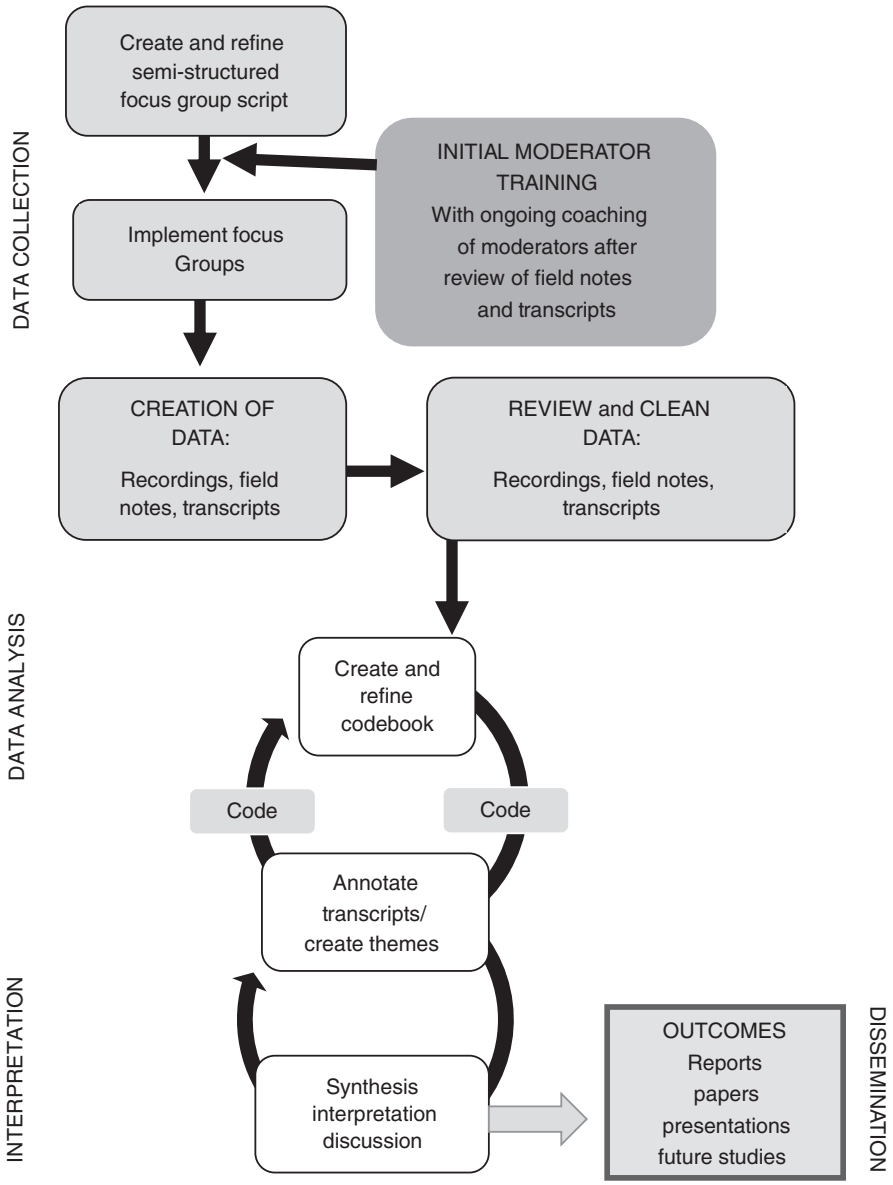

FIGURE 2 Study flow

2015). We will analyse transcripts using a deductive coding scheme informed by the socioecological model and our working definition of bladder health. All transcripts will be imported into DeDoose®, an online platform for qualitative data analysis designed to facilitate the organization and analysis of qualitative data. As a web-based platform, it will be accessible in real time from multiple locations. This will facilitate the analytical work performed at a single site for the initial content analysis and will also allow for site-specific analysis as needed for selected scenarios, populations, or age-specific considerations.

Memoing entails making notations of researchers' conceptual and theoretical insights relating to the themes and potential codes. Although it is part of the analytic process, memoing also plays an important role in the development and articulation of conceptual and theoretical frameworks during the interpretative phase of the study. Review of the field notes will be completed to complement the memoing process, contextualize focus group data and identify any unique codes or concepts that may augment the initial coding scheme.

The codebook will be developed after each life course group is complete to ensure that it is applicable to all the data (inclusive of new concepts/topics/subthemes). Each code will be designated by name (typically using participant phrasing) and specified by an operational definition with inclusion and exclusion criteria and quotes from focus group excerpts illustrative of codes. Variations within codes will generate subcodes. Patterns and associations across codes and coded text segments will be analysed to develop thematic categories that indicate relationships among codes. These relationships can be configured in several ways, including linear, sequential, circular, concentric, and hierarchal arrangements.

Coders will be trained in the codebook and in DCA. The analysis core members (Figure 1) will read all the transcripts independently and develop a list of coding categories that capture the range of participants' responses. Using an iterative process, team members will

TABLE 4 Focus group guide questions and corresponding categories of the PLUS conceptual framework

Focus group concepts[a]	Individual biology/ body	Individual mind/ behaviour	Interpersonal	Institutions and organizations	Society and community
Healthy bladder					
1. Have you heard about the bladder (where it is)?					
2. What are your ideas about what it means to have a Healthy Bladder? (or When you hear the phrase Healthy Bladder, what does this mean to you or what comes to mind) • Do you ever even think about your bladder and it being healthy or not? • How does it work/function (i.e., what does it do)? • How does it feel to have a healthy bladder?					
3. What are your ideas about what it means to have an unhealthy bladder? (or When you hear the phrase Healthy Bladder, what come to mind?)					
4. In your view, what are some of the things that help people to have a Healthy Bladder? • Anything we do in our daily routines? • What we do? What we eat/drink? • Anything about our environment at home? At school? At work? In the community?					
5. What are some of the things that might cause our bladders to be unhealthy? (or cause bladder problems) • Anything we do in our daily routines? • What we do? What we eat/drink? • Anything about our environment at home? At school? At work? In the community?					
6. Are there certain conditions that might affect your bladder health?					
7. Are there rules at home or on the job that might affect your bladder health?					
8. When your bladder gets full or is ready to empty, how does that feel to you? • How do you respond to that feeling? • How do you decide whether to hold it for a while or to go ahead and go to the bathroom?					
Knowledge acquisition					
9. What have you heard about the bladder, where it is, and what it does?					
10. How/where, did you learn about your bladder and how it works? • From whom? Your parents? Siblings? Friends? • Was it part of any health class at school?					
11. How do you think people (your age) learn about bladder habits, that is, when to go to the bathroom or how often? • Does someone tell you about this? Or did you just figure it out on your own? • Does anyone teach people your age any certain way to urinate (posture? hygiene?)					
12. If someone (your age) had a question about their bladder and/or bladder function, who do you think they would talk to? • If you had a problem with your bladder, whom would you want to talk to?					
LUTS and care-seeking					
13. What challenges have you (or people your age) faced with the bladder, how it feels, or how it works?					
14. How do you (or people) cope with the challenges when it happens? • What do you (they) do to avoid it happening? • Did you (they) go for treatment?					

(Continues)

TABLE 4 (Continued)

Focus group concepts[a]	Individual biology/ body	Individual mind/ behaviour	Interpersonal	Institutions and organizations	Society and community
15. Is there a certain time of day (or night) when your bladder is especially a problem?					
16. Are there certain places or activities when your bladder is especially a problem?					
Terminology					
17. What do you (people your age) call it when you go to the bathroom to pass urine? • Running to the bathroom frequently? • Waking up at night to go to the bathroom? • What do you call it when someone has accidental loss of urine before they can get to the bathroom?					
Public health messaging					
18. We are thinking of developing some programs to inform the public about bladder health. • Do you think people will be interested in this type of information? • Would the information be useful? • What are the best ways to get this information to people? (TV? social media, internet? pamphlets? classes?)					

Note: Abbreviations: LUTS, lower urinary tract symptoms; PLUS, Prevention of Lower Urinary Tract Symptoms.
[a]Shaded boxes show the level of the PLUS conceptual framework that a particular concept may inform.

compare results until a consensus is reached on the codes and their definitions. Following the completion of this process, the coding team will compile the resulting coding scheme and the definitions of the codes into a codebook. A separate team of coding staff will then use the codebook to code all transcripts.

The investigators will conduct weekly supervision meetings with staff and resolve coding disagreements through consensus. Developing the codebook will be an iterative process and refinements may be made during the debriefing sessions described below (see Data Interpretation). Additional research questions and analytical approaches may emerge, prompting subsequent re-analysis of the data. These data management and analysis approaches meet the 'Standards for Reporting Qualitative Research' for content analysis and grounded theory, as described by O'Brien et al. (O'Brien, Harris, Beckman, Reed, & Cook, 2014) and recommended by others (Bourgeault, Dingwal, & Vries, 2010; Bryant & Charmaz, 2010; Corbin & Strauss, 2008).

4.3 | Data interpretation

Data interpretation is an iterative and reflexive process for deriving meaning, making theoretical connections, constructing explanatory frameworks and drawing relevant and credible conclusions supported by the data. The socioecological model and life course approach will guide the initial phase of the interpretative process. Subsequently, data interpretation will proceed as an open-ended, inductive process guided by team science and informed by a transdisciplinary perspective that uses the integrative expertise and experience of social and behavioural scientists, clinicians and interventionists, public health researchers and educators and community-based advocates.

The key mechanisms of data interpretation are data immersion and team dialogue, which will require regularly scheduled conference calls and dedicated face-to-face meetings. During these interactions, we will discuss the emerging themes and insights from the analysis. We will include focus group moderators in the debriefing process to ensure that their perspectives are represented. The emergence of team insights that transcend disciplines and cut across socioecological contexts can usher in innovative ways of thinking about the healthy bladder and how to promote bladder health. Additionally, the insights will be shared with community engagement groups when feasible to obtain feedback on the interpretation of emergent insights.

4.4 | Validity and reliability

Validity and reliability in qualitative research are often discussed as credibility and trustworthiness (Holloway & Galvin, 2016; Lincoln & Guba, 1985; Miles, Huberman, & Saldaña, 2014). The following strategies will be employed for building credibility and trustworthiness of our data and interpretations at multiple points during our study.

TABLE 5 Quantitative measures

Construct	Questionnaire	Tool specifics
Lower Urinary Tract Symptoms: Adults	LUTS Tool	• Developed through qualitative focus groups and nonmedical terminology to assess for LUTS (Coyne et al., 2012) • 22-item tool with subscales that include: incomplete emptying, frequency, urgency, nocturia, urgency UI, and stress UI with physical activity and increased intra-abdominal pressure • Response options included 1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = almost always and symptoms were asked within a 1-week recall • Each question has two parts to measure both the frequency and bother of symptoms • Total LUTS scores are computed as the sum of all responses to the LUTS Tool items
Lower Urinary Tract Symptoms: Children	ICIQ-CLUTS[a]	• Validated self-administered LUTS questionnaire in young and older adolescents (5–18 years old) • Consists of 12-item Likert scaled screening instrument of two biometrically robust domains of symptom severity and impairment (adaptation/bother) • For this study, of the eight questions specifically on LUTS, only questions on stress UI severity, urgency, and pain with urination were asked
Toileting Behaviours	TB-WEB	• Consists of 26 items designed to measure women's voiding behaviours in public and private settings • Domains include: 1) Premature voiding, 2) Strained voiding, 3) Place preference for voiding, 4) Delay voiding, 5) Position preference for voiding • Scoring: 5-point Likert-type rating scale to indicate frequency of the behaviour (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always) • Higher scores represent greater frequency of negative toileting behaviours
Demographic and Medical History	Demographic and Medical History Questionnaire	• Variables: age, race, ethnicity, gender identity, sexual orientation, education, socioeconomic status, and occupation, medical conditions, pregnancy history, parity (including mode of delivery), and self-rated health

Note: Abbreviations: LUTS, Lower Urinary Tract Symptoms; ICIQ-CLUTS, International Consultation on Incontinence Questionnaire – Pediatric Lower Urinary Tract Symptoms; TB-WEB, Toileting Behaviors-Women's Elimination Behaviors.

[a]De Gennaro M, Niero M, Capitanucci ML, von Gontard A, Woodward M, Tubaro A, Abrams P. Validity of the international consultation on incontinence questionnaire-pediatric lower urinary tract symptoms: a screening questionnaire for children. J Urol. 2010 Oct;184(4 Suppl):1662–1667.

4.4.1 | Before and during data collection

Moderator training will support validity by ensuring that different focus groups were asked similar questions and that the context of the focus group was conducive to open and honest answers from participants with a range of backgrounds. This increases what Lincoln and Guba (1985) refer to as 'dependability,' which offers transparency in our research approach, and what Holloway and Galvin (2016) refer to as 'authenticity and fairness.' Researchers will have prolonged engagement with the study and its data, with the same researchers involved in and observing data collection and interpretation to offer opportunities for reflection and awareness of context.

4.4.2 | During analysis

Our analytic strategy has several built-in methods with attention to credibility and trustworthiness. Coders will be trained, and transcripts will be double-coded for accuracy of code assignment; coders will also be trained to look for consistencies and inconsistencies with codes and emerging themes. Research team members who observed the focus groups will be involved in the inductive code development and will oversee the coding process to ensure that context is kept relevant and at the forefront of coding decisions. A detailed accounting of coding decisions and actions will be maintained to provide a 'decision trail' of analytic decisions (Holloway & Galvin, 2016).

4.4.3 | During interpretation

Interpretation teams will consist of experienced investigators who work together to infer from data and seek alternative explanations, rather than relying on disciplinary paradigms. The investigator team represents a range of disciplines and expertise, with varying levels of previous experience in bladder health and qualitative research. This diversity will aid the interpretation process, with fewer assumptions about what will be learned or found in the data and will help triangulate interpretive findings. Also, during interpretation, credibility and trustworthiness will be supported through community validation strategies, a variation on member checking. The preliminary findings will be presented to multiple stakeholder groups to 'check' the findings against the experiences and expertise of other knowledgeable informants, including community members, research participants, moderators, RCs, and other PLUS investigators.

4.5 | Ethical considerations

Institutional review board (IRB) review was completed in July 2017 using a central process for six of the seven sites. This included having one of the research centre serve as the lead for the IRB process and the other five sites' IRBs giving oversight to the primary lead site. The internal IRB for the seventh site did not have a process in place to support using such a reliance agreement, so it completed a separate approval process using the same protocol and materials as the primary site. Participants will complete the written informed consent process when they arrive for the focus group.

To assure confidentiality, participants will be asked to select and use a pseudonym or a number to identify themselves when they are speaking. Instructions to the participants will include asking them to not use names during the discussion. The moderator will be trained to use friendly reminders to limit mentioning of specific names of places or people during focus group discussion and to have focus group participants use their pseudonym when speaking to facilitate transcription. Finally, any personal identifiers used inadvertently will be deleted from the written transcripts.

While the protocol is low risk, we considered the potential for participants to become uncomfortable or distressed by discussing bodily functions or experiences. Using a trauma-informed lens, the research team was cognizant of the high prevalence of adolescent and adult women experiencing trauma in the United States. In recognition of the potential that a participant may have a negative response to discussing bodily experiences, a trauma-informed approach was used to develop a protocol based on best practices to manage distress should it arise during the conduct of a focus group session (Baccellieri et al., 2018).

5 | DISCUSSION

The protocol for the SHARE focus group study uses a transdisciplinary approach to design, develop and implement research investigating adolescent and adult women's perceptions of bladder health and function to address gaps in existing qualitative and quantitative bladder health research. Merging clinical, social behavioural and public health perspectives, our transdisciplinary approach brings together investigators with a unique array of expertise.

Innovative approaches for focus group recruitment include leveraging the networks of previously established community partnerships to recruit adolescent and adult women of all ages from diverse racial and ethnic groups (i.e., White, African American, Hispanic [both English-speaking and Spanish-speaking]) and rural, urban, and suburban communities across the United States. This approach augments the transferability of the study by facilitating the inclusion of diverse and underrepresented populations. This further addresses the gaps of prior qualitative investigations. Future investigations should expand inclusion of underrepresented populations. Additionally, community engagement research would optimally include community partners in the initial development of the study design.

Because this is not a longitudinal study, we are not able to interview participants more than once, making a life course design beyond the scope of this study. However, SHARE does apply a life course perspective on bladder health and function by recognizing that experiences during childhood, adolescence, and adulthood can accumulate to have an impact on bladder health over time. Adolescent and adult women will be asked to reflect on their current and past experiences during the focus groups. This approach will enable us to collect data that, combined across age groups, may inform future life course research questions. For example, identifying perceived facilitators of and constraints on toileting behaviours at different ages could contribute to new understandings of how accumulated environmental risk and protective factors may have an impact on bladder health. This approach can lead to the development of further life course research questions or strategies to address facilitators and barriers to bladder health.

The SHARE protocol systematically employs a socioecological conceptual framework to structure the focus group interview guide and carry out data analyses and interpretation. This approach is facilitated by the collaboration of SHARE investigators whose own programs of research have focused on different levels of social ecology across the individual, interpersonal, institutional, community, and societal levels.

The development of the SHARE protocol was a process that unfolded over time, requiring insight and flexibility to respond to emerging issues. For example, early in the protocol development process, we recognized the need to develop and implement a centralized training program for focus group moderators to assure consistency of research procedures across sites. Additionally, we recognized the need for a distress protocol to sensitize moderators to the potential for emotional distress during focus group sessions and provide guidelines for responding to distress. We also found it necessary to make adjustments to study design and instrument development to accommodate adolescent and Spanish-speaking populations.

5.1 | Limitations

Study limitations include potential difficulties in making comparisons or drawing meaningful conclusions about variation in bladder health attitudes, beliefs and behaviours among age, race, ethnic, or residential subgroups. Additionally, while this is a study about bladder health and function among adolescent and adult women and includes participants with and without LUTS, it is not designed to make comparisons based on participants' symptomology or clinical status.

6 | CONCLUSIONS

This multi-site qualitative focus group study employs best practice approaches to conducting a focus group investigation, including an organizational and operational structure that promotes transdisciplinary team science. Use of the PLUS conceptual framework, which employs a socioecological model with a life course perspective, will allow for potential insights and new understanding of the lived experiences of adolescent and adult women's bladder health and/or LUTS.

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CONFLICTS OF INTEREST

None.

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