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UNIVERSITY OF CALIFORNIA,
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A Qualitative study to understand the experiences and barriers of home bladder manometry for
pediatric neurogenic bladder patients from the parent, provider, and nursing staff perspectives

THESIS

submitted in partial satisfaction of the requirements
for the degree of

MASTER OF SCIENCE

in Biomedical and Translational Science

by

Amanda Marie Macaraeg

Thesis Committee:
Professor Antoine E. Khoury, Chair
Chancellor's Professor Zeev N. Kain
Professor Sherrie H. Kaplan

2022

DEDICATION

To

my parents Chris and Millie, my brother Austin, my boyfriend Nicholas, colleagues, and friends

in recognition of their unwavering support.

To chasing dreams

*I dreamed it all ever since I was young.
They said I wouldn't be nothing,
Now they always say congratulations
Worked so hard, forgot how to vacation
They ain't never had the dedication.*

Post Malone
Congratulations

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LIST OF ABBREVIATIONS

AUA: American Urological Association

CDC: Centers for Disease Control and Prevention

CHOC: Children's Hospital of Orange County

CIC: Clean intermittent catheterization

EAU: European Association of Urology

ESPU: European Society of Pediatric Urology

HM: Home manometry

NGB: Neurogenic Bladder

SB: Spina Bifida

UDS: Urodynamics

VUDS: Video Urodynamics

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ABSTRACT OF THE THESIS

A Qualitative study to understand the experiences and barriers of home bladder manometry for pediatric neurogenic bladder patients from the parent, provider, and nursing staff perspectives

by

Amanda Marie Macaraeg

Master of Science in Biomedical and Translational Science

University of California, Irvine, 2022

Professor Antoine E. Khoury, Chair

Background: Patients with neurogenic bladder require lifelong management and close follow-up to prevent upper tract damage and renal deterioration. To date, urodynamics is the gold standard test to properly assess bladder pressures and volumes. Home bladder manometry is a novel technique that provides a low-cost and simple method to evaluate bladder pressures and volumes during clean intermittent catheterizations. Previous literature has shown that home manometry measurements predict urodynamic and ultrasound findings; however, no literature has been published on challenges and barriers faced by caregivers with the process.

Objective: This study serves as Phase 1 of a two-phase study to identify common themes concerning parent/caregiver attitudes surrounding home bladder manometry. We investigate the perspectives of home manometry through representative stakeholder engagement using key informant interviews and focus group discussions to explore perceptions and experiences with home manometry and to identify barriers and challenges with the process.

Materials and Methods: We performed a qualitative study through interviews and focus group discussions with twenty-three stakeholders. Stakeholders included parents/caregivers, providers, and nursing staff. Parents were asked questions related to their home manometry education, experience with provided materials, technique when performing the procedure, and overall evaluative criteria. Nursing staff and providers were asked questions related to experiences teaching home manometry and their perspectives on family understanding. Grounded Theory Methods were used to analyze transcripts and identify preliminary concepts that described attitudes towards the current home bladder manometry process.

Results: Twenty-three interview participants were adults (median age = 39 years, range 26-66): 10 were parents (43%), 9 (40%) providers, and 4 (17%) nursing staff. The six preliminary themes identified during discussions were an Evaluative measure, Maturation/Patient-Specific Characteristics, Sources of Error, Materials/Technology, Home Environment/Context, and Education/Learning Experience. The emergent concepts of improvement strategies and need for standardization became evident.

Discussion: Home bladder manometry is a feasible and beneficial way for neurogenic bladder patients to monitor their bladder pressures and volumes at home. However, our study identified barriers that impact families and patient care. There is a need for standardization of instructions and modification of materials to improve these patient/family experiences. The way that home manometry is presented and taught to families can impact their understanding and ability to execute the procedure at home. The perspectives of all important stakeholders helped to highlight barriers and identify solutions that can be implemented to improve the home manometry process.

INTRODUCTION

Preventative Treatment of Neurogenic Bladder Patients

Neurogenic bladder is a condition that results from a disruption in bladder innervation. It is most commonly associated with spinal abnormalities and nervous system damage. If left untreated and unmonitored, patients with neurogenic bladder (NGB) may experience elevated bladder pressures and renal deterioration.¹ Various guidelines and protocol across multiple associations recommend a conservative approach for managing pediatric patients with NGB.^{2,3,4,5} The purpose of a conservative approach is to monitor and manage bladder function to avoid renal deterioration. Treatments under this approach include anticholinergic use, clean intermittent catheterization (CIC) and use of various diagnostic tests to monitor kidney and bladder function.

Methods of Bladder Evaluation: Urodynamics vs. Home Manometry

Video urodynamics (UDS) is the gold standard diagnostic test used for assessing bladder volumes and pressures.⁶ This procedure must be performed in-clinic because it requires professional operation and equipment to evaluate bladder, urethra, and sphincter muscles storage and voiding characteristics. Unlike home blood pressure testing, there is currently no validated alternative method to monitoring bladder pressures and volumes at home.

Home Manometry: A novel method for bladder pressure and volume evaluation

Since 2008, clinicians within the Urology Division at CHOC Children's Hospital of Orange County have introduced a home bladder management technique to patients with NGB. This technique allows patients and their caregivers to perform home bladder manometry by keeping a home pressure/volume diary (PVD). Home bladder manometry is a method recommended to NGB patients that can be implemented to measure their bladder pressures and volumes at home while performing their routine intermittent catheterizations.

Home PVD does not alter these patients' current bladder management regimens as measurements are recorded at the time of their regularly scheduled catheterizations. This process requires catheterization equipment, a simple ruler to measure pressure, a urine collection container to measure volume, and a pen and paper to record the measurements. Our initial study of 30 pediatric patients showed that low PVD pressures at maximal CIC volumes were strongly correlated with UDS parameters indicating normal pressures, while high PVD pressures correlated with UDS pressures indicating the need for more aggressive bladder management.⁷ A subsequent validation study of 52 additional patients confirmed previous correlations with UDS parameters in addition to findings that no patients with home bladder pressures <20cm H₂O had grade 3-4 hydronephrosis.⁸

Although home bladder manometry is not meant to serve as an alternative to UDS, Hidas *et. al* and Huen *et. al* have proven it to be a useful tool in monitoring patients' bladders and identifying those who may require additional urodynamic testing. However, since home bladder manometry is a novel method of recording bladder measurements, the CHOC Urology Division currently has only anecdotal evidence of how well-accepted it is with NGB patients, their parents, and their clinical team.

Study Objectives

We conducted a cross-sectional, mixed-methods study to qualitatively evaluate the experiences and barriers of stakeholders involved in the care of NGB patients using home bladder manometry. This study focuses on Phase I of a two-phase study designed to comprehensively understand and evaluate attitudes surrounding home bladder manometry. The Grounded Theory Process was utilized to conceptualize the survey-making process and help guide us to final survey generation.⁹ Phase I consisted of key informant interviews and focus

group discussions to generate themes through integration of feedback from parents/caregivers and clinic staff involved in these patients' care. Information collected from these discussions was analyzed and organized to identify components of the process that may be improved within the clinic. Additional feedback from participants will be integrated to implement changes within the clinic and help determine which items should be included in the final survey. Phase II, which will commence after the completion of this study, involves survey generation, administration, and analysis. The survey will allow us to improve their experiences, provide families with additional resources, and present overall feasibility of performing home bladder manometry.

BACKGROUND

Pathophysiology of Neurogenic Bladder secondary to Spina Bifida

In neurogenic bladder (NGB), individuals are unable to control their bladders.¹⁰ This lack of control is caused by neurological defects, often due to spinal abnormalities, that block central nervous system signals to the bladder. NGB patients require lifelong treatment and regular follow-up to preserve urinary function and kidney health.

Spina bifida (SB) is a congenital condition commonly associated with NGB. Approximately one in every 2,758 babies born in the United States each year are diagnosed with spina bifida.¹¹ Depending on the location and severity of the neural tube defect, long-term complications including paralysis, neurologic deterioration, and bladder and bowel dysfunction may occur. Regardless of severity, patients require close follow-up appointments and testing from childhood to adulthood by various specialists, including urologists, to monitor associated conditions that may occur.

The role of the urologist in these patients' care is pertinent in renal and bladder preservation. Nerve damage caused by SB may alter or block central nervous system signals to the bladder, causing NGB children to be at-risk of elevated bladder pressures and renal deterioration. Bladder dysfunction caused by SB may present as overactive bladder, underactive bladder, or a combination of both. Overactive bladder presents as urinary incontinence, or leakage. This is caused by detrusor overactivity in which the bladder wall muscles involuntarily contract.¹² The second type of NGB is underactive bladder, which presents as prolonged urination time and incomplete bladder emptying.¹³ This occurs when detrusor muscle activity is reduced, thus causing the patient to have a difficult time excreting urine. Nonetheless, if left untreated, NGB may lead to urologic complications including vesicoureteral reflux, recurrent

urinary tract infections (UTI), and in more severe cases, renal failure.¹⁴ Urologists' primary goal is to help these patients maintain safe bladder pressures, achieve urinary continence, and preserve overall renal function.

Updated Guidelines for NGB Management

As treatment techniques for NGB slowly evolve, various associations have released updated NGB management guidelines within the past decade. This includes the European Association of Urology/European Society of Pediatric Urology (EAU/ESPU), American Urological Association (AUA), Centers for Disease Control (CDC), and the National Spina Bifida Registry. Although the exact timeline of recommendations varies across associations, all advocate for a proactive and conservative approach to managing neurogenic bladder in children and adolescents. Each association's guidelines outline the recommended timeline of follow-up visits, diagnostic tests, and interventions that pediatric urologists should follow when caring for these patients.^{2,3,4,5}

Diagnostic Tests and the importance of Urodynamics

These organizations recommend that urologists perform bloodwork and urinalysis, renal-bladder ultrasounds, and urodynamics (UDS) to assess kidney and bladder function. UDS is the gold standard test performed to evaluate overall function of the bladder. During the 60-minute procedure, patients are artificially filled with contrast to evaluate bladder detrusor muscles storage and voiding characteristics. Through UDS, clinicians can assess bladder capacity, maximum detrusor pressure, and detrusor leak point pressure.¹⁵ This assessment of bladder function allows urologists to determine the next steps in managing the patients' bladder, whether it be surgical intervention or adjustment of the existing conservative management regimen.¹⁶

A Conservative Management Plan

In addition to diagnostic and follow-up testing, the guidelines recommend a conservative management regimen involving clean intermittent catheterization (CIC) immediately after birth, with or without anticholinergic use. Anticholinergics are medications used to block acetylcholine, thus decreasing involuntary detrusor contractions. This is typically given to patients with overactive bladders.

The primary form of bladder emptying is CIC, which was established in 1972.¹⁷ This process is performed by inserting a catheter through the urethra and into the bladder to allow for urine drainage. This technique allows patients who cannot voluntarily void to maintain safe bladder emptying pressures and potentially avoid renal deterioration and/or the need for surgical intervention. Patients who begin catheterizing early on in life and continue to do so as instructed have been shown to have decreased renal complications compared to those who start later and are non-compliant with the process.¹⁸

Novel home bladder monitoring techniques

As NGB-SB treatment continues to evolve and clinicians begin to focus more on conservative management strategies, various institutions have piloted different methods of measuring bladder function at home and assessing outcomes similar to that of Urodynamics.

Walter *et al.* created a bladder pressure gauge in 1996 for at-home use by patients who perform CIC.¹⁹ In 1998, the pressure gauge was given to 11 pediatric patients with myelomeningocele to assess instrument accuracy and its ability to produce results similar to the vesical, abdominal, and detrusor pressures produced on Urodynamics.²⁰ The pressure gauge was attached to a connecting tube and measurements were recorded during CIC. Results showed that home full and empty pressure were not statistically different than that of UDS vesical and abdominal pressures, respectively. Home detrusor pressures were estimated by subtracting home

empty pressures from home full pressures. Estimated home detrusor pressures were significantly greater than UDS detrusor pressures.

Findings from the previous study prompted a subsequent study on 9 pediatric patients with myelomeningocele. This was performed to estimate detrusor pressures at home using different empty pressure parameters than the previous study. Results showed that almost empty bladder pressures at home were not statistically different than UDS abdominal pressures.²¹ This measurement produced home detrusor pressures that were not statistically different than that of UDS.

Nearly two decades later, Ruzhynsky *et al.* pilot tested a novel handheld device called the Peritron+ in a group of 10 adult females with voiding dysfunction to determine if bladder vesical pressures were comparable to that of UDS.²² The device was connected to a water transducer and UDS equipment. Regular UDS measurements were recorded at the time of the procedure and vesical pressures were recorded at different bladder filling intervals throughout the procedure. Results showed that Peritron+ produces accurate vesical pressures when compared to UDS and may be used by professionals in the clinic or by patients at home to monitor patients at risk of high bladder pressures.

More recently, Cooper *et al.* developed two devices, the cystomanometer and cystoelastometer - both are used to approximate bladder pressure measurements during CIC similar to that of UDS.²³ Adult and pediatric patients with NGB were enrolled in the study. Measurements recorded from both devices were taken in the clinic and uploaded directly to a phone application. Findings showed that measurements from both devices strongly correlated with similar UDS findings. A follow-up pilot study was performed to test and report the experiences of at-home cystomanometer use in 14 pediatric patients. Results showed that the

device functioned well during initial use; however, after 4 weeks, eight out of 13 devices had hardware issues.²⁴

Home Bladder Manometry at CHOC Children’s Hospital

Similar to that of the aforementioned studies, the CHOC Urology Group aimed to develop a technique to monitor bladder pressures and volumes at home and to determine the correlation between home measurements and the gold standard UDS. This approach differed from the other techniques. Rather than utilizing novel devices that automatically measure pressures, this home bladder manometry technique simply requires the patient’s CIC catheter, a urine basin, a ruler, and extension tubing (if needed). Home manometry is performed during a patient’s regular CIC routine (Figure 2.1). The patient lies supine and is asked to relax and breathe calmly. After inserting the catheter into the bladder, parents/caregivers are instructed to hold the catheter upwards, wait until the urine level settles, and measure the height of the urine column in the catheter using the centimeter units on a ruler with the zero level with the penoscrotal junction in males and with the urethral meatus in females. This is an estimate of the bladder detrusor pressure. Urine is then drained into a urine basin, and the urine volume recorded.

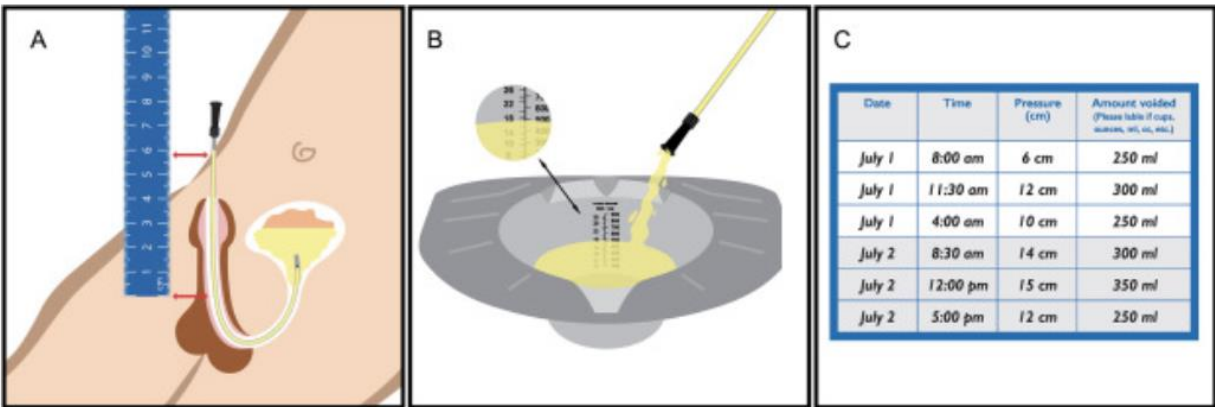


Figure 2.1. Home Bladder Manometry Instructions for a Male Patient. A) Pressure is measured by recording from the base of the penis to the level of urine in the catheter. B) Urine is

drained, and volume is measured using the mL markings in the basin. C) Date, time, pressure, and volume are recorded on a log and returned to the clinic at the next outpatient visit or VUDS appointment.

Hidas *et al.* have shown that home manometry bladder pressures are reliable measurements in predicting bladder safety according to UDS measurements in 30 pediatric NGB patients.⁷ Huen *et al.* validated Hidas' findings in an additional set of 52 patients. Furthermore, none of the patients with home bladder pressures lower than 20cm of water had high grade hydronephrosis (grade 3 or 4).⁸ Hydronephrosis, or dilatation of the kidney, results from mechanical or functional obstruction due to high pressures in the bladder impeding flow of urine from kidney to bladder. Progressive hydronephrosis may cause renal damage if left unmonitored and untreated.

This method of home manometry differs from the others because it is inexpensive and feasible for patients to perform if they are already catheterizing. Although clinicians believe this is a simple technique that patients can do at home, our study was conducted to answer the question: how exactly do the patients and their families perceive the process?

The importance of qualitative research in understanding novel techniques

The use of qualitative research is increasing within the healthcare field. It helps researchers understand ideas such as patient perspectives, patient satisfaction, and patient needs. Stakeholder engagement is a qualitative research method that is used to understand thoughts and perspectives on a certain phenomenon.²⁵ The goal of this project was to use qualitative research methods to investigate the perspectives of all important stakeholders regarding the home manometry process. The information gathered will be used to help better understand overall perspectives, and to determine what is working, what needs to be refined, and what changes can be made to improve the home manometry experience.

METHODS

Protocol Development

Study protocol and methodology were developed through cooperation and guidance from the CHOC Urology Research Team, MS-BATS thesis committee, a urologist with experience developing questionnaires for NGB patients, and an additional qualitative expert from an outside institution. Literature review on existing bladder management techniques and qualitative research methods was done prior to initial protocol development.

An initial consultation with the external urologist was performed to share the initial protocol and invite feedback for feasibility and methodology adjustments. The second qualitative expert provided insight on their experiences with patient-centered research, theme generation, and overall qualitative analysis. Finally, monthly discussions with the thesis committee members and bimonthly meetings with the Urology Research Team were held to discuss methodology updates, allow for suggestions, and to ensure that all members were satisfied with the final study design.

Ethical Considerations

Initial institutional review board (IRB) documents were submitted to the in-house IRB at CHOC Children's Hospital of Orange County on December 20, 2021. The IRB is an administrative body consisting of qualified committee members who are responsible for reviewing documentation for potential research studies to be performed at an institution. The in-house IRB committee, in particular, is responsible for ensuring that human subjects rights for investigator-initiated studies are protected.²⁶ IRB approval was obtained, and the study was approved with an exempt status on February 24, 2022 (IRB No. 2111181). The study coordinator learned proper methods of moderating qualitative discussions prior to conducting the open-ended interviews and moderating the focus groups. Additionally, prior to interview or focus group

commencement, participants were informed of the study purpose and expectations, and were required to sign electronic consent forms in REDCap Web (see Appendix A for final study protocol).

Methodology – Grounded Theory Methods

A cross-sectional, qualitative study was deemed to be the most suitable study design to evaluate the parameters that we wished to assess. Grounded Theory Methods were utilized to systematically organize the study methodology, conceptualize the interview and focus group processes, and to prepare for Phase II (survey generation). This methodology allowed us to generate themes regarding the home manometry experience based on data gathered from participant responses rather than formulating answers contingent upon predisposed assumptions.²⁷ Additionally, because of the novelty of the technique at hand, there is no previous literature discussing the experiences of home manometry, nor are there any existing articles discussing those with other home bladder monitoring techniques developed by other institutions. This inductive approach to allowed us to simultaneously collect and analyze data to reach our final theory surrounding the topic and was therefore considered to be the most appropriate for this study.

Data triangulation was incorporated into the study design to ensure data comprehensiveness and enhance validity.²⁸ Using this method, we decided to include all key stakeholders involved in the home manometry process. This included parents/caregivers involved in the patient's everyday care, providers who provide these patients with medical treatments and recommendations, and nurses who directly teach patients how to perform home manometry. Through data triangulation, all key individuals involved in the home manometry process had the opportunity to share their personal thoughts, opinions, and experiences with the

technique. Incorporation of unique viewpoints from various individuals aided us in understanding all aspects of the home manometry process and further strengthened the study validity.

Questioning Route Development

The purpose of a questioning route is to methodically organize and develop qualitative interview questions in advance. This helps to ensure that questions being asked are relevant to the study and asked in a sequential order. If developed and asked correctly, questions will prompt responses that answer the research question and evoke conversation between participants and/or the moderator. Questioning routes are also used to ensure the moderator asks questions using terminology that does not invite any bias in the participants' responses. Finally, a list of probing questions was incorporated into the questioning route. Probing questions are used to elicit more in-depth responses and may be asked if a participant requires more encouragement to discuss the topic of interest. Questioning routes are typically used for focus groups while interview guides are used for individual interviews; however, both have similar structures and include the same types of questions depending on what information the researcher wishes to obtain.

Individualized semi-structured, open-ended questioning routes were created for each subgroup of participants (parents/caregivers, providers, and nurses) using Kreuger's guide to questioning route development.²⁹ Open-ended questions are phrased in a manner that prompt more elaborate responses rather than one-worded "Yes" or "No" answers. This allows the participant to think less about the "what," and more about the "why" or "how." After the initial questioning route draft was created, the study coordinator hosted a brainstorming session with the urologists and nurse practitioners involved in the home manometry process and invited them

to make modifications. All questioning routes went through multiple rounds of revisions and were approved by the Urology Research Team.

Each questioning route included five types of questions: opening, introduction, transition, key and ending. A single opening question was used to initiate focus group discussions – this is a question that all participants can answer. Opening questions were not used during key informant interviews because these discussions were more intimate and did not involve more than one participant. The opening question was then followed by an introductory question to ease the participants into thinking about and discussing home manometry. A transition question was then asked to get more into the specifics of home manometry experiences. The next, most important part of the questioning route was the key questions. Key questions allowed participants to provide detailed responses about each aspect of home manometry and facilitated data collection that would further be used for the bulk of data analysis. Finally, ending questions were asked to encourage participants to think about all the responses they provided, allow them to share any additional thoughts, and close out each discussion.

Questioning routes were refined using an iterative approach. If deemed necessary, questions were evaluated after each interview and were altered, removed, or added depending on the need for additional information or rewording due to confusion. This approach allowed us to adapt to the participants' responses and enhance the questions to be asked in subsequent interviews. The Flesch-Kincaid readability test was utilized to determine grade level understanding and ensure that questions would be comprehensible to participants. The grade level readability of the parent/caregiver, provider, and nursing staff questioning routes were 5.5, 5.7, and 6.1, respectively. Final versions of each questioning route can be found in Appendix B.

Participant Recruitment

Inclusion and Exclusion Criteria

Key stakeholders involved in the care of NGB-SB patients were eligible to participate in the study: this included parents/caregivers, providers (attending, fellows, and nurse practitioners), and nursing staff (registered nurses and licensed vocational nurses). Inclusion criteria were individuals 18 years or older who have experience with and knowledge about the home bladder manometry process. Additional inclusion criteria for the parent/caregiver cohort were that their child must be younger than 18 years of age, have a neurogenic bladder diagnosis secondary to spina bifida or tethered cord, and perform clean intermittent catheterization (CIC) as part of their regular bladder management regimen. Exclusion criteria included: patients older than 18 years of age and/or a primary diagnosis other than spina bifida or tethered cord. Individuals with English and Spanish primary languages were eligible to participate in the study.

It is important to note that the birth prevalence of spina bifida amongst the Hispanic population is higher than that of the non-Hispanic white and black populations³⁰: 3.80 per 10,000 live births versus 3.09 and 2.73 per 10,000 live births, respectively.³¹ Additionally, 51.3% of the patients in CHOC's Neurogenic Bladder Database are Hispanic, 45.6% non-Hispanic, and the remaining 3.1% have an unknown ethnicity. Racial and ethnic disparities within the healthcare system exist due to factors including level of education, household income, and health insurance.³² Additionally, if language barriers are present, interactions between providers and patients may reduce effective communication and affect the patient's ability to receive proper treatment.³³ Therefore, the inclusion of Spanish-speaking parents/caregivers was necessary to account for any cultural differences that may potentially be identified between ethnic groups.

Patient Screening

Patients in our NGB REDCap database (IRB No. 180209) were screened for initial eligibility. Once eligible patients were identified, patient names, medical record numbers, dates of birth, current age, primary diagnosis, and primary phone number were obtained from the medical records. A comprehensive list of all eligible patients was saved on CHOC's secure server and used during the recruitment process.

Participant Recruitment

Providers and nursing staff were recruited via email or in-person contact in the clinic. Prior to parent/caregiver recruitment, a Spanish-speaking team member received formal training from the study coordinator on recruitment techniques and proper consenting methods. The study coordinator and Spanish-speaking personnel called eligible participants from the screening list based on primary languages identified in the patient's medical records. Study objectives, expectations, risks/benefits, and participant rights were discussed (see Appendix C for introductory statements). Individuals were provided with the opportunity to ask any questions regarding the study.

Obtaining Informed Consent

The electronic informed consent document was pre-approved and created in accordance with IRB standard. A Spanish version of the consent form was translated through a certified translation service using the IRB-approved English document. Both English and Spanish versions were uploaded to REDCap Web, approved by the CHOC REDCap manager, and put into Production Mode prior to dissemination.

Once all elements of the consent were discussed and agreed to during initial recruitment, participants were sent the consent document via email. The landing page provided participants with an option to choose from the English or Spanish version. Each participant had to provide their name, age, signatures date of signature, and best form of contact on the consent document. Formal consent submissions were received directly through the REDCap portal. Participants were then contacted to schedule a timeslot for their key informant interview or focus group discussion with the study coordinator. Invitations to Zoom meetings were sent out prior to each discussion.

Data Collection

Methodological triangulation was incorporated by using two methods of data collection^{34,35}: individual key informant interviews and focus group (FG) discussions. Key informant interviews and FG discussions differ in structure and benefits, elicit distinct answers, and may potentially offer different results. The strategy of using different types of understanding a phenomenon allows for more robust data collection by inviting opportunities to share experiences in different settings.

Key informant interviews are one-on-one discussions between an interviewer and a participant. These take an average of 20-30 minutes. Individual interviews are typically performed when there is little to none known about a phenomenon. Additionally, they help to uncover personal feelings and experiences about the topic at hand and allow for suggestions on ways to improve it.³⁶ Because of the intimate nature of these conversations, interviewers can focus on the single participant and tailor the questioning route according to answers provided. This method of qualitative research may be a more suitable environment for individuals with reserved personalities who do not feel comfortable discussing sensitive topics in the presence of

strangers³⁷. The number of interviews to be conducted is contingent upon the availability of resources and ability to reach saturation. Recommendations on how many individuals should be interviewed varies within the literature^{36,38}; however, between 10-25 participants was determined to be an acceptable number. Although more time consuming for the interviewer compared to an FG discussion, individual interviews provide more comprehensive results that help researchers obtain in-depth data about the phenomenon of interest.

On the other hand, focus groups are discussions between a moderator and a small group of 4-6 participants with homogenous characteristics.³⁷ These take an average of 1 to 2 hours depending on the number of questions asked and the amount of discussion amongst participants. Focus groups allow participants to reflect on others' responses, invites similar or opposing perspectives and allows a researcher to gather data quicker than individual interviews. Some participants may also feel more comfortable sharing experiences in a group setting with similar individuals as opposed to an individual interview. Although this is an efficient method of compiling qualitative data, it may be difficult for the moderator to keep participants on track and stay within the scheduled timeframe. Additionally, dominant and rambling talkers may overwhelm shy participants and result in a disproportionate number of responses.

Conducting key informant interviews and focus group discussions in conjunction with one another has proven to enhance data richness by obtaining generalized and descriptive responses in different settings.³⁹ This methodological triangulation allows the researcher to evaluate whether convergent or divergent concepts emerge between the two methods.

Focus groups were the primary form of qualitative data collection; however, key informant interviews were offered when presented with recruitment challenges. Challenges include conflicting schedules with other participants, the inability to fill up a single focus group

with at least four people, and participants who requested individual interviews. This technique of switching out focus groups for key informant interviews has shown to have no effect on study quality or data richness and was deemed appropriate for this study with respect to time and resources available.⁴⁰

Interviews and FGs were hosted by a single moderator for English interviews, and with the assistance of a professional translator for Spanish interviews. Zoom, a virtual conference application that allows individuals to meet using audio and visual software, was used to host all discussions. In-person discussions were considered; however, Zoom was determined to be the safest, most efficient option considering transportation, schedules, and the current pandemic. Zoom allows meeting hosts to record and save meetings, which would later be used for data analysis. Study objectives, descriptions of home manometry, and ground rules were outlined prior to each key informant interview and focus group discussion.

Data Analysis

NVivo 12 software was used for all analyses. The NVivo Transcription service was used for preliminary transcription of recorded interviews. The study coordinator reviewed transcripts and fixed any errors produced during the automated process. Recordings were transcribed verbatim, except for stammers, which were excluded.

Data analysis was conducted using Grounded Theory Methods according to Charmaz²⁷ and coding techniques developed by Saldana.⁴¹ Analytic memos were written throughout the data collection and coding processes to reflect on and conceptualize the data, their relationships, and any potential themes that emerged. First Cycle Coding was performed as an initial assessment of the data and used to organize data to codes. Eclectic coding followed and was utilized to consolidate redundant codes and eliminate ones that were not relevant to the study

purpose. Finally, Second Cycle Coding was performed to reorganize codes produced during the first cycle. Codes were grouped into categories based on similarity, and final themes were generated during this process. Saturation was determined when no new themes or concepts emerged from each subsequent interview. Inter-rater reliability of the final codebook was measured using the Fleiss Kappa statistic. A kappa statistic greater than 0.80 was considered to be almost perfect agreement between raters.

Data Quality

The research team was involved in all aspects of the study. Study protocol, methodology and questioning routes were discussed and agreed upon to ensure face validity of the measure.

As previously mentioned, the study coordinator facilitated and moderated all interviews and focus groups. However, a core team of 3 individuals, the coordinator, research fellow, and research administrator, met frequently to discuss participant findings, emerging themes, and potential further directions of the study. Throughout the interview and FG period, the study coordinator held debrief sessions with the research administrator after each subsequent discussion.

All transcripts were coded by the study coordinator, with a random sample of the transcripts being sent to the research fellow to determine accuracy and readability. The codebook containing themes, codes, and definitions were discussed and circulated amongst all members of the research team as analysis progressed.

Results

Sixty-three out of the 484 patients in the NGB REDCap database fit the study inclusion criteria. Of these patients, 11 of their parents were enrolled in the study. A total of twenty-four participants were recruited, consented, and enrolled into the study; however, only 23 were active participants (Table 4.1). Ten (43%) were parents/caregivers, 9 (40%) providers and 4 (17%) nursing staff. Age of participants ranged from 26 to 66 years old (median 39±8.2). Eighteen (78.3%) were females and the remaining 5 (21.7%) were males.

	Parent/Caregiver (n=10)	Provider (n=9)	Nursing Staff (n=4)
Median Age	39±8.2	39±8.3	31±6.3
Sex			
Male	2 (20)	3 (33.3)	0
Female	8 (80)	6 (66.7)	4 (100)
Primary Language			
English	8 (80)	9 (100)	4 (100)
Spanish	2 (20)	0	0

Table 4.1 Participant Demographics. Characteristics of participants interviewed in the study including age, sex, and primary language spoken during the interview or focus group discussion.

A total of 18 interviews were conducted. This included a combination of individual key informant interviews, group key informant interviews, and focus group discussions (Table 4.3). All interviews lasted an average of 27.25 minutes (range 11.87-51.05 minutes). Analytic memos were recorded after each subsequent interview (see Appendix D).

	Individual Interview (n=15)	Group Interview (n=2)	Focus Group (n=1)
Mean duration (minutes)	27±9.6	26.1±3.7	20.2
Relationship to patient			
Parent/Caregiver	8 (53)	1 (50)	0
Provider	7 (47)	1 (50)	0

Nursing Staff	0	0	1 (100)
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Table 4.2. Interview Characteristics. Interview duration and participant-to-patient relationship for each type of interview.

Individual parent/caregiver experiences of 9 patients were assessed (Table 4.2). These interviews captured a diverse range of perspectives based on patient demographics and clinical characteristics. Characteristics between male and female patients were similar. The average age of patients at the start of home manometry fell within the regular preschool age (3-5 years), while the average age at the time of the interview was around 10 years old. All patients had a primary diagnosis of spina bifida. Most patients were white (88.9%), non-Hispanic (66.7%), and had private insurance (66.7%). The patient’s primary urologist was recorded to account for differences in parental perspectives that may be provider specific. Urologists were numbered from 1-4 to ensure privacy.

	Female (n=5)	Male (n=4)
Mean age at time of Interview in years (range)	10.14 (3.2-15.8)	10.5 (9.1-15.2)
Mean age at 1st HM in years (range)	4.5 (0.1-8.5)	3.8 (1.5-4)
Primary Diagnosis		
Spina Bifida	5 (100)	4 (100)
Tethered cord	0	0
Parental Primary Language		
English	4 (80)	3 (75)
Spanish	1 (20)	1 (25)
Race		
White	5 (100)	3 (75)
Other	0	1 (25)
Ethnicity		
Not Hispanic	3 (60)	3 (75)
Hispanic	2 (40)	1 (25)

Insurance		
Public	2 (40)	1 (25)
Private	3 (60)	3 (75)
Location of Primary Defect		
Thoracic	2 (40)	0
Lumbar	1 (20)	3 (75)
Lumbosacral	2 (40)	1 (25)
Primary Urologist		
Urologist 1	3 (60)	3 (75)
Urologist 2	0	1 (25)
Urologist 3	1 (20)	0
Urologist 4	1 (20)	0

Table 4.3. Patient Characteristics. Patient demographics and clinical characteristics obtained from the medical records.

One-hundred eighteen codes were generated through First Cycle Coding. Analytic memo notes were written for all clinic staff interviews (see Appendix E). Once Second Cycle Coding was completed, a final set of 33 codes was generated. Analytic memo notes were composed to describe relationships within and between subgroups (see Appendix F). Thematic saturation was reached prior to the final interview as no new themes were identified. It was determined that adequate information on home manometry experiences had been collected and that no additional information would change the final themes generated.

Six major themes regarding the home bladder manometry process emerged: Evaluative, Maturation/Patient-Specific Characteristics, Sources of Error, Materials/Technology, Home Environment/Context, and Education/Learning Experience. Relevant codes were placed into each theme (Table 4.4). Themes were ranked by importance, which was weighted with respect to the total number of code references (see Appendix G for final codebook). Inter-rater reliability of the final codebook was assessed by 3 raters and was found to be almost perfect agreement ($\kappa=1$).

Table 4.4. Major Themes categorized by most to least references		
Theme	Files	References
Evaluative	18	259
Maturation/Patient-Specific Characteristics	18	141
Sources of Error	18	122
Materials/Technology	18	119
Home Environment/Context	18	98
Education/Learning experience	18	59

Theme 1: Evaluative

The first theme that generated the most responses was an evaluative measure. All participants shared evaluative responses regarding home bladder manometry. This theme aims to discuss personal perspectives on home manometry. In order of most to least references, codes that fit under this theme included Understanding, Recommendations, Clinical Utility, First impressions, Home Manometry vs. Urodynamics, Child feelings, and Control/Independence (Table 4.5). Participants were also asked to rate the ease or practicality of home manometry on a scale from 1 to 5 (Table 4.6).

All parents expressed the same level of understanding: home manometry helps to understand bladder function through pressure and volume measurements and is used to assess the safety of their children’s bladders. The most common recommendations were with regards to teaching methods and materials provided. Almost all parents recommended hands-on demonstrations as the primary form of teaching. Additionally, many participants suggested custom catheters with markings on them or a more durable ruler to make the pressure measurement process easier. Providers and parents acknowledged that home manometry is a good bladder screening tool that may be used to help determine bladder safety and management in a conservative fashion. It is a simple, non-invasive, and inexpensive technique that children feel indifferent towards. Some children are curious and ask questions when they see their parents

taking measurements during CIC; however, they are not bothered by the procedure. Interestingly, nursing staff did not think it was a good way to monitor NGB patients' health, nor did they think it added value to their care. This point of view may be biased due to their experiences and relationships with patients. Nurses were able to identify additional issues with the technique that providers were unaware of. When compared to UDS, parents trusted UDS more than home manometry; however, children were more comfortable with the latter procedure. Moreover, parents perceived home manometry to be difficult and stressful upon first presentation; and although they agreed to perform it, providers are often initially met with procedural questions. Nonetheless, home manometry gives parents a sense of control over their child's bladder health.

Table 4.5. Theme 1: Evaluative Findings

Code	Group	Illustrative Quotation
Understanding	Parent	"... they wanted to find out why and how best to help her stay dry throughout the day and see what was going on with her bladder and see if it was holding and retaining enough urine or if it was an overactive bladder."
Recommendations	Provider	"I think if we develop a catheter for them that has measurements on it, that has centimeter markings on it, that might make it easier because it becomes a one-person job if they can hold it up straight."
	Parent	"The learning process... I think it needs to be more hands on rather than video. People tend to learn more as you do it rather than you watching something from it. I know that's been my experience."
	Nursing Staff	"... and there's not like a standard procedure for it. So if there is one standard way, everyone that was doing VUDS was getting the pressures as well as volume, then it'd be a little bit more accurate."
Clinical Utility	Parent	"... it's really an easy and non-invasive way of really learning more about your child's bladder. You know, it is quite simple, and you can gain a lot of information by just doing it."
First Impression	Parent	"At the beginning we knew absolutely nothing about this technique so it was a challenge..."
	Parent	"I think the first time you do it, it's always a little intimidating as a parent."

	Provider	“They’re usually open to doing whatever we recommend. And it’s more so their reaction is ‘How do we do it?’ And they’re just interested in learning about how to do it correctly.”
Home Manometry vs. Urodynamics	Parent	“For the sake of trying to be as accurate as possible, as sterile as possible, I would rather go into the office personally.”
	Parent	“Obviously at home, she’s more comfortable. She is with mom and dad, and it’s something that’s familiar.”
Child Feelings	Parent	“Doesn’t bother him at all.”
Control/Independence	Parent	“It definitely helps because we’re more in-tune, we’re more observant to different aspects of his health that we wouldn’t have been if that weren’t the case.”

Table 4.6. Average Practical and Ease Ratings					
Question	Parent/Caregiver (n=9)	Parent of girls (n=5)	Parent of boys (n=4)	Provider (n=9)	Nursing Staff (n=3)
On a scale from 1 to 5, 1 being very easy and 5 being very difficult, how would you rate the ease of performing home manometry?	2.8	3.5	2	2.3	-
On a scale from 1 to 5, 1 being very practical and 5 being not practical at all, how would you rate the practicability of home manometry?	-	-	-	-	3.7

Theme 2: Maturation/Patient-Specific Characteristics

The next theme covered ideas and discoveries involving home manometry with respect to maturation and patient-specific attributes. Seven relevant codes were identified: experienced vs. non-experienced, practice makes perfect, older vs. younger, child cooperation, self-catheterizing children, girls vs. boys and pathology (Table 4.7).

In general, older patients who have experience performing CIC and/or have done home manometry in the past are more open to performing home manometry. Providers expressed that this technique is more difficult to perform on girls than it is for boys; however, parents of girls

and boys of all ages expressed that they became more comfortable with home manometry the more they practiced it. Although providers believe that younger children may have more difficulty remaining still during the procedure, all parents expressed that their children were cooperative due to the nature of performing regular catheterizations. One mother shared that her toddler would very seldom move around during the procedure, but these were random movements and did not have to do with discomfort with home manometry. In terms of comfort, 2 out of 3 children self-catheterizing children were comfortable performing home manometry with their parents' assistance, and one child was not. Many patients with NGB do not feel any sensation below their hips due to the pathology of their diagnosis. Therefore, comfort was not found to be an issue with home manometry.

Table 4.7. Theme 2: Maturation/Patient-Specific Characteristics

Code	Group	Illustrative Quotation
Experienced vs. Non-Experienced	Provider	"If I just taught someone how to do CIC for the first time, I probably wouldn't teach home manometry on the same day. I think that would be a little overwhelming, but a lot of these patients who are learning home manometry, they've been doing this for years. So, it doesn't seem too much for them"
	Parent	"... like after a couple of times where I got the hang of where it (the urine) was in the catheter... after a couple of times, then that was easy."
Practice makes perfect	Parent	"I mean, if you're catheterizing your child at home, it's quite self-explanatory."
Older vs. younger	Provider	"I think for the younger kids, it's not the process of the measurement, it's how easy it is to catheterize. I think that usually becomes the biggest thing."
Child Cooperation	Parent	"Generally, he was quite still, I think after a while they kind of get to knowing that it's time for the catheter and they stay still."
Self-catheterizing children	Nursing Staff	"All the kids that have come through, they're pretty good about the parents helping them. They feel pretty comfortable. Like they'll self-cath and then the parents just kind of get the ruler for them because the ruler does have to be facing straight up, so it's impossible for them

		to do it while they're sitting. And then the other kids are in wheelchairs, so they do need help..."
Girls vs. boys	Provider	"With females, I think it's a little more difficult, especially if they're babies and trying to kind of get the catheter in and hold it and measure and things like that. I've heard people say that's more difficult."
Pathology	Provider	"... it's spina bifida, and typically those kids, male or female, don't have much sensation in the genital area... And by default, that means usually home manometry, is a little easier too..."

Theme 3: Sources of Error

A variety of difficulties with the home manometry process were identified amongst all participants. This included nuances of technique, uncertainty of accuracy, and the fact that home manometry may be considered a complex procedure (Table 4.8). Every parent had slightly different variations in home manometry technique. However, they all experienced difficulties determining the best, most feasible way to achieve accurate measurements. Some nuances included how to manage multiple things at once, who should do what, and what order of steps to follow. This variation in technique caused confusion amongst individuals as to whether the measurements being obtained were accurate or not. Few parents did not receive clear instructions on the technique and expectations of home manometry. Overall, home manometry is a complex procedure: it requires new equipment, is not standard practice, and presents challenges to those performing it. Because of the complexity of SB in general, home manometry may be seen as an additional chore added on to the list of health care issues to tend to.

Table 4.8. Theme 3: Sources of Error		
Code	Group	Illustrative Quotation
Nuances of Technique	Parent	"It was kind of hard because like so many things, you're using both of your hands to do everything. Your baby's there and then you have to run it like, write it down to remember all these things. I didn't have it as organized as it could be..."

	Nursing Staff	“I think the variables are just too much. Like if mom were to do it on one day and then if the patient’s moving... and mom grabs it (the measurement) when it first hits one number, and then dad does it the next day and he kind of waits to let it settle and then it’s hitting a different number, it’s just too much variables in it.”
Uncertainty of Accuracy	Parent	“‘Am I doing it right? Am I not doing this correctly?’” A lot of second guessing because I’m not a nurse.”
	Parent	“... I’m not like a doctor, and I know that I even reported like the wrong numbers... I’m not a medical practitioner, so I think that they need to be the ones doing this, because it’s easy for us to make those mistakes, not record it right, not understand what it is.”
	Parent	“I mean, I don’t know if I’m being super precise right now, measuring because I’ve got to hold the catheter and I have two hands, so I cannot hold a measure next to it.”
Complex Procedure	Provider	“I feel like more often the response is kind of like, ‘This seems like a lot,’ and that ranges from everybody like babies, parents of babies, to teenagers themselves, and their parents.”

Theme 4: Materials/Technology

Participants discussed materials/technology used during the home manometry process, and their experiences with each one. Thoughts revolving around extension tubing, catheters, urine collection containers, measuring tools, additional materials and accessibility were discussed (Table 4.9). For one, it is difficult to perform home manometry if the catheter is opaque, incompatible with extension tubing, or deviates from the patient’s norm. Most parents opted out of using the urine basin provided by the clinic and used their own collection containers instead. Similarly, nearly half of the parents opted out of using the paper rulers provided by the clinic and used their own, more durable rulers. Only a few parents used other materials in addition to what the clinic provided: this included chux (disposable pads in case of spillage), gloves, and sterile wipes. Although material accessibility was acknowledged amongst almost all clinic staff, only two parents had issues with receiving supplies.

Table 4.9. Theme 4: Materials/Technology		
Code	Group	Illustrative Quotation
Extension Tubing	Parent	“It’s hard to keep it in place. We’ve only used it once or twice. It’s just harder to keep in place and then everything kind of gets tangled a bit.”
	Nursing Staff	“... if their catheters have a bad attach(ment), they’re like, ‘How do you guys want us to do this? If the catheter has a bad attachment. Like we can’t use a ruler to measure the pressure.’”
Catheters	Provider	“And I think that is probably a barrier for parents, is making sure they have the catheters that can be used for it.”
Urine collection containers	Parent	“I thought it (the urine basin) was easy to use. Emptying into the basin is super easy.”
	Parent	“... That was really hard trying not to knock it over, trying to get her to open her legs enough...”
Measuring tools	Nursing Staff	“The ruler is flimsy. It’s just a paper ruler so it’s not too accurate if they don’t place it correctly and hold it up straight.”
	Parent	“It seemed easier for us to get that wooden ruler to help with the measuring, so we got that separate.”
	Parent	“I also recall that the measuring tool they gave me was made out of paper... after it got wet, I just couldn’t use it anymore. So I found that something durable, like a plastic measuring stick is more helpful and is needed.”
Additional Materials	Parent	“I buy the gloves and wipes on my own.”
Accessibility	Provider	“It’s so hard to get supplies, even their normal catheters in the right size, and the right lengths...”

Theme 5: Home Environment/Context

Another area of interest discussed throughout interviews were considerations regarding patient’s home environments and family dynamics (Table 4.10). Home manometry requires two people to complete, not including the child. Most parents emphasized the need for having a second person available, while three parents were able to do home manometry independently because of previous experience with another child, use of alternative materials to eliminate the need for a second person, and simply because no one else was available to help. Home

manometry does not disrupt families’ everyday routine because the kids are already catheterizing. On average, home manometry takes about 5 minutes longer than normal CIC. Parents understand that the process is time consuming, and therefore dedicated time to perform home manometry.

Table 4.10. Theme 5: Home Environment/Context		
Code	Group	Illustrative Quotation
Personnel	Parent	“I noticed that you had to have two people to be able to do this. You needed two pair hands.”
	Parent	“Yes (I tried to do it on my own), and I ended up in tears.”
	Provider	“Home manometry... it’s a two-person job.”
Everyday Routine	Parent	“When we last did it, it did not change the routine in any way because we were already catheterizing him at those intervals.”
	Parent	“I got a plan for it, I got to make sure that there’s that dedicated day every few months where we complete this.”
Time	Parent	“... this test, it’s just time consuming, and it’s not really changing anything else in their day, it’s just taking the time to do it throughout the day.”

Theme 6: Education/Learning Experience

The final theme generated through analysis was Education/Learning Experience. The 7 types of home manometry education discussed were hands-on demonstrations, videos, verbal explanations, pamphlets, additional support, non-physical demonstrations and drawing diagrams (Table 4.111).

Most parents received verbal explanations and pamphlets with printed instructions. Most parents did not express any concerns with these forms of teaching, although almost all participants suggested hands-on demonstrations would be the best method of learning home manometry. Some parents requested to be able to see the video, which was also determined to be another useful resource in teaching home manometry. Providers expressed that patients who receive hands-on demonstrations and are shown the video demonstrate better understanding than

others. Few parents were shown non-physical demonstrations, drawn diagrams of the process, and were offered additional support. All parents were asked to rate their home manometry learning experiences on a scale from 1 to 5, 1 being very good and 5 being very poor (Table 4.12).

Table 4.11. Theme 6: Education/Learning Experience

Code	Group	Illustrative Quotation
Hands-on Demonstration	Nursing Staff	“They prefer we show it to them... and then we do the first reading. Like I said, we help them cath and then take the numbers down for the volume and then record the pressure.”
Video	Provider	“I think they understand it pretty well since we added the videos. I think a video is worth a thousand words, and the fact they can refer to the videos when they’re not in the clinic is super helpful.”
Verbal Explanation	Parent	“... I mean the nurses at CHOC are always good at explaining things and making sure you understand before they let you leave, so you know.
	Parent	“... it’s hard if they’re just kind of trying to explain it to you and you’re not physically seeing it.”
Pamphlet	Parent	“They provide you with... instructions to how it is to be done at home. And your chart that you have to fill in.”
Offering Additional Support	Parent	“... if I had any questions, I would call, and they would answer them. ... And they provided me, you know, if I had any questions, they would answer it.”
Non-physical Demonstration	Parent	“... they used a catheter. They didn’t do anything on my child.”
Drawing Diagrams	Parent	“... he even like drew a picture on the sheet that’s over the table.”

Table 4.12. Average Learning Experience Rating

<i>On a scale from 1 to 5, 1 being very good and 5 being very poor, how would you rate your home manometry learning experience?</i>	
Total (n=9)	2.2
Sex	
Males (n=4)	1.8
Females (n=5)	2.6
Primary Language	
English (n=7)	1.9
Spanish (n=2)	3.5

DISCUSSION

Through Grounded Theory Methods and the incorporation of data and methodological triangulation, this study revealed that there are numerous components that go into home manometry that must be accounted for when setting expectations for patients and their families. Stakeholder engagement allowed us to explore home manometry (HM) perspectives of parents/caregivers, providers, and nursing staff. There were no major differences between participants with different primary languages, race/ethnicity, or insurance statuses. However, we did identify few differences between age, sex, and experience levels.

Previous literature has shown that engaging patient and provider perspectives may be a useful strategy to inform curriculum development.⁴² Through stakeholder engagement, we were able to understand perceptions of all important individuals to improve an existing measure. There is nothing existing in the literature that evaluates experiences with home bladder manometry techniques. However, the novelty of qualitative research has allowed researchers to explore quality of life⁴³, address challenges⁴⁴, and assess patient needs for CIC alone.⁴⁵

A qualitative study on adult patient experiences with self-catheterization found that communication between nurses and patients helped ease the acceptance and normalization of CIC⁴⁶. This is one factor that may be considered when teaching patients HM for the first time. A subsequent study found that quality of life for patients who perform CIC may be affected by factors such as sex, type of catheter, comorbidities, and technical difficulties.⁴³ This is similar to our findings that patient-specific characteristics, materials, and sources of error are important considerations in HM. Not only are these themes evident for home manometry, but they were found to affect quality of life in adult CIC patients as well.

Specifically in the pediatric population, a recent study showed that caregivers of NGB children (76% of which had a primary diagnosis of spina bifida) face challenges with catheterizing techniques and material accessibility.⁴⁴ Although home manometry requires additive steps and materials, this technique does not add much to regular catheterization. Caregivers face similar challenges with catheterization technique and accessing materials for CIC itself.⁴⁴

Unique Insights of the Study

Although some challenges and factors that affect home manometry are similar to those identified with CIC, we still discovered several unique insights through this study. For one, home manometry is a unique technique with no prior data evaluating the process. Additionally, there are various differences between CIC and home manometry. CIC is a technique that must be done by NGB patients. Because they are unable to voluntarily void, catheterization is the only method of urinary drainage. There are additional requirements for HM on top of what is typically needed for CIC. While CIC can be done by the patient themselves, HM cannot. HM requires additional personnel to handle the materials and record measurements. According to parents, HM takes an average of 5 minutes longer than regular catheterizations. Finally, different materials are used for both techniques. CIC only requires a catheter, whereas HM requires a ruler and urine collection container to take measurements. Challenges with these factors have been identified through this study.

Moreover, patients were cooperative when implementing home manometry into their CIC regimen. Parents shared that their children were compliant when asked to sit still during this procedure. Finally, our findings confirmed the providers' assumptions on how well parents understand the importance of HM. Providers identified general barriers that families face,

whereas nursing staff identified more specific challenges with regards to technique and accuracy. Nonetheless, all challenges were discussed more in-depth through the parent interviews.

Emergent Concepts

Two emergent concepts became evident: improvement strategies and the need for standardization. Regardless of initial impressions and overall understanding, parents seemed to have issues regarding the same elements of HM. In addition, important considerations must be made when setting expectations for HM. For the most part, provider assumptions of parent thoughts and experiences were accurate. Interestingly, nurses did not have the same attitudes towards home manometry as the providers did. Nonetheless, we have collected important data that will help us understand home manometry and improve the process moving forward.

Overall Perceptions of Home Manometry

Providers' perceptions on how well families understand the concept and importance of home manometry were proven to be true during parent interviews. Understanding seems dependent upon how the providers explain HM to the families. One provider said she uses layman's terms to ensure the families understand the general purpose of the procedure. While all providers and most parents agreed that HM was a good way to monitor NGB children's health and that it added value to these children's overall care, the nursing staff did not. Nursing staff identified challenges that families face with HM that providers were not aware of. Additionally, this point of view may introduce some bias because at the time of the focus group, the nursing staff were still new to the clinic and only had 1 to 6 months of experience with HM. While it is important to address the challenges identified by nursing staff, it is also important that the

providers ensure their staff have all the knowledge regarding home manometry and that the overall importance is understood.

When first introduced to HM, parents viewed the procedure as “difficult” and “tricky.” This confusion explains why providers are asked further questions about the purpose of HM and procedural specifics on how it should be performed. Families require clear and concise information and instructions regarding the specifics of a novel procedure, especially if they have never performed it before.

Overall, patient age, sex, and experience level did not affect the parents’ evaluative perceptions of HM. Most parents and providers acknowledged to some degree that HM is a simple bladder screening tool that helps providers determine bladder safety and manage these children in a conservative fashion. In general, children feel indifferent towards the procedure, and are more comfortable doing HM than they are UDS. Home manometry has given parents a sense of control of their child’s bladder health. The ability to measure bladder pressures and volumes at home not only helps the provider but gives the families independence in monitoring their own child.

Characteristics to consider when setting expectations

When setting expectations for home manometry, providers must consider each patient’s individual characteristics and home environments. For one, patients who are older and more experienced are more open to and capable of performing home manometry. Although not interchangeable, age and experience do seem to go together. Children who regularly perform CIC or have done home manometry in the past are typically older and more experienced with catheterization in general.

Regardless of the initial reactions previously mentioned, parents of children of all ages shared that home manometry gets easier the more they practice it. One provider described this as an “evolution of reactions,” and this has proven to be true throughout the interviews. Parents typically agree with what the provider is asking them to do; however, once they go home and attempt to execute HM themselves, they’re presented with many difficulties that they could not have foreseen in the clinic.

Providers also believe that girls have a more difficult time with HM when compared to boys. This assumption proves to be accurate as well. The average ease rating was a 3.5 for parents of girls, and a 2 for parents of boys. Providers attribute this to their pathology: girls have a more difficult time catheterizing in general because of their anatomy. Additionally, 2 (40%) girls needed different catheters to perform HM. All girls required extension tubing. Although only 3 girls used the extenders, one mom who did not use it mentioned that it was too difficult to use while the other did not receive it at all. These additional materials deviate from these kids’ norm and may be the cause of difficulty amongst girls. This could be overcome by providing girls with the longer male catheters for the purpose of performing home manometry.

Nonetheless, all parents have noted that their children are cooperative with HM. This may be because catheterizations are already part of their regular bladder management regimen. Practically, children cannot help during this procedure because any movement may increase their abdominal pressure and cause a discrepancy in the measurements. Therefore, children aren’t asked to do any additional work aside from taking a few more minutes out of the day to lay there during the procedure.

Aside from patient-specific attributes, home context is another factor that contributes to parents’ experiences with and abilities to execute HM. This technique is meant to be performed

by 2 people as per provider instructions, which was acknowledged by more than half of the parents. Whether it be the various materials that need to be held, or trying to keep the child still, home manometry typically requires the help of two people. All but 3 parents expressed concerns with this requirement: sometimes both parents are not always available at the time of catheterization to help with home manometry measurements. There are also single parents who do not have additional hands at home to help. Availability of personnel is important to consider when putting a requirement in place because not everyone may have the means to execute this.

The final home attributes are everyday routine and time, which were not an issue for parents. According to parents, HM takes about 5 minutes longer than regular catheterization. This need for extra time was not an issue for parents because, as previously mentioned, these kids are already catheterizing. Parents also shared that they have designated days and/or times that they do home manometry. Provider confirmation that parents can set aside extra time and devise a plan for HM may help increase compliance by holding the family accountable to it.

Improvement Strategies

Interview and focus group data have shown that strategies with regards to materials and education should be considered to improve the overall home manometry process. Experiences shared by participants in all three groups helped to identify parts of the process that were difficult. Additional suggestions on ways to improve were welcomed.

When asked for recommendations, the most common suggestions for the education process were to offer hands-on demonstrations, show the videos during teaching, and provide clear and concise instructions on the purpose of HM. Providers have expressed that families who receive hands-on teaching demonstrate a higher understanding of HM and are more likely to

produce accurate results. Interestingly, the 3 children that received this form of teaching were 4 years old and patients of Urologist 1. Although this sample size is too small to draw any conclusions, it is important to note that Urologist 1 is the clinician who developed home manometry.

Aside from a hands-on demonstration, parents suggested that an instructional video would be a helpful form of education because it helps to visualize what is expected. One parent expressed that she received an instructional video for peristeen enemas, and it helped that she was able to refer to this once she left the clinic. Prior to this study, the CHOC Urology Clinic already had these teaching methods in place. Parents/caregivers participating in this study may not have received these methods because their child was instructed prior to this implementation.

Finally, providers and nursing staff should provide families with clear and concise instructions upon initial presentation. Although all parents demonstrated a reasonable amount of understanding, more than half of them expressed concerns about receiving unclear instructions. These confusions were with regards to expectations, technique, and overall importance. Two parents were not told how long the provider wanted them to do the procedure. These families ended up doing home manometry for a few months as opposed to a few days. The remaining parents didn't know when to take the pressure measurement after catheter insertion, what additional information to record, and what the main importance of the procedure was. It is important for providers and nursing staff to take their time explaining the importance and teaching families how to do home manometry in order to achieve more accurate measurements and a higher compliance rate.

In terms of materials, amongst all interviews, participants had at least one suggestion for each material provided: the most common being catheters, extension tubing, and the measuring

tool. Catheters vary in length, diameter, lubrication, and opacity. The type of catheter that each patient receives is dependent upon on their age, sex, and size. While some patients' regular CIC catheters are compatible with home manometry requirements (i.e., are long and transparent enough), others are not. Therefore, these children require new equipment for HM. This exchange of catheters may be an issue for some families who are already accustomed to their regular catheter. Not only does this deviate from their norm, but additional materials are used that may complicate the technique even further.

Extension tubing is another material that most parents required for home manometry. While one parent of a boy did not have any issues with this, all five parents of girls did. Two parents said the extender did not attach to the catheter well, two were not offered the extension tubing, and one did not attempt to use it because it was too difficult. This seems to be an issue mainly for females, as most are used to performing CIC with short catheters. When asked to do HM, most required a catheter that deviated from their norm (60%) and were required to use extension tubing, which did not always attach properly. This can make HM frustrating – not only are they using different materials, but the materials are incompatible with one another and are difficult to maneuver particularly if they were accustomed to using shorter catheters. This introduces another level of barriers that may make the process more difficult.

Moving forward, the paper ruler provided by the clinic seemed to be an issue for about half of the parents. Parents mentioned that this tool is flimsy, difficult to hold up, and may get wet if there is urine spillage. One nurse and one provider agreed that the paper ruler may be difficult to use and can produce inaccurate measurements. Four parents opted out of using the paper ruler and used plastic or wooden ones instead. One parent mentioned that using a more durable ruler eliminated the need for a second person altogether.

Some providers expressed issues with material accessibility. Although this was only mentioned by two parents, this is a significant factor that may affect a family's ability to execute the process. Providers and nursing staff should confirm that all materials are available prior to instructing families to perform home manometry.

Need for Standardization

When considering all feedback gained from this study, we found that there is a need for standardization of the home manometry process. Like the improvement strategies, this comes in two directions: materials and education. Although a generalizable standardization of materials may not be practical due to variations in each patient's individual characteristics, it may be beneficial to find or develop catheters that come in various sizes that works for home manometry. Ideally, this would be a catheter that is transparent, has centimeter markings on it, and attaches well to the extension tubing. This type of catheter may help eliminate the need for extension tubing, a ruler, and potentially the need for an extra person. Other suggestions for material improvements would be a durable ruler and universal extension tube that can attach to all catheters.

The education process requires standardization as well. Moving forward, nursing staff should continue doing hands-on demonstrations and sharing the instructional video during HM teaching visits. A standardized technique with step-by-step instructions would be beneficial to families. This, in conjunction with visual hands-on demonstrations, may help patients and their families reproduce similar results at home. Finally, providers should standardize the expectations of HM. Interview data shows that expectations vary by provider and may not be clear to the nursing staff. It is important that all clinic staff are on the same page with regards to HM

expectations, and that families thoroughly understand these expectations before leaving the clinic.

Conclusion

Monitoring bladder pressures and volumes has become an area of interest for urologists caring for pediatric NGB patients.^{7,8,20,21,23,24} Although all vary in technique, equipment, and comparisons to UDS parameters, we found that stakeholders involved in our home bladder manometry process believe in its clinical utility. Parents/caregivers have sufficient understanding of the importance and can execute the procedure proficiently with practice. Additionally, most patients do not experience any discomforts and are cooperative during HM. Adjustments with materials and the education process would help to eliminate any sources of error and improve families' overall experiences with home manometry.

Limitations

Although all important stakeholders were enrolled, there is a limitation of external validity, as responses from this study are only representative of the CHOC NGB-SB population. Moreover, the data obtained were solely from the parent, provider, and nursing staff perspectives. Although patients do not perform the procedure themselves, it may be worthwhile to interview patients as they may have different perspectives on the home manometry process. Additionally, although Spanish parents were interviewed, we did not find any differences between English and Spanish participants. A sample of two Spanish speaking parents may be too small to draw any conclusions, as there are cultural differences and barriers that the Latinx population faces. Hosting additional interviews with Spanish participants may help capture any additional barriers they face, if existent among the NGB population. Finally, although we

initially intended to host focus group discussions for the parent/caregiver group, we were only able to host key informant interviews. Focus groups may have produced different responses as participants can discuss amongst each other and bounce ideas off one another. Nonetheless, we still received insightful information through the interviews.

Future Directions

The next step to improving home manometry and its related process is to hold a meeting with providers, nursing staff, and researchers to discuss the future of home manometry. Clinic staff should implement strategies to address issues with the current process identified through this study. Additionally, data from this study provides foundation for survey development and dissemination (Phase II). Survey questions may be generated using themes and codes identified during the interview and focus group process. A comprehensive item refinement process may be used to consolidate the measure. Once simplified, the measure will be pilot tested for in-clinic use, construct validity will be assessed, and a factor analysis performed to assess variability.

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Appendix

Appendix A. Final IRB Study Protocol

Title

IRB #: 2111181

A Study to Understand the Experiences and Barriers of Home Bladder Manometry for Pediatric Patients with Neurogenic Bladder

Location

Children's Hospital of Orange County

Principle Investigator

Antoine Khoury, MD

Division of Pediatric Urology

Protocol Version Date

February 7, 2022

Background and Significance

Neurogenic bladder is a condition most commonly associated with spinal abnormalities and nervous system damage. If left untreated and unmonitored, patients with neurogenic bladder (NGB) may experience elevated bladder pressures and renal deterioration (McGuire et al 1981). The most recent European Association of Urology and European Society of Pediatric Urology (EAU-ESPU) guidelines for managing NGB suggests a conservative approach (Stein et al 2020). The purpose of a conservative approach is to monitor and manage bladder function to avoid renal deterioration. Treatments under this approach include anticholinergic use, clean intermittent catheterization (CIC) and various diagnostic tests at outpatient visits, one of which is urodynamics (UDS).

UDS is the gold standard test used for assessing bladder volumes and pressures (Watanabe et al 1996). This procedure requires equipment to reproduce voiding patterns and measure how well the bladder, urethra, and sphincter muscles can store and release urine. Unlike home blood pressure testing, to date, there is no validated alternative method to monitoring bladder pressures and volumes at home.

However, the Urology Division at CHOC designed a bladder management technique that was introduced in and has been used in the clinic since 2008. This technique allows patients and their caregivers to perform home bladder manometry by keeping a home pressure/volume diary (PVD). Home bladder manometry is a method of measuring bladder volumes and pressures at home for NGB patients who routinely perform CIC.

Home PVD does not alter these patients' current bladder management regimens as measurements are recorded at the time of their regularly scheduled catheterizations. This process requires a ruler-based manometer to measure pressure, a urine basin to measure volume, and a pen and paper to record the measurements ([Video 1](#)). Our previous study of 30 pediatric patients showed that low PVD pressures at maximal CIC volumes were strongly correlated with UDS parameters indicating normal pressures, while high PVD pressures correlated with UDS pressures indicating the need for more aggressive bladder management (Hidas et al 2017).

Although home bladder manometry is not meant to serve as an alternative to UDS, Hidas *et al* have shown it to be a useful tool in monitoring patients' bladders and identifying patients who may require additional UDS testing. Because home bladder manometry is a novel method of recording bladder measurements, our division currently only has anecdotal evidence of how well-accepted it is with NGB patients and their caregivers.

We propose a cross-sectional, mixed-methods study to qualitatively evaluate the experiences and barriers that parents/caregivers of NGB patients have with home bladder manometry. This two-phase study is designed to comprehensively collect data describing attitudes surrounding home bladder manometry. The Grounded Theory Process will be utilized to conceptualize the survey-making process and help guide us to final survey generation (Chun et al 2019). Phase I consists of focus group discussions to generate themes through integration of feedback from families, caregivers, and clinic staff involved in these patients' care. In addition to literature reviews and clinical knowledge, data from these discussions will be analyzed and organized to identify themes that will be included in the final survey. Additional feedback from focus group participants will be integrated to help determine which items should be included on final survey. Phase II involves survey generation, administration, and analysis. The survey will allow us to improve their experiences, provide families with additional resources, and present overall feasibility of performing home bladder manometry.

Research Question

The primary research question is how do neurogenic bladder patient’s caregivers perceive their experiences performing home bladder manometry and what barriers do they face when it comes to performing appropriate care?

Objectives/Aims

To qualitatively understand caregivers’ experiences with performing home bladder manometry and to determine what barriers they face to provide the additional resources and care they may need to improve their ability to record these measurements at home.

Methods

Outcomes

Primary outcomes

- Phase I
 - Theme generation from focus group discussions
- Phase II
 - Parent/caregiver survey experience scores on performing home bladder manometry
 - Parent/caregiver survey needs assessment scores

Selection of Participants

	<u>Phase I: Focus Group</u>	<u>Phase II: Caregiver Survey</u>	<u>Phase II: Retrospective Chart Review</u>
<u>Inclusion Criteria</u>	<p><i>Must fit one of the two following criteria–</i></p> <p>1. Parent/caregiver of a patient aged 1-18 years who has neurogenic bladder</p> <ul style="list-style-type: none"> • Must be at least 18 years old to participate • Children of eligible participants must: <ul style="list-style-type: none"> ○ Have a neurogenic bladder diagnosis secondary to spina bifida, tethered cord, or a spinal injury ○ Perform CIC (clean intermittent catheterization) as a standard of care ○ Have performed home bladder manometry at least once in the past <p>2. Clinic staff directly involved in these patients’ care</p> <ul style="list-style-type: none"> • Nurses, nurse practitioners, urology fellows, pediatric urologists 	<p>Parent/caregiver of a patient aged 1-18 years who has neurogenic bladder</p> <ul style="list-style-type: none"> • Must be at least 18 years old to participate • Children of eligible participants must: <ul style="list-style-type: none"> ○ Have a neurogenic bladder diagnosis secondary to spina bifida, tethered cord, or a spinal injury ○ Perform CIC (clean intermittent catheterization) as a standard of care ○ Have performed home bladder manometry at least once in the past 	<p>Children with a neurogenic bladder diagnosis secondary to spina bifida, tethered cord, or spinal injury</p> <ul style="list-style-type: none"> • Must be 1-18 years of age • Must perform CIC (clean intermittent catheterization) as a standard of care • The child (or their parent/caregiver) must have performed home bladder manometry at least once in the past
<u>Exclusion Criteria</u>	<ul style="list-style-type: none"> • Pediatric patients <18 years of age • Parents/caregivers <18 years of age • Parents/caregivers of patients who: <ul style="list-style-type: none"> ○ Do not have neurogenic bladder ○ Have never performed home bladder manometry ○ Have neurogenic bladder secondary to diagnoses other than 	<ul style="list-style-type: none"> • Pediatric patients <18 years of age • Parents/caregivers <18 years of age • Parents/caregivers of patients who: <ul style="list-style-type: none"> ○ Do not have neurogenic bladder 	<p>Pediatric patients who:</p> <ul style="list-style-type: none"> • Do not have neurogenic bladder • Have never performed home bladder manometry • Have neurogenic bladder secondary to diagnoses other than spina bifida, tethered cord, or a spinal injury

	spina bifida, tethered cord, or a spinal injury ○ Have non-neurogenic neurogenic bladder ● Clinic staff who are not directly involved in these patients' care	○ Have never performed home bladder manometry ○ Have neurogenic bladder secondary to diagnoses other than spina bifida, tethered cord, or a spinal injury ○ Have non-neurogenic neurogenic bladder	● Have non-neurogenic neurogenic bladder
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Type of Study and Date Range of Data

This is a cross-sectional, patient-centered survey study design. The Grounded Theory Process will be utilized as a stepwise approach for final survey generation and will require preliminary focus group data. Phase I will consist of semi-structured focus group discussions involving parents/caregivers and clinic staff. Discussions will be conducted to understand general thoughts and experiences surrounding home bladder manometry. Participants will be identified via physician and clinic staff recommendation. Data from these focus groups will be analyzed to identify potential themes that may be included in the final survey. Phase II consists of final survey generation and administration. Generation of the final survey will involve input from the research team and individuals who participated in the focus group discussions in Phase I. Once the final survey is generated, it will be administered to the parents/caregivers of patients who fit the inclusion criteria. Eligible survey participants will be identified via Cerner by screening for Urology or Spina Bifida visits with available home manometry data and by performing scheduling checks for patients undergoing Urodynamics after December 15, 2021. Any participants identified as eligible going forward will be added as the study progresses.

Total number of Sites/Subjects

This will be a single-institutional study performed within CHOC. We plan to collect data from 30 participants for focus groups (Phase I), and 45 participants for the survey portion (Phase II). However, for the purposes of medical record review, data on up to 100 patients may be reviewed to identify eligible participants for the focus groups and the survey.

Study timelines

We anticipate collected data for this study over a period of three years.

Data Collection and Management

Informed Consent

- a. PHASE I: Informed consent will be required for focus group discussions. Prior to conducting focus groups, a short excerpt will be read to participants via telephone call explaining the purpose of the discussion. Participants will be made aware that the focus group will be recorded, however participation is completely voluntary. Participants have the opportunity to ask questions or terminate their participation in the discussion at any point in time. Electronic consent will then be obtained via REDCap Web prior to focus group commencement. A sample paper informed consent that will be replicated on REDCap web has been attached for review.

- b. PHASE II: We request waiver of formal informed consent for the home bladder manometry survey. Consent for survey participation will be acknowledged prior to administration of the survey. Parents/caregivers will be contacted or approached at time of their child's regularly scheduled appointment at CHOC if they meet eligibility criteria. In lieu of formal written consent, participants will be provided with a short narrative preceding the survey, which provides an overview of the purpose of the survey. Participants will be made aware that completion of the survey is voluntary and that they can ask any questions. If parents/caregivers agree to complete the survey, it will be facilitated electronically through REDCap Web. The language of the informal consent process for the survey will be submit as an amendment prior to survey commencement to keep with the study record.

Data Collection

- a. This is a mixed-methods study requiring three parts: focus group data, survey data, and medical record data.
- b. A single REDCap Web database will be stored on CHOC's secured server with three different instruments:
 - i. Focus group informed consent documents (PHASE I)
 - ii. Survey data (PHASE II)
 - iii. Medical record data corresponding to each survey submission (PHASE II).
- c. PHASE I: Focus group data collected for purposes of this study will be collected and recorded via Zoom video conferences. A sample of the questions asked during the focus group is attached with this application. These questions are organized to cover all themes we deem important but focus group participants may provide their own feedback outside of these questions.
- d. PHASE II: A REDCap Web survey data collection tool will be stored at: <https://redcapweb.choc.org>. Surveys will be administered and submitted directly via a REDCap Web link. The participant's email and their child's date of birth will be entered by each participant prior to survey commencement and submitted on the survey. This is the minimum amount of data that we need to be able to link survey answers to the corresponding patient. The data may be viewed in the REDCap data collection tool. Since the survey has not yet been created, it is not attached with this application. Once created from the focus group discussions, we will submit the survey as an amendment to keep with the study record.
- e. PHASE II: Demographic and clinical data on the children (i.e., patients) of the parents/caregivers will be extracted from an existing clinical database that already resides in REDCap on CHOC's server (IRB # 180209). If there are any additional gaps to fill in, electronic medical records in Cerner will be utilized to collect this information. All information collected from the existing database and Cerner will be stored in a third instrument under the same project on REDCap Web. This information will only be collected once the survey has been completed and submitted via REDCap Web. This information will be used to define the study population based on demographics and clinical characteristics so that this information can be aggregated and reported as a part of future publication. A data collection sheet is attached with this application.
- f. A separate subject ID key will be housed on the CHOC server for purposes of data integrity during the data collection process and destroyed upon project completion.

Data Management and Security

- a. PHASE I: Focus group recordings and transcripts will be stored on the CHOC server and only designated team members will be provided with access to the files. A waiver of

signed consent will be obtained for both the audio/video recording process and the focus group participation.

- b. PHASE I: Focus group waivers of signed consent forms will be submitted and collected directly via a REDCap Web link. These forms will be saved in a single instrument on REDCap Web. Only designated team members will be provided with access to the consent forms.
- c. PHASE I: Audio and video recordings will be transcribed upon focus group completion and erased at the end of the study.
- d. PHASE II: A CHOC REDCap Web database (<http://redcapweb.choc.org>) will be used to facilitate survey data collection. This will be the second REDCap Web instrument developed for this study. The participant's email address and their child's date of birth will be entered by the participant on the survey form and submitted via REDCap Web along with their survey answers. This is the minimum amount of identifiable data that we will need to be able to link survey answers to demographic and clinical information. Only designated study team members will be provided with access to the database.
- e. PHASE II: Clinical and demographic data collected from the medical records will be stored on an Excel file on the CHOC server. Data will be de-identified as no PHI will be collected in this database. Only designated team members will be provided with access to this file.
- f. PHASE II: Study personnel will be responsible for linking survey submissions to the correct patient's clinical data. If the survey is administered in-person, the MRN of the patient whose parent/caregiver completes the survey will already be saved in a separate key. Once the corresponding survey has been received, the survey ID will immediately be linked to the patient in the key. If the survey is administered via email, the patient whose parent/caregiver completes the survey will be identified by the email and/or date of birth provided in the survey. Once identified, the patient will be assigned a study ID number in the separate key and linked to the corresponding survey ID. This key will be stored in an Excel file on CHOC's server and will only be accessible to designated team members.
- g. A study ID will be assigned to identify subjects in REDCap web. A study ID will be assigned to link surveys to clinical data. The subject identifier key will be kept in a separate Excel file on CHOC's server with password protection that links the study ID to the medical record number, name of the patient, date of birth, and survey responses.
- h. All data analysis files will be stored on the CHOC server and only designated study personnel will be provided with access to analyses.

Risks and Benefits

There is no direct benefit to participating in this research. However, the knowledge gained may be used to help improve home bladder manometry care for future patients. There is minimal risk to participating in this study. The main risk is the loss of confidentiality of personal self-reported health information. Study staff will comply with applicable laws and policies to best protect the subject's information. Risk will be mitigated by the secure data management plan outlined above.

Statistical Considerations

1. Statistical Software
 - a. PHASE I:
 - i. Qualitative analysis of focus group discussions will be performed using NVivo software.
 - b. PHASE II:

- i. Statistical tests will be conducted using SPSS Statistics 28.
- 2. Power Calculation
 - a. This is a qualitative study that will be used to analyze and understand experiences that a cohort of parents/caregivers within our clinic have surrounding a home bladder monitoring technique. We estimate that a sample size of 45 survey participants will be sufficient to analyze the outcomes we intend to study.
- 3. Primary Outcomes
 - a. PHASE I: Focus Group Discussions
 - i. Identify common themes and potential questions for the final survey
 - ii. Understand the relationship between different descriptions that individuals may have
 - b. PHASE II: Final Survey
 - i. Parent/caregiver experience scores on performing home bladder manometry
 - ii. Parent/caregiver needs assessment scores
- 4. Statistical Analysis
 - a. PHASE I: Focus Group Discussions (NVivo Software)
 - i. Focus Group recordings and audio files will be transcribed into text
 - ii. Relationships between words, phrases and expressions will be used to generate potential themes to be used as final survey items
 - iii. Diagrams of theories and concepts will be created to visualize and understand the relationship between potential themes
 - b. PHASE II: Final Survey Analysis (SPSS Statistics)
 - c. Survey scores will be analyzed and represented using means and standard distribution.
 - d. Dimensionality and clustering of the items included in the survey will be assessed using Factor Analysis.
 - e. Cronbach's alpha will be used to assess internal reliability.
 - f. Construct validity will be tested to ensure that our survey contents are testing what they intend to.
 - g. Sub-group analysis
 - i. We will also analyze survey findings based on age groups, duration of CIC use, severity of neurogenic bladder, and other clinical variables.

Appendix B. Final Questioning Routes

Home Manometry Parent/Guardian Interview Questioning Route

(Flesch-Kincaid Readability: 5.5)

Thank you again for being here today. My name is Amanda Macaraeg and I have been working with the CHOC Urology Research group for the past 4.5 years. I am here today with ____, a parent of one of our kids here at CHOC, and we are going to be discussion home manometry, or the home bladder pressure test.

Introduction Question (1)

1. Think back to the first time the doctor asked you to do home bladder manometry. Again, home manometry is the process of recording your bladder pressures and volumes at home. Why do you think they asked you to do this?
 - a. I know it is something your provider asks you to do. Do you feel like you understand the importance of home manometry?
 - i. Please explain
 - ii. In your own words, can you explain why you think it is important?

Transition Question (1)

2. Try to recall the last time you and your child performed home manometry. What were your first impressions when first doing this?

Key Questions (4-6)

3. Do you think home manometry is a good way to monitor your child's health? Please explain your answer.
 - a. To what extent were the measurements helpful or not helpful in understanding your child's health?
4. What was the home manometry learning process like for you?
 - a. What equipment and materials do you use? Explain your accessibility to these materials.
 - b. How would you describe your experience using these materials? Was anything particularly easy or difficult for any specific item?
 - i. (Things for moderators to keep in mind: Catheters, long vs short, extension tubing, ruler type, tape measure or heard ruler... would a catheter with measurement markings be helpful?)
 - c. Do you use the same catheter for both CIC and home manometry?
 - d. How were you taught the process (in-clinic instructions from nurses, pamphlets, video)? Which helped you the most?
 - e. POLL: How would you rate your home manometry learning experience? 1 being very good and 5 being very poor (5-point scale)
5. Think about your experiences with measuring and recording bladder pressures and volumes at home. How would you describe your overall experience with this process?

- a. Is any part of the process particularly easy? Is any part particularly difficult?
 - b. CIC time vs. Home manometry time
 - c. POLL: On a scale from 1-5, 1 being very easy and 5 being very difficult, how would you rate the ease of performing home manometry?
 - d. Would you recommend home manometry to other parents who have children with neurogenic bladder?
6. How would you compare your overall experiences with video urodynamics (VUDS) (which requires coming into the office) and home manometry (which is performed at home)?
 - a. What comforts and discomforts does your child experience with both procedures? Compare the two.
 7. What is your child's comfort level with performing home manometry?
 - a. For those of you with children who can self-catheterize when performing clean intermittent catheterization, how do they feel about performing home manometry with your help?
 - b. How cooperative is your child when performing home manometry?
 - c. Are you able to keep your child still during this process? Does this differ from their usual CIC method?
 8. What feelings does your child have towards performing home manometry?
 - a. What are some specific verbal or non-verbal cues that your child has expressed?
 - b. Is your child any different because he/she was asked to do home manometry?
 9. Is your life any different because you have been asked to perform this? Is your child's life any different because they perform this? If so, how?
 - a. How does performing home manometry fit into your everyday routine?
 - b. How does it fit into your child's everyday routine? Has your child expressed any complaints needing to perform home manometry with regards to school, chores, physical activities, etc.?

Ending Questions (1-2)

10. Given all the information you have shared with us today, do you think home manometry adds value to your child's overall care? Please explain your thoughts.
11. We value your thoughts and feelings and want you to help us evaluate this process. We want to know how to improve this process for you and your child and the differences that it could make to other children and families. Is there anything that we missed during our discussion that you would like to share with me?

Home Manometry Provider Interview Questioning Route

(Flesch-Kincaid Readability: 5.7)

Opening Question (1)

1. Tell us your name and how long you've been at CHOC

Introduction/Transition Question (1)

2. Try to recall the last time you instructed a family to perform home manometry. What are the typical reactions you receive when introducing home manometry for the first time?
 - a. Can you explain more?
 - b. Have you had any other types of interactions?
 - c. Does everyone agree to it? Do some refuse?

Key Questions (4-6)

3. Do you think home manometry is a good way to monitor neurogenic bladder patients' health? Please explain your answer.
 - a. To what extent are the measurements helpful or not helpful in understanding these children's' health?
 - b. What sort of impact do you think this will have?
 - c. What would you need to change in order to accomplish this?
4. What are your impressions on how well the families understand home manometry?
 - a. Do they ask any questions?
 - b. Do you think they understand the importance
 - c. Any verbal/non-verbal cues they show to express this
5. From the times you've spoken with families, how physically comfortable do the patients seem with home manometry?
 - a. Differences with age groups or boys vs. girls?
 - b. For children who can self-catheterize when performing clean intermittent catheterization, how do they feel about performing home manometry with others' help?
 - c. How cooperative are the children when performing home manometry?
 - i. Are parents able to keep the child still? Fussy?
6. Think about when families come in for follow-up visits after being instructed to perform home manometry. What is some of the feedback you received from them?
 - a. What are some things that seemed easy for them? Did anything seem particularly difficult?
 - b. How compliant are families with completing home manometry and providing the measurements to us?
 - i. What are some reasons parents don't bring in forms?
 - c. POLL: On a scale from 1-5, 1 being very easy to do and 5 being very difficult, how would you rate the ease of performing home manometry?
 - i. Do you think this is practical for people to do?

7. Still thinking about your interactions with the patients and their families, have mentioned anything specifically encouraging/discouraging about the process?
 - a. Any feedback with regards to the teaching process?
 - b. Any particular issues with accessing supplies and the supplies provided to them
 - c. Barriers to actually getting measurements when doing CIC?
 - d. From your conversations with families, does performing home manometry fit into their everyday routines?
 - e. Have parents/patients expressed any complaints needing to perform home manometry with regards to their regular daily schedules (school, chores, physical activities, etc.)?

8. In what ways can we improve home manometry or its related experience? (Suggestions)
 - a. Please tell me more
 - b. Please give me an example
 - c. Please help me understand

Ending Questions (1-2)

9. Given all the information you have shared with me today, do you think home manometry adds value to these children's overall care? Please explain your thoughts.
10. We value your thoughts and feelings and want you to help us evaluate this process. We want to know how to improve home manometry for children and families. Is there anything else that you'd like to share with me that we may have missed during our discussion?

Home Manometry Nursing Staff Interview Questioning Route

(Flesch-Kincaid Readability: 6.1)

Opening Question (1)

1. Tell us your name and how long you've been at CHOC

Introduction/Transition Question (1)

2. Try to recall the last time you taught a family how to perform home manometry. What are the typical reactions you receive when teaching families how to perform home manometry for the first time?
 - a. Are there differences between age groups? Boys vs. girls? Race/ethnicities?

Key Questions (4-6)

3. Do you think home manometry is a good way to monitor neurogenic bladder patients' health? Please explain your answer.
 - a. To what extent were the measurements helpful or not helpful in understanding these children's' health?
4. How would you describe the teaching process?
3min/person – 15min
 - a. Is there anything particularly easy or difficult for you during the teaching process?
 - b. From the parent and patient perspective, which part of the learning process seems easiest for patients? Which part do families struggle with?
 - c. What equipment and materials do patients use? How accessible are these materials for the patients in the CHOC Urology clinic? What equipment do patients tend to have difficulty accessing?
 - i. (Things for moderators to keep in mind: Catheters, long vs short, extension tubing, ruler type, tape measure or heard ruler... would a catheter with measurement markings be helpful?)
 - d. Which learning process seems to help patients the most (in-clinic instructions from nurses, pamphlets, video)? What reactions do you get?
 - i. Differences between boys/girls, age groups, race/ethnicities
5. From your experiences and knowledge, how comfortable do the patients seem while learning and performing home manometry in the office?
 - a. For children who can self-catheterize when performing clean intermittent catheterization, how do they feel about performing home manometry with others' help?
 - b. How cooperative are the children when performing home manometry?
 - i. Are parents able to keep the child still? Are you able to keep the child still during teaching?
6. Think about when families come in for Urodynamics appointments after being instructed to perform home manometry. How would you describe their satisfaction with this process?
 - a. What is some of the feedback you received from them? What are some things that seemed easy for them? Did anything seem particularly difficult?

- b. POLL: On a scale from 1-5, 1 being very practical and 5 being not practical at all, how would you rate the practicability of home manometry?
7. What feelings do children have towards performing home manometry?
- a. What are some specific verbal or non-verbal cues that patients have expressed? What are some things that parents have shared with you after doing home manometry?
8. Are your interactions with these families any different because of your experiences with teaching them home manometry? Do patients or their families' lives seem any different because they have to perform home manometry?
- 2min/person – 10min*
- a. From your conversations with families, does performing home manometry fit into their everyday routines?
 - b. Have parents/patients expressed any complaints needing to perform home manometry with regards to school, chores, physical activities, etc.?

Ending Questions (1-2)

9. Given all the information you have shared with us today, do you think home manometry adds value to these children's overall care? Please explain your thoughts.
10. We value your thoughts and feelings and want you to help us evaluate this process. We want to know how to improve this process for you and your child and the differences that it could make to other children and families. Is there anything that we missed during our discussion? Is there anything we should have talked about but didn't?

Appendix C. Introductory Statements for Interviews and Focus Groups

Good morning and welcome. thanks for taking the time to join me in discussing home bladder manometry today. My name is Amanda Macaraeg and I represent CHOC Urology, in which I've been doing research with for almost 5 years.

Overview of the topic

You were invited to participate in this study because you are involved in the care of a child with neurogenic bladder and have previously helped them perform home bladder manometry.

We want to tap into those experiences and your feelings towards home manometry. This information would better help us improve you and your child's experiences when performing home manometry

Introduction to the topic

Home manometry is a new way for people who perform clean intermittent catheterization to record bladder pressures and volumes at home. Nurses in our clinic have given you instructions on how to do this. Bladder pressures are recorded by measuring the amount of urine in the catheter using a ruler. Bladder volume is measured by emptying the catheter into a measuring basin and recording the volume of urine.

Ground rules

Make sure you are in a quiet space for the next 15 to 30 minutes.

As mentioned, we are recording this session by video and audio because we do not want to miss any of your comments. Your name will not be included in any final reports and your comments are confidential. These recordings will be used for analysis purposes, are only accessible to the study team, and once transcribed will be destroyed.

Please try to refrain from using your child's name. When speaking about them, use the terms "my child" or "my daughter or son."

Questions will be saved for the end. If you have any questions for me, we can go over them at the end. If I'm unable to answer them at this time, I will ask the appropriate person on your behalf and email you or call you with the correct answer. I may also defer you to the clinic as they may be the best source to answer clinical questions.

Finally - there are no wrong answers. Please share your own thoughts and points of view on home manometry. This is a safe space - we want you to feel comfortable with sharing your own experiences and we want to capture your true feelings towards home manometry. With that being said, let's get started.

Appendix D. Initial Analytic Memos Post-Interview

Thursday, May 12, 2022

Participant(s): A1, A2

Relationship to patient: Provider

Venue: Zoom meeting

Time start: 4:36PM

Time end: 5:07PM

More difficulty getting people to participate in the NICU. At first, they are more concerned with other issues due to SB aside from their NGB. Ask a lot of questions at first due to initial confusion. More “seasoned” patients who are more acquainted with CIC seem to have an easier time doing home manometry. Girls may have more difficulty. Older kids not uncomfortable with their parents help. Suggestion: create a catheter that already has markings on it

Monday, May 16, 2022

Participant(s): A3

Relationship to patient: Provider

Where: Zoom meeting

Time start: 4:47PM

Time end: 5:26PM

Parents seem to have a good understanding on the importance of home manometry. Educates the parents as much as possible. Rated ease “2.” Reiterated importance of home manometry and that parents seem to understand why they are doing it. Girls may have more difficulty. Suggestion: create a catheter that already has markings on it.

Tuesday, May 17, 2022

Participant: P1

Relationship to patient: Parent/Caregiver

Where: Zoom meeting

Time start: 12:16PM

Time end: 12:49PM

12y/o son. Overall positive interaction. Overall seems easy. Her son is almost 12, had a bladder augmentation and has a monty for a year. At first it was difficult to keep him still (when he was younger). Now much easier. Parents changed their lives around to accommodate his needs – both wfh so have no issues with collecting measurements every 3 hours. Have done home manometry about 10-12 times. No issues with obtaining materials. No issues with overflow in the catheters. Rated learning process as very good and at-home process as easy. No discomforts from son because he has no sensation down there and is used to it. Was able to reiterate the importance of home manometry, seems to have a good understanding of what will happen if they don’t manage pressures and why they are doing it. Would recommend to other parents. Nothing but positive comments. Suggested it may be difficult for those with younger kids OR those who didn’t start CIC until later on. She started catheterizing her son at 3 weeks old. He’s used to it. Suggestion: helpful when nurses demonstrate how to do it in person. Loves CHOC Urology team and especially Dr. Khoury!

Wednesday, May 18, 2022

Participant: NP1

Relationship to patient: Provider

Where: Zoom meeting
Time start: 1:30
Time end: 1:57

HM important. No specific differences between age groups. Some parents have issues with accessing supplies. Discussed difficulties with extenders mainly for girls. Parents seem to understand HM well.

Wednesday, May 18, 2022

Participant: A4
Relationship to patient: Provider
Where: Zoom meeting
Time start: 2:15
Time end: 2:42

HM is important. Parents have a good understanding of home manometry. Makes sure to explain the importance of home manometry to them when asking them to do it. Parents don't seem to report any issues with doing it. Thinks the teaching process is sufficient. Suggestion: have a model in the clinic to have parents perform HM on to show that they understand how to do it.

Thursday, May 19, 2022

Participant: P2
Relationship to patient: Parent/Caregiver
Where: Zoom meeting
Time start: 12:00
Time end: 12:49

12y/o daughter. Now lives in New Mexico. Has 2 daughters with SB (this interview was for the younger daughter only). Learned how to do home manometry at CHOP. Didn't have a demonstration with nurses at CHOC, provider and nurse only explained how to do it. Never needs extender, mentioned that she might have needed it once but it was only because urine shot out when daughter sat up and was trying to tell mom something. No issues with getting materials. Gets easier with time. Only mom and daughter are present when doing home manometry – daughter will hold catheter while mom takes measurements. Daughters HATE VUDS. Time difference between regular CIC and home manometry is probably 10 minutes. Has a good understanding of the importance. Would recommend to parents if their kids really needed it.

Friday, May 20, 2022

Participant: F1
Relationship to patient: Provider
Where: Zoom meeting
Time start: 10:05
Time end: 10:19

HM is important. Parents seem to have a good understanding of why they're doing it, no one refuses. No differences between age groups or between boys and girls. 50/50 compliance

Sunday, May 22, 2022

Participant: P3

Relationship to patient: Parent/Caregiver
Where: Zoom meeting
Time start: 3:55
Time end: 4:19

8y/o son. Doesn't really seem to understand the importance of home manometry, more so just does it because the physician asks her to. Has done it 2 or 3 times, doesn't have any issues with it except that it's overflowed a couple of times. Son did not self-cath the times that he's done home manometry, so it's usually her and sometimes her husband doing it. Son first did it around 4y/o, asks a lot of questions because he wants to know what's going on but didn't have an issue with it and was physically cooperative – just give him a book or something to keep him preoccupied. Nurses provide them with extension tubing that they've only had to use a couple times but fits well with his existing catheter. No issues with access to supplies.

Monday, May 23, 2022

Participant: P4
Relationship to patient: Parent/Caregiver
Where: Zoom meeting
Time start: 1:00PM
Time end: 1:32PM

3y/o daughter. Doesn't really know why she was asked to do this, just does what the doctor asks her to do. Thinks it's important, can vaguely explain to me in her own words why (bladder pressures). Daughter has never had VUDS done. Her daughter is super young so may be a lot for her to remember at the moment (since she is still learning about spina bifida). Rates HM as 4 difficult. First did it within the first month of life. Really difficult to do when her husband wasn't home. Fits okay into her schedule, does not work anymore. Daughter is 3y/o, no sensation in her legs – indifferent. Suggestion: have a demonstration/be able to do it herself in the clinic for the teaching process. Was never told when to stop recording these measurements. Overall great experience with CHOC especially Urology – Dr. Chuang is her provider. Positive interactions with all urology staff!! *Dog barking in the background and kids playing/talking*

Tuesday, May 24, 2022

Participant: P5
Relationship to patient: Parent/Caregiver
Where: Zoom meeting
Time start: 6:10PM
Time end: 6:55PM

8y/o daughter. Overall positive interaction, however, has had a lot of issues with home manometry. Understands the importance of why she does it and agrees with the urologists. Daughter was able to stay still both times. Daughter feels uncomfortable doing VUDS and more comfortable doing HM in the comfort of her own home. VUDS Suggestion: doctors ask questions in a way that her daughter can understand better (Ex: "Do you feel full?" – Perhaps provide an analogy to help her better understand). Daughter has a good understanding of why she is doing home manometry, but initially has a lot of questions. Takes an additional 10ish minutes compared to CIC. Suggestion: provide gloves, pee pads, additional personnel to help with doing home manometry. Typically, her and her husband do home manometry, however, there have been times where she has done it herself. Daughter cannot self-cath. Uses a different catheter than usual CIC + extension tubing. HM catheter is a lot flimsier. Difficulties attaching tubing to extension – must put the catheter in first THEN extension in once catheter is in child.

When the two are already attached, she must release/let in air to allow urine to flow from cath to extension. When putting the catheter in first then attaching the tubing → runs the risk of overflowing/urine spewing out of the catheter. Sometimes does not get measurements because of this overflow. Uses a lot of pee pads just in case of spillage. The fellow explained home manometry very well. Suggestion: having in-clinic demonstrations is helpful.

Wednesday, May 25, 2022

Participant: P6, P7

Relationship to patient: Parent/Caregiver

Where: Zoom meeting

Time start: 5:00PM

Time end: 5:30PM

12y/o daughter. Hate home manometry. Understands the importance. Would only recommend to other parents if it was the only option. Used a different catheter for CIC, the one provided is too stiff. Recommend providing more specific directions (clarify when to take measurements) and to demonstrate it in the office. Has gotten easier over time. Daughter hates both VUDS and home manometry. She can self-cath and doesn't really enjoy having to do home manometry with her parents help. Has done it about 4-6 times. They need 3 sets of hands to do this. Initially it was hard to do without husband's help, however since daughter can self-cath she helps mom take measurements. 3/5 teaching process, 5/5 at-home process. Mom doesn't like doing it – mentioned that she isn't a physician and that she feels more comfortable with the doctors doing this.

Wednesday, June 1, 2022

Participant: P8

Relationship to patient: Parent/Caregiver

Where: Zoom meeting

Time start: 4:05PM

Time end: 4:45PM

8y/o son who does not self-cath. Single mother so has difficulty with finding someone to help her. Used to have to plan out when to do HM – ex would plan to do HM when one of her sisters was over for the weekend. Feels more comfortable doing urodynamics because the doctors are the ones doing it. Not sure if she's doing it right/accurately. Did not receive a demonstration or a video when first learning how to do it. Process has gotten a little bit easier because her son is able to stay still now and has gotten used to doing it on her own. Son currently uses a female catheter for regular CIC but is instructed to use the male catheter when doing HM. Hard to work with this since it isn't their usual catheter.

Thursday, June 3, 2022

Participant: N1-N4

Relationship to patient: Nursing Staff

Where: Zoom meeting

Time start: 10:04AM

Time end: 10:31AM

Do not think home manometry is helpful in understanding NGB children's health. N3 left a few minutes into the interview. N2 + N4 don't think it adds value to their care, N1 thinks yes and no. Harder for girls and younger kids. People have issues with extension tubing because the extensions only fit in 2 of the catheters they have, so sometimes they need to provide families with different catheters.

Thursday, June 16, 2022

Participant: F2

Relationship to patient: Providers

Where: Zoom meeting

Time start: 4:15PM

Thinks home manometry is helpful and that parents understand. No one declines to do it, more so there is some initial “pushback”. Has been getting more positive feedback lately. Reiterated a few times that she has been getting back much better measurements lately thanks to pre-VUDS appointments and nursing instructions. Doesn’t always ask for pressures at all times – suggested that we should be more specific with how often we would like them to take measurements. Good indicator to use prior to VUDS → ex, recent patient came back with good pressures but had higher pressures on VUDS (random spikes) and was able to keep them on a more conservative regimen. Rates ease a 2/5.

Carlos and Amelia – Spanish interpreters

Friday, June 17, 2022

Participant: NP2

Relationship to patient: Providers

Where: Zoom meeting

Time start: 11:10AM

Time end: 12:20PM

Thinks home manometry is useful in understanding patients care. Patients understand the general gist of why they’re doing home manometry (it measures pressures and volumes) but those who come in for more concerning reasons/that have VUDS get a more in-depth explanation compared to those asked to do it for their annual F/U visit. Had a lot of great feedback in terms of catheters and extensions. Difficult for our office to get those supplies, people have issues using extension tubing and the speedi cath does NOT fit with the extensions. Insurance is stingy and it’s hard to justify why we need additional materials for something that isn’t standard (i.e., adding on 30 male length catheters for every Female catheter for the purpose of manometry). We have resources that give us extra catheters, but this may be difficult for outside institutions to get. Doing home manometry may be easier for boys because of what they have. Parents don’t personally give much feedback – one encouraging thing is that some families are happy when they consistently get lower pressures – goes back to understanding the purpose. Rates ease 1.

Monday, June 20, 2022

Participant: F3

Relationship to patient: Provider

Where: Zoom meeting

Time start: 3:10PM

Time end: 4:00PM

Thinks home manometry is helpful in understand these patients’ health. Mentions issues with compliance. Believes that parents appreciate the demonstrations/diagrams during the teaching process. The provider introducing/instructing a family to do home manometry may be an aspect to consider when thinking about how well parents/families understand the process. Differences in physical comfort between younger kids and those who are more independent and can self-catheterize. In terms of keeping the child still, it really

depends on pathology (ex. whether the child can feel sensation down there). Suggestions: having a sticker to put directly onto the catheter, a phone app to directly upload the measurements to, and standardizing how many measurements we ask for. Would instruct families to do home manometry at her next institution. Understands that there may be a barrier to receiving materials at other institutions.

Wednesday, July 13 2022

Participant: P9

Relationship to patient: Parent/caregiver

Translator present: yes

Where: Zoom meeting

Time start: 8:00AM

Time end: 8:45AM

This interview was translated by a Spanish interpreter. His experience with home manometry was similar to that of other parent participants. In the beginning it was difficult, but it got easier as they became more comfortable with it. He was very appreciative of the care that his child receives. It's important to note that, different from other participants, he sees home manometry as a way to be able to understand and be more aware of his child's health. Thinks it's important to have both parents present, however both him and mom were able to do home manometry independently so long as they had a wooden ruler instead of the paper one.

Tuesday, July 26, 2022

Participant: P10

Translator present: yes

Relationship to patient: Parent/caregiver

Where: Zoom meeting

Time start: 10:10AM

Time end: 10:58AM

This interview was translated by a Spanish interpreter for the first half, then done solely in English for the second half. The translator was on standby just in case any clarification was required. Overall, mom seemed to not have a good experience with home manometry. She did not have extra help to do the procedure. She would recommend it to other parents but does not think it is a good way of monitoring her child's health, nor does she think it adds value to their health. Her daughter is comfortable with both home manometry and Urodynamics. Her daughter is a teenager now but does not self-catheterize. Emphasized the importance of making sure parents know what resources are available instead of parents having to ask. She did not get enough information prior to doing home manometry because it seemed like the nurses were in a rush to get to the next patient. She also did not receive all materials the first time around.

Appendix E. First Cycle Analytic Memos

Differences between +/- Monitoring NGB Health within Clinic Staff (7/12 at 12:25PM)

Generally speaking, all clinicians (attendings, fellows, and nurse practitioners) find home manometry to be a great tool for + **monitoring NGB health**. This can be attributed to their level of understanding and knowledge of the procedure. As a general understanding of the CHOC urology standard of care, these clinicians focus on the preventative aspect of care. All clinicians (except F2) mentioned that home manometry is a great **bladder screening tool** to gain insight of the safety of bladder pressures and monitor kidney health. Additionally, it is a helpful tool in **determining bladder management**. All clinicians have mentioned that it plays a role in determining their care - whether it be altering the catheterization regimen, recommending a bladder Botox procedure, or proposing additional ultrasound or urodynamics testing. Finally, clinicians view it as a procedure that gives patients and their families a sense of **independence** or **self-empowerment**. While this concept of self-empowerment is tied to *patient/family understanding*, from a physician standpoint, parents have a sense of control because they have the means to monitor their bladder pressures and volumes on their own. NP2 has even had families come back "really excited" because their pressures are low. As patients/families understand the importance of what comes out of home manometry, they tend to feel a sense of self-empowerment through having some control of their child's care.

On the contrary, nurses who actually teach the families how to do home manometry had different standpoints on this idea. Although N2 said it was not helpful, N4 said they did not have an opinion, and N1 did not respond, their attitudes towards home manometry being helpful were more negative than the clinicians. Reasons provided include: ROOM FOR ERROR, too many variables, and issues with materials - all of which may lead to inaccurate readings. Note that nurses have direct interactions with families in regards to teaching home manometry, which may be why they have different insight than clinicians, who only review the logs when the patient returns to the clinic. Clinicians are more optimistic in seeing results that come from the procedure, while nurses are more realistic in seeing the nuances in technique and supply that come with doing home manometry.

Barriers to consider/assess so far:

- 1. materials (catheters and extension tubing)*
- 2. types/number of variables being collected*
- 3. reasons for error*

+/- Adds value to their overall care (7/12 3:30PM)

Although similar to +/- monitoring NGB health, the question of whether or not participants believe home manometry adds value to their overall care was asked at the end of each interview/focus group discussion. This was purposely done to tie together their thoughts and bring the discussion back to the main point of: is home manometry helpful/worthwhile for patients to do? Similar to the previous memo, clinicians all agreed that yes, home manometry adds value to these patient's overall care. On top of it providing clinicians with **additional information**, it is a relatively **simple, inexpensive, and non-invasive** procedure used by individuals who are **already catheterizing**. From a clinician's perspective, home manometry is a cost-efficient, easy way to obtain critical information that may alter the patient's bladder management regimen *without* having to perform tests such as ultrasound or urodynamics, which take time, resources, and money to do.

On the other hand, clinic nurses (N2 and N4) do not think it adds value to their care, with the exception of N1 who sees both sides of the issue. N1 sees the benefit of the additional information, however accuracy is the biggest concern for all nurses. Because there are **too many variables**, again, there is **room for error**, thus **accuracy** of measurements is in question. In addition to numbers produced, various different factors must be taken into account for this: age of the patient, whether or not they are already catheterizing, when to take the measurements (*nuances in technique*), and the materials provided (**ruler** and **extension tubing**). These items do not necessarily address the "value" component directly, rather they do so indirectly as they involve the materials, technique and experience levels involved that actually produce the measured outcomes. It seems as if they do not see an additive value because of the potential for error caused by these various issues.

Additional things to consider:

- 1. Nuances in technique*
- 2. Materials*
- 3. Reasons for error*
- 4. age & experience*
- 5. There are distinct differences in attitudes towards home manometry between clinicians and nurses. This may be something that needs to be addressed.*

Compliance (7/12 5:00PM)

"I forgot" is a common theme and reasoning behind non-compliance. According to F2, compliance has increased as our teaching became more streamlined and individualistic to the patient and procedure. N1 and F1 believe there is a 50/50 compliance rate. Higher compliance in older kids, more experienced kids, and those coming in for (V)UDS. Reasons for not bringing in forms: no time, numbers didn't make sense, NGB is a **secondary issue**, or it's just too hard. F1 attributes non-compliance to the fact that home manometry takes time, energy, and discipline. Considering all factors, I believe this to be true - it is an additional step in their existing catheterizing routine that requires more supplies, in addition to extra time, help, discipline and patience on the family/patient's part.

Things to consider to improve compliance:

- 1. Ensure all supplies are available*
- 2. Standardizing logging requirements*
- 3. Adjust instructions/intros to home manometry - emphasize importance, instruct when to exactly to record*
- 4. Offer alternatives for those who do not have extra help*
- 5. Send out reminders a week or two before the patient's f/u visit or VUDS appt (?)*

Patient-specific differences (7/13 10:06AM)

GIRLS VS. BOYS

One major difference that almost all clinic staff have discussed are differences between **girls vs. boys**. Female and male physiology is very different in terms of where and how the catheter is inserted and therefore what types of catheters are used for CIC. A2, A3, NP1, NP2, and N2 directly acknowledge that *home manometry is more difficult for girls*. This seems to be directly linked to their regular catheterization regimens. Girls typically have shorter catheters - this is because "where the catheter comes out and the pubis are pretty similar" (F2), whereas boys require a longer catheter because it needs to extend through the penis in order to reach the bladder, and also extend through the tip of the penis to allow for urine drainage. The reason girls do not typically use longer catheters is because 1) they don't need it and 2) a shorter catheter allows for easier, direct drainage (whether it be into the toilet or into a diaper). A3 notes that catheterizing girls is harder in general. Home manometry is more translatable for boys because it does not add much to their routine - most boys already have longer catheters. Whereas girls, the concept of manometry deviates from their regular routine because they either need a different catheter or extension tubing to allow for measurements. Many of the problems I'm noticed thus far have to do with materials, specifically catheters and extension tubing, and the central issue of non-standardized materials for home manometry may be the reason that it's more difficult for girls. On the other hand, difficulties in the male NGB-SB population are that they are less cooperative (A4) and need to ensure that they are taking measurements from the correct location (F2).

girls have shorter catheters and boys have longer ones, take measurements starting at different places,

Things to consider:

1. *Girls - more difficult because it deviates from their regular CIC (additional materials required)*
2. *Boys - less cooperative*
3. *Boys - ensure they are measuring from the correct location to avoid "erroneous measurements"*

EXPERIENCED VS. NON-EXPERIENCED

Another patient-specific variable to consider is **experienced vs. non-experienced** individuals. Everyone except N4, NP2, and F2 directly acknowledge that experience plays a big role in patients' and families comfort with home manometry. However, this comes from two separate directions - experience with catheterizing in *general* and experience with home manometry.

In terms of CIC, it is standard that all spina bifida patients with concern for neurogenic bladder begin catheterizing at their initial visit. Whether it be a younger patient (baby in the NICU or prenatal consult), OR an older children who was just transferred from a different institution and never performed CIC - all CHOC urologists instruct these patients to begin CIC. In this population, there seems to be some reluctance towards doing home manometry. The concept of catheterizing ("learn(ing) how to identify the urethra... use(ing) all these new equipment", F2) *in addition to* having to fill out home manometry logs can be **overwhelming** if presented with other tasks, uncomfortable, and challenging for families. A1, A2, F2, and F3 have weaned off of doing this and will typically wait until a later visit to introduce home manometry. For those who are not already catheterizing or have just been instructed to begin, the RN's don't ask for pressures, they "just do the volumes," N1. For those who are on a regular CIC regimen, they seem to be more on board with doing home manometry. This is because these "seasoned patients" (A2) are already comfortable with the concept of neurogenic bladder and catheterization.

On the other hand, patients who have experience with doing home manometry in the past seem to be more comfortable and have less issues with it. People tend to learn they you go. Practice makes perfect, so once you get into the groove of catheterizing and taking measurements simultaneously, and once you've

created a routine that works for you during the procedure, you become more "proficient" (A3) with it, and it becomes simpler and more straightforward.

Things to consider:

1. Allow families to get comfortable with CIC before adding on the additional task of home manometry
2. Teach home manometry at a visit after CIC introduction

OLDER VS. YOUNGER > patient movement

Another distinct patient-specific comparison group is **older vs. younger** patients. Generally, it seems as if the older patients are more comfortable and consistent with home manometry because they require less help, they're more independent, they understand their pathology and the reason for doing home manometry better, and they are more "familiar" (A2) with the catheterization process. Younger kids seem to have a more difficult time and feel more uncomfortable because these families are new to CIC and their diagnosis in general. Similar to experience vs. non-experienced, there is a lot of information that these patients and their families need to take in at once. Younger kids are more concerned about *how* to catheterize, and less concerned about taking down measurements. One major factor to consider for the younger population is **patient movement** (NP1, N1, N3, A1, A3). These kids are more squirmy, more difficult to calm down, and tend to move around more during the process. Maturation is a major factor to take into account with home manometry. As the kids get older, they become more used to CIC because they are on a regular schedule, they become more knowledgeable about their own pathology, and they are more independent in the sense that some are even able to **self-catheterize** themselves. Learning how to do home manometry, let alone understand neurogenic bladder and spina bifida, can be a lot for families to take in. However, as you get older and create a routine for yourself, it may be easier to add on additional steps in that regimen.

Things to Consider:

1. Offer suggestions on ways to keep the child still
2. Wait until the child is used to catheterizing before introducing home manometry
3. Emphasize importance of home manometry in the child's bladder management routine

SELF-CATHETERIZING CHILDREN

Although many of the patients who can **self-catheterize** are older, I did not necessarily code these two together, because there is potential that younger kids are able to catheterize themselves (depending on home environment and pathology). Home manometry *cannot* be done by the patient alone (A3): if the patient is lying flat and sits up to hold up the catheter and take measurements, the bladder pressure will increase, and the readings will be inaccurate. Generally, patients seem open to accepting help with home manometry (A1, A2, NP2, F1, F3) especially because their parents are/have already been involved with CIC at some point (F1, NP1). N1, who directly demonstrates and teaches the families home manometry, says "they're pretty good about the parents helping them. They feel pretty comfortable." F2 mentions that a potential issue may be if a female patient requires help with home manometry and a person of the opposite sex is involved in the process, that may be uncomfortable to them. NP2 and A4 have not received or observed any direct feedback for this topic.

Things to consider:

1. Patients who self-catheterize require help from others - find ways to make this more manageable with just 1 person (?)

Only F3 and A3 mention **pathology**, however this is a great thing to note considering a majority of spina bifida patients have no sensation in the genital area, meaning catheterizing shouldn't be uncomfortable and therefore home manometry should not be either since there are no changes in catheter insertion.

Initial Reactions

According to A1, there is a "**very real dichotomous reaction**" between age groups and experience levels. This is an excellent way to describe the reactions that clinic staff have witnessed from patients and families with regards to home manometry. Clinic staff have had a myriad of initial reactions: confusion, doubt in their ability to do it, excitement due to potential outcome, and reluctance because of inexperience with catheterizing (F3) and other issues going on with the child (A3). Most reluctant attitudes come from patients who are younger and have less experience with catheterizing.

There is also an "**evolution of reactions**" (A1) between initial introduction/learning and actually going home and executing the procedure. All clinicians have agreed that everyone is receptive to the idea of home manometry: patients tend to listen to their physician's recommendations so long as the supplies are available, and the instructions are clear. One thing to note is that *instructions are very important!* Families have asked questions and the purpose (F1, F3, NP1, A4) and about procedural specifics (F1, F3, NP1, NP2, N2, A2). A3, F1, and F2 share that families are receptive when provided with an explanation as to *why* this is necessary and *how* it will help them (physician and patient). Considering the questions asked about why they're doing it, how it will be possible, and what exact steps need to be taken - it is crucial that all of this is provided when introducing home manometry.

Although initial introduction is generally met with acceptance, this is where the evolution of reactions comes into play. NP2 and A4 specifically mention that just because they initially agree does not mean that they are actually compliant. This is tied to **learning vs. execution** because some patients come back with no measurements due to things such as "overflowing" (NP2). Although they verbally agreed to do it, there is a difference between learning how to do something and actually being able to execute it yourself. People are always **learning at different rates** (A3). There also needs to be a certain level of understanding for the importance and technique of home manometry. Because of this, **compliance** may be linked to how the clinicians introduce home manometry and what information is provided to the families.

Things to consider:

1. *Dichotomous reactions between age groups and experience levels*

2. *Evolution of reactions between initial introduction/learning vs. execution*

Introduction --> asking questions --> initial receptiveness --> learning vs. execution --> compliance

MATERIALS/TECHONOLOGY (7/13 12:40PM)

The current materials being used for (and provided by the clinic) home manometry are as follows: catheters, extension tubing, paper ruler, and urine basin. **Catheters** are an issue for people of all ages and sexes. Some patients require a different catheter than what they use for their typical CIC. Reasons for needing a different catheter vary from length, to size, to opacity, to whether it will fit into the extension tube or not. Families have asked how to get catheters; and if we're unable to provide them with the correct

catheters, how are they supposed to do this? Some families have also mentioned that they don't have enough catheters for the amount of home manometry entries the clinician is asking for.

Extension tubing seems to be another material that is difficult to use. The tubing provided by the clinic can be fiddly, messy, and difficult to use. Considering the steps taken during home manometry, using extension tubing also requires two people - one to hold up the long extension tube column while the other person measures. Although there are many difficulties with extension tubing, this is necessary to have for patients whose catheters are too short or are at risk for higher pressures (due to urine overflowing out of their current catheter).

The **catheter-to-extension attachment** is an issue mainly because the extension tubing that we provide only attaches well to two of our catheters (N1). All the NP's and RN's, in addition to A1, shared that often times, the catheters do not attach well to the extension tubing. In turn, patients either need to work with the materials they have and force the 2 to connect *or* be given a new catheter just for home manometry, even if they use a different catheter for CIC. If the extension tubing is too flimsy, it won't attach well to the catheter. A bad attachment can lead to leaking and unsatisfactory and uncomfortable experience with home manometry.

Catheters and extension tubing seem to be a huge limiting factor in the home manometry process because there is no 1 standard catheter and/or extension tube for it, additional supplies are not always available, and patients typically become accustomed to their usual catheter.

The final material mentioned is the **paper ruler**. NP2 and N2 agree that this is flimsy, makes it harder to measure the pressure, requires two hands and therefore affects accuracy.

Things to consider:

1. *Everyone uses a different catheter (length, size, opacity)*
2. *Universal extension tubing?*
3. *Provide families with/recommend a plastic ruler*

Logging Requirements (7/12 4:00PM)

Although a majority of clinic staff offer a sense of **flexibility** for when patients/families should take these measurements, there is no set of standardized requirements across the board. While some ask for just morning, morning and evening, once a day, multiple times throughout the day, over the weekend, the week prior to urodynamics, etc.; these instructions all seem to be dependent upon the patient's home environment (availability of extra help, school/work schedules) and the purpose for home manometry (**urodynamics vs. routine follow up**). NP2 mentions that when coming in for urodynamics, there's more "hand holding" and a greater sense of urgency to complete home manometry logs as compared to those doing it to get a baseline for routine follow up. Patients coming in for urodynamics are seen within a few weeks compared to those coming in for routine follow up who are seen months or a year after being instructed to do home manometry. Reasoning for doing home manometry is directly linked to **Compliance**. One recommendation offered by F2, F3, N2 would be to **REC - clarify and standardize requirements**. N2 noted that a standardized routine may help improve accuracy.

Things to consider:

1. *Creating standardized home manometry requirements*

2. Clarifying these requirements to families

ADDITIONAL CONSIDERATIONS (7/13 1:06PM)

There are additional things to consider. Home manometry takes **discipline** to remember to do, **energy** to actually execute, and **patience** to record the correct measurements on the family/patient's part. The process may be **burdensome** and may therefore be met with reluctance because this can be seen as an **additional task** for a **secondary issue**. These patients have complex diagnoses that do not only involve urology. Depending on the patient/family, urology may be seen as a secondary issue as these patients are being seen by multiple different clinicians for various issues. Another reason for reluctance may be that home manometry is **not a standardized process** - not only are there no standard instructions across the CHOC board, but it is also not a standard procedure for all NGB-SB patients.

From NP2's perspective, personal benefit decreases as difficulty increases.

EVALUATIVE (7/13 1:12PM)

There is some **uncertainty of accuracy** from both the clinic staff perspective and the family perspective.

Some patients will try to do home manometry and come back with no numbers because "I keep getting various numbers. It didn't seem right to me" (F1). Other times, clinicians will review the logs and see that the numbers are incorrect or and may ask the family to return demonstrate (A3, NP1). The nurses emphasize that there are **just too many variables**. There is a lot of **ROOM FOR ERROR** - whether it be due to materials, patient cooperativeness, who is taking the measurements, when the measurements are being taken, where you're measuring from, what instructions you were provided, etc.

When comparing **home manometry vs. urodynamics**, the general perception is that home manometry is beneficial for low-budget facilities who may not have the resources to perform urodynamics often *or* for patients that you do not want to subject additional testing to. Home manometry differs from urodynamics in that home manometry allows clinicians to understand what is going on with the bladder during regular filling, as opposed to UDS which fills the patient with artificial fluid (A3, F2). It is important to note that home manometry should not be used in replacement of urodynamics: it is a good screening tool for these patients, however UDS/VUDS is the gold standard and needs to be done to understand the true bladder pressures/volumes.

Finally, how well do the clinic staff perceive families' **understanding** of home manometry?

From the clinician perspective, patients and families seem to understand the general concept of bladder safety, pressures, and volumes (F3, NP2, A1, A3, A4). NP2 has had patients come back with logs and address that their numbers are lower meaning pressures are lower - this shows an added layer of understanding, that being able to come back and describe your findings. Additionally, A2 and F3 see that older kids understand it better. NP1 and A4 also believe that kids who come back and return demonstrate in the office have a better standing - this may be because they are able to show how exactly they retrieved their measurements, and therefore clinicians can determine the accuracy of the measurements. F3 notes that understanding may be provider-dependent, and all attendings have emphasize the way they explain it to their families. It's important that the providers are explaining it in way that the family will understand (i.e., A1 uses "layman's terms") in order for them to understand it better. Below are some additional thoughts on how well patients/families understand it

F2: Videos + in-person demonstration --> increased understanding

F1: 50/50 - seem like they understand but whether their measurements are accurate is in question

Things to note:

1. *Patients understand the general concept of home manometry being for monitoring bladder pressures, volumes, and overall safety*
2. *The way you describe and introduce home manometry to a family is important ("layman's terms")*
3. *Those who can interpret their own numbers/return demonstrate the process have a better understanding because you can gauge whether or not their measurements are accurate based on their ability to interpret findings or the way they are doing it or*

TEACHING (7/13 11:30PM)

Clinicians provide an introductory **verbal explanation**, nurses set up pre-VUDS visits where they do an **in-person demonstration**, show families the **video**, and provide them with take-home **pamphlets** with instructions. The video is a nice additional tool to provide for families when they are doing manometry at home, however many families still request home manometry teaching appointments. Therefore, videos should not be used to replace the in-person demonstration. One thing that A4 does is put the video directly on the parent's phone - that way they have easier access to it when they get home. N1 and N2 specifically mention that the patients and their families *prefer that they (nurses) show them* how to do home manometry. Additionally, F2, NP1 and NP2 mention that those who come in for in-person demonstrations seem to be more compliant with home manometry and seem to have a better understanding of it

Things to consider:

1. *In-person demonstrations work well*
2. *Videos should be used as a supplemental source, not as the primary source*

HOME ENVIRONMENT/CONTEXT (7/13 1:51PM)

"Home manometry is a two-person job" (A3). Having an **extra person** may be a limiting factor to doing home manometry and is something that everyone has mentioned. Some older, more independent patients may be able to do home manometry with just the help of 1 person; however, for the most part, an additional person is required. One to hold up the catheter near the pubis and near the opening, one to hold the tape measure and write down the measurements. This is a limiting factor considering people's home environments: some people may be single parents, some may have work throughout the day, etc. This is something to consider and that will be discussed more in the parent interviews. **Time** and **everyday routine** coincide with one another: we understand that home manometry takes extra time, but how much exactly? Do families have extra time throughout the day to dedicate to home manometry? And how does this procedure fit into their everyday routines? Clinic staff acknowledge that it fits into their *regular catheterization schedule*, however because it takes extra time, it can be seen as a burden. School, work, the family's regular daily routine, etc. may also limit the families as to when they actually have time to take these measurements.

Things to consider:

1. *Offer additional support to those with only 1 parent/caregiver*
2. *Offer alternatives for kids with only 1 parent/caregiver*
3. *Alter logging requirements to be standard but also account for those who don't have much time*

4. *Home manometry takes extra time - how do we shorten this process?*

Nuances with technique (no codes but a potential theme?)

Clinician unknowing

Won't be used for analysis

Generally, there are many things that clinicians are unaware of. F3 offers the perspective that this may have to do with the patient-physician relationship: would you go up to your teacher and tell them you don't like something? Or what's wrong with it? Most likely not. This may also be associated with how long the individual has been working at CHOC and the number of interactions they've had with these patients. Some things clinicians are unaware of are:

- self-cath kids' comfort (2)
- how it fits into their everyday schedule
- how cooperative kids are
- what's discouraging with the process
- how well they *truly* understand home manometry
- how often other clinicians instruct patients to do home manometry
- how consistent they are
- how they receive connection tubing

Appendix F. Second Cycle Analytic Memos

Please reference Coding > Codes > Thematic Framework v2 7-21 for the following memos

Themes generated and ranked by the highest number of references (files/references):

1. Evaluative (18/259)
2. Maturation/Patient-Specific Considerations (18/141)
3. Sources of Error (18/122)
4. Materials/Technology (18/119)
5. Home Environment/Context (18/98)
6. Education/Learning Experience (18/59)

EVALUATIVE - perspectives and ideas surrounding home manometry as a whole

This theme aims to discuss all personal thoughts, perspectives, and opinions on any/all aspects of home manometry *and* the clinician's perspectives on these ideas, either personally or based on personal experiences.

- **Understanding** of home manometry was the evaluative topic that was discussed most amongst all participants (except the nurses, who were not asked questions regarding their understanding or perspective on how well they think families understand home manometry).

More than half (5/9) of the clinicians believed that patients and their families understand the general concept that home manometry is performed to measure bladder pressures and volumes, and to essentially measure bladder safety. This proved to be true, because all parents explained the same degree of understanding in terms of bladder function and the importance of protecting the kidneys. Additionally, 3/8 parents mentioned that information obtained from home manometry is useful for the doctors and may be used as a screening tool to see if additional tests (Urodynamics) or alterations in their child's current regimen are needed (5/8). F3 mentioned that patient/family understanding may be provider-dependent, and F1 said that they seem to understand home manometry but whether they do it correctly is a different issue. F2 believes that families who have hands-on demonstrations and that have been shown the videos seem to have a better understanding, and NP1 believes that those who return demonstrate seem to understand better. Parents also believe that home manometry has helped them to understand their child's body better and has given them the opportunity to monitor their child's health on their one. P5 notes that "understanding that sometimes you're going to have some volume, and sometimes you're not going to have anything, and understanding that you're not doing anything wrong, that that's exactly the reason why they need the pressure test. Because they need to understand what the bladder is doing at certain times of the day." This is a great example of parent understanding - in addition to the concept of bladder pressures and volumes, mom was able to elaborate that measurements aren't always going to be perfect and that you're not doing anything wrong, rather that is something that the physicians must assess to give feedback or make recommendations for the child's bladder routine. On the contrary, P10 mentions that although she knows it has to do with the bladder, she doesn't understand how it's helpful in monitoring the bladder nor does it add value to her child's overall care - she attributes this to the clinical team's lack of description about the importance of the procedure.

- The second highest ranked Evaluative code was **Recommendations**. There were a variety of different recommendations, however most recommendations were with regards to improvements in the teaching process and the materials provided for the process. One recommendation that 8/9 parents and both NPs mentioned was providing a hands-on demonstration during teaching. It's important to note that within the past few months, hands-on demonstrations done by the nurses have become a standard of teaching in the clinic, and many of these parents were initially taught how to do home manometry many years ago. Three parents who did not have the opportunity mentioned that it would be nice to have videos available to take home would have been helpful. Other recommendations were with regards to materials, with the main recommendation being custom catheters, whether it be a sticker with measurements on it or a catheter that is already marked (this way, the ruler may be able to be eliminated altogether). Catheters, which will be discussed in the Materials/Technology section, are the most important component of the process, and quite a few patients seem to have issues with the ones they are provided. Suggestions on better equipment and overall, a better supply kit (i.e., a plastic ruler instead of paper, better extension

tubing, better urine cup) were recommended, in addition to having supplies available in general. One parent suggested the clinic provide them with additional supplies (betadine, wipes, chux). One interesting suggestion made by 2 clinicians and 1 parent was a home manometry app - if families were able to log and submit their measurements directly online, that may increase compliance for those who forget to bring their logs in person. This would be beneficial to both the family and the clinician to ensure that you can hold them accountable of actually taking down the measurements. Some recommendations only mentioned once were telehealth for teaching, in-clinic model for demonstrations, a simpler process, and alternatives on how to do it with just 1 person, and additional materials for practice. One recommendation that stood out to me was a Hispanic parent said it would be helpful to get input and reassurance from other families who have done this before. Knowing that other families have been able to perform home manometry could help newer families feel more comfortable and feel reassured with learning a new technique.

- **Clinical Utility** was assessed based on the purpose and usefulness of the procedure, and how practical it is to execute it. All clinicians in addition to 2 parents acknowledged that home manometry is a good bladder screening tool that can be used to assess bladder function and establish overall safety. Participants from both the clinician (7/9) and parent (5/8) groups emphasized the importance of home manometry in terms of determining the patient's bladder management regimen. A3 says "it allows us to provide them with care based on data... more scientific rather than artificially." Clinicians mention that measurements obtained from home manometry can help them determine whether more testing needs to be done, how to change their CIC regimen, if additional medications are required, if surgery is required, and overall helps to make decisions about their care. Similarly, parents mentioned that it's helped the doctors determine if their child's current regimen is working in terms of CIC routine, keeping their child dry, and more tests/closer follow-up is needed. In addition to this, 4 parents and 4 clinicians have mentioned that home manometry is simple. These kids are already catheterizing (2 parents 4 clinicians), at least 1 participant in each group has acknowledged that it provides additional information about the child's bladder, it's non-invasive (1 parent, 2 clinicians), and inexpensive (2 clinicians). Overall, home manometry is beneficial in terms of determining bladder safety and management in a conservative fashion.

- **First Impressions** from the parents' perspectives and the clinician's understanding of their perspectives was assessed. All clinicians mentioned that generally, families are receptive to home manometry when first being introduced to it. Two parents said that they agreed to doing it because the doctor's asked them to. With a general understanding of how it is when you go to the doctor for a check-up, you usually do what you're asked to, right? Which may be why families are receptive to performing a new technique regardless of how easy or difficult it may seem. For those who have a better understanding of the importance of home manometry, they seem to express initial excitement knowing that they may potentially be able to reduce their catheterizations or the number of tests to be done (A3, F2). On the other hand, some parents express reluctance, either because they have no experience with CIC yet or because they already have a lot of tasks at-hand (F3, A3).

All parents noted that their first impression was that home manometry is difficult, challenging, tricky, and stressful. One mom even said, "We hated it." Everyone discussed personal reasons as to why their first experience was so challenging, however overall, it seems like a complex process (which will be discussed later) that requires many steps and various considerations. Some parents mentioned difficulties in terms of technique (how to hold up the catheter and when to measure), the fact that you need multiple people to be able to do it, and that they were not sure how accurate their measurements were. Because it's a brand-new procedure that you're not familiar with, the first time is more intimidating (TN), and it takes some time to get comfortable with it (JG). To add on, nurses said that families express some confusion about the procedure and clinicians mentioned that families generally ask procedural questions and specifics about the purpose of home manometry. Given this information, I believe clinicians should be specific about what they tell the family to ensure they are able to execute the procedure at home and also understand why they are doing it.

A1 mentions that there is an evolution of reactions, and I think this coincides with what the parent participants shared. "Sometimes hearing us say it versus going home and then actually having tried to do it several times, there's a dynamic nature to their reactions about this." This goes along with **practice makes perfect**, which will be discussed later.

Finally, P4, the mother of a 3-year-old, mentions that home manometry was "a lot." In her daughter's first month, even her first year, it seemed like even more on top of what she'd already been instructed to do to care for her daughter. A1 says there is "a very real dichotomous reaction" between age groups. Although most parents

mentioned difficulties with technique, P4 mentioned the complexities of her child's diagnosis and having so many new things to learn/deal with. This differs from kids who are older and already have experience with CIC.

- Because home manometry was created to be used as an adjunctive procedure to Urodynamics, comparisons between **Home Manometry vs. Urodynamics** was another topic of discussion with everyone except P4, whose daughter has never had urodynamics done before.

Similar to **Understanding**, parents, clinicians, and nurses seem to all have the same general ideas surrounding home manometry and urodynamics, just from different angles. One benefit to having home manometry is that it is inexpensive and fits into the child's regular catheterization regimen, as opposed to UDS which is expensive and takes time and effort. In terms of the complexity of UDS, most parents have alluded to the idea that children are more comfortable with home manometry than they are with UDS. Clinicians state that UDS uses artificial contrast, and they are not filled at a physiologic state (F2/A3) - therefore, UDS and home manometry give very different measurements. From the parents' perspective, filling their child's bladder to capacity (5/7) seems to cause the kids a lot of discomfort. Generally, being in the office is more uncomfortable because there are nurses and doctors surrounding you which can feel intimidating, and the procedure does take a long period of time (3/7). Home manometry offers the convenience factor of being able to do it in the comfort of your own home, on your own time, and during CIC - which should already be part of these kids' routine. One mom also mentioned that both of her daughters have gotten UTI's after UDS, which they did not get after home manometry. However, overall, 6/7 parents mentioned that they trust UDS a lot more than home manometry because it's done by a professional in the clinic, and that they don't want home manometry to be a replacement of it (DL/TN). Nurses have also mentioned that the true pressures need to be done by VUDS and UDS. This coincides with our initial and validation studies that home manometry is *not* meant to replace urodynamics. It is a good screening tool to be used supplementary to UDS for kids that you are monitoring, *and* you may avoid the risk of exposing them to UDS (4/7). Overall, parents think UDS is more accurate than home manometry, but children are more comfortable with home manometry.

- Another important factor to consider is the **child's feelings** towards home manometry. Nurses mention that children probably feel indifferent, and that it depends on the age. F3, the parent of a 3y/o, said her daughter probably felt indifferent because she was too young to know what was going on. Some kids are curious and ask questions about what and why their parents are measuring their catheterizations, however they don't seem to have any particular feelings about home manometry (3 boys 2 girls). The parents of 2 girls and 1 boy mention that their child expresses reluctance towards the procedure: 1 girl doesn't like having to sit still, 1 doesn't like the time that they must take to do it, and the 1 boy may see it as an inconvenience. Nonetheless, all children seem to comply, and do as they are told so long as they're informed as to why they are doing it.

- **Control/independence** is the last evaluative code. 4 clinicians believe that home manometry gives parents the power to have some control over their child's health because it gives them the opportunity to monitor the bladder on their own. Home manometry is a process that gives families some form of independence in their child's care and can empower them to make general assessments on bladder function.

P2: "And with my child and her bladder, I want to make sure, you know, that we do everything possible to keep that bladder as healthy as we can"

P9: "It definitely helps because I think we're more in-tune, we're more observant of different aspects of his health that we wouldn't have been if that weren't the case."

P8: "But it gives me that peace of mind, so it's kind of a wash"

MATURATION/PATIENT-SPECIFIC CONSIDERATIONS - What attributes must we consider with regards to home manometry expectations?

This theme aims to discuss the various attributes that may affect a child and their family's ability to execute home manometry, and the stark differences between overall experiences and perspectives with regards to age, sex, and experience.

- The first attribute to consider is whether the patient is **experienced vs. non-experienced**. This can go in two directions: experience level with home manometry, or experience level with CIC in general. A majority of the clinicians mention that patients who already routinely catheterize and are comfortable with the process are more willing open to doing home manometry, as opposed to patients who have not started CIC yet, in which N1 says "the

parents don't even feel comfortable cathing. And it's even worse to be asking for them to be recording volumes and recording the bladder pressure."

The second side of experienced vs. non-experienced is with regards to home manometry: has the family done it before? If so, according to F2 and F3, families are more on-board because they know what is involved in the process and what may come out of it (alterations to their regular bladder regimen, i.e., potentially reducing the number of catheterizations if home manometry measurements are safe). This is confirmed by most parents who have agreed that because you know what to expect, once you get into the groove of things, you become more comfortable with the process as it's only a few additional steps to your regular CIC routine. I thought it would also be important to note that P2 has an older daughter who was instructed to do home manometry by a CHOP urologist, so she already knew what to expect when being asked to do this at CHOC.

-- A subcode that I identified under **experienced vs. non-experienced** is **practice makes perfect**. I think this is fitting considering the more experience you have, or the more practice you get - the better the process gets at the more comfortable (and potentially accurate) you become! A3 said "after a few weeks, they're very comfortable with their home manometry." This proved to be true based on 6 different parent responses. Practicing and doing home manometry everyday helped parents to get more comfortable with home manometry: the first couple of times are more difficult, however "It gets easier over time, for sure" (P1) and "The easier part is just knowing what you're doing and knowing that you're following the correct steps. Once you know what you're doing, it's super easy and simple" (P5).

A3 compared home manometry to contact lenses, which I think is a perfect analogy for this process:

"Ask them, "how was it the first week you were trying to get the lens in? And how is it today?" So, most people now they just toss them in, right? It's so easy after they've tried, they've become good at it for the first week. You try and stick your finger in your eye and keep your eyelids from blinking. Not easy. I remember I used to wear contact lenses. The first week was like miserable. I said, "Why do I have to go through this?" Right? But once you've done it a few times, then you just throw them. It's nothing. So, this becomes the same. At the beginning, it's a little bit fiddly, and then once they got the hang of it, it's straightforward. It's easy".

- The next major topic identified in this theme was with regards to age-specific considerations between **older vs. younger** patients. Generally speaking, a majority of clinicians and all nurses agree that home manometry is more difficulty and not as easy to take in the younger population than it is for the older population. Reason being because the child is still not comfortable/used to catheterizing, families don't know how it will be possible to do with two sets of hands (and if that extra set of hands will even be available to help), and the parents are worried about how cooperative the child will be. Two parents (1 girl, 1 boy) mentioned that now that their child is older and can catheterize directly onto the toilet, home manometry is more cumbersome (P8) because cathing on the toilet is "easy, really quick" (P6). Although these kids are already catheterizing, this does deviate from their norm - although they may have previously catheterized laying down, they've become accustomed to cathing directly on the toilet and now they must go back to laying down just for this procedure. Home manometry in younger kids is more difficult because they are not already catheterizing and they require multiple people, whereas in older kids, they are already performing CIC and may be able to do home manometry on their own. On the contrary, this may be more cumbersome for older kids because it's a deviation from their norm - they now have to lay down to catheterize whereas they typically do it directly in the toilet.

-- Two subcodes came out of this code: **child cooperation** and **self-catheterizing children**. 9 clinic staff have mentioned that patient cooperation is something to consider while doing home manometry - 5 of which believe it is age-specific and mainly younger kids move around/are more squirmy, while 4 did not specify the age group. All parents mentioned that their children have been cooperative during the procedure, 4 parents specifically saying that they were more cooperative when provided with the purpose of home manometry. One boy mom (P1) and 1 girl mom (P4) mentioned that when their children were younger, it was a little more difficult to keep them still, however P4 says that these are usually random movements since her daughter has no sensation down there. One mom empathizes with the parents of younger children, "I would feel sorry for a parent that had a little one that wouldn't be able to hold still. I mean, I'd never experienced it, but I think it would definitely be more challenging to perform it on a younger child." Additionally, parents have acknowledged that any movements/laughing can alter the abdominal pressure and give them inaccurate measurements or cause the child to overflow, so they make sure to remind their child not to move before they begin home manometry. A couple moms have also mentioned having to make sure

their child doesn't kick the urine cup over. Although not many of the parents I spoke to seemed to have issues with their children moving around during, this may just be the specific group of parents that I interviewed since clinicians and nurses seemed to have heard feedback on more kids who move around. This movement isn't because of discomfort, rather it could be due to random/spontaneous movements, laughter, or the child sitting up out of curiosity. From the parent's perspective, it seems as if it's important to remind the child not to make any movements to ensure that readings are accurate. Some kids are even able to help hold the cup or measuring tape (P6), writing down the numbers (P2), and holding the ruler (P9). P3 mention that she thinks she can now do it just her and her son (without additional help) now that she's already done it a couple times. Overall, kids are generally cooperative and don't experience any discomforts with home manometry because of limited sensation of the bladder and urethra.

-- The second subcode is **self-catheterizing children**. Clinicians and nurses have mixed opinions on how comfortable self-catheterizing children are with doing home manometry with the help of others. Some have said that kids are open to assistance especially because their parents are/were previously involved in catheterizations, while others did not hear any direct feedback with this manner. The former is confirmed by P1 and P2 (1 girl and 1 boy mom), who mention that their kids are comfortable with having their parents help. Some clinicians suspect that some kids may be so independent that they are past the age of wanting others help, and this is confirmed by P3: "She doesn't like it. She's getting so independent, she just kind of wants to be left alone." There are mixed thoughts on this topic, however it seems patient-dependent on a case-by-case basis. This is not particularly linked to either sex or a specific age group.

- The next patient-specific characteristic is sex: comparing differences and similarities between **girls vs. boys**. All excerpts within this code came solely from clinician and nurse interviews. Refer to Clinic Staff Memos for more information. Based on parent interviews, ease ratings for girl parents were a 3.5 while boys were a 2. Additionally, 2/5 girls required different catheters while only 1/4 boys did. All girls needed extension tubing - 3 who used it had a difficulty with the extender (1 of which was not offered it the first time around), while the 2 others mention they probably needed it but 1 didn't know how to use it and the other did not receive the materials. The difficulty in girls may be because, again, it is harder to catheterize girls in general. Girls typically use shorter catheters and therefore require either longer catheters solely for HM, or extension tubing, to be able to measure the pressures. This can become difficult if you're already used to your normal routine and you're being given materials that deviate from your norm: short vs. long, lubricated vs. non-lubricated, stiff vs. flimsy. Although these issues with the materials can apply to boys, more girls required different catheters and all required extension tubing, whereas only 1 boy mom (P3) was offered extension tubing and only needed to use it a few times but had no issues. In terms of catheters, only 1/4 boys required a different catheter, and this was difficult because her son was so young (2y) and usually used a female catheter, whereas for home manometry he required a male length one and it was floppy and hard to keep up and therefore mom always required more assistance from another person.

- The final code is **pathology**. F3 and A3 mention that children with SB do not feel any sensation in the genital area so home manometry should not bother the child or cause them any pain/discomfort. This is confirmed by 3 parents of 2 girls and 1 boy. However, it is important to note that because SB is such a complex condition, these kids already have so much on their plate and so many other specialties they need to see and treatments to consider due to their child's pathology (A1, A2, F2). P4, the mother of a 3-year-old girl, acknowledges that within the first year of life, there was so many more "concerns" that the family had to deal with. Home manometry may just be seen as an additional task on that list of "concerns" that the family needs to tend to, which is why it's important to consider pathology when setting expectations for home manometry. No, the children don't experience any discomforts due to their diagnosis; however, they are already "tasked with a lot of health care issues" and home manometry "becomes a bit of a burden on them to add yet another task" (A3).

SOURCES OF ERROR - There is room for error when performing home manometry without the guidance and assistance of a healthcare professional by your side. What are some factors that may contribute to these errors?

This theme aims to discuss the different sources of error that parents have experienced, and clinic staff have acknowledged with the actual process of performing home manometry. What issues do parents have in common? In what, if any, ways can we improve these reasons for error? I believe this theme, although it does not have the most references within transcripts, is super important. These are specific experiences that parents have shared in their technique and complexities with the procedure that we, as their clinical team, can evaluate and address to improve the overall HM experience.

- **Nuances of technique** is something that all parents, the chief of the division, and the nurses who teach HM have acknowledged. Now before getting into the specifics of what was discussed, I think it's important to note that in general, if a technique is not standardized, there is going to be room for error. This can be due to instructions given, materials provided, your home environment, the person you are doing the procedure on... there are various factors that you must take into account. Everyone's technique is different, however if most people are having the same issues, maybe there can be a way to standardize and simplify the process for all.

When diving into each parents' interview, I've found that all the nuances with technique are similar across age groups, sexes, and experience levels with home manometry and catheterizing. In terms of technique, the biggest issue seems to be finding a way to stay organized and finding the best, most efficient way to execute the procedure. The first step that some parents mentioned was remembering to have all the materials on-hand, on top of the regular CIC materials, and remembering to record. During HM, many parents questioned which order of steps to do the process in. When should you insert the catheter? When do you attach the extension tubing? Who should do what? How do you keep the child flat? How are you supposed to hold the ruler to measure if your hands are already preoccupied? What should they do if the child overflows? Every parent mentioned some type of nuance with technique, all relating to when to execute each step and how to make the process simple and smooth as possible. A list of each of the things with the number of times they were mentioned are listed below for reference.

girls:

- how to keep the child flat²
- should the child's legs be up or down
- juggling many things at once²
- issues with measuring tape/being able to hold it³
- when to record
- who should do what³
- forgetting to write it down
- how to stay organized
- how much to insert the catheter
- being able to hold the catheter up straight/in place⁴
- remembering to have all materials²
- remembering to record
- what steps to do it in
- when to attach extension tubing²
- what to do if they overflow²

boy:

- how to juggle multiple things at once with different people²
- issues holding the measuring tape²
- is the catheter up straight
- when to take measurements
- what to do if overflow
- remembering to have paper there
- remembering to have all materials
- how to keep them still

Overall, it's important to address the general issue of there being nuances with technique. If there is a way to standardize the technique, make certain steps simpler, or provide families with a step-by-step guide on how to do home manometry and who should do what, this may make HM much more feasible for families moving forward. It helps to have instructions on how exactly to do something especially if you are new to the process.

- **Uncertainty of accuracy** somewhat goes along with the previous code, **nuances of technique**. Interestingly, nearly half of the clinicians (4/9) and 2/3 of the nurses have acknowledged that there is only some level of confidence as to whether measurements that parents present are accurate or not. This observation is confirmed by the almost all the parents (6/9). Because of the nuances of technique, parents question themselves as to whether the measurements they are recording are actually accurate. There seemed to be a lot of second guessing in terms of if

they are doing it right. One mom even admitted to reporting numbers using the wrong measurements. Another mom questions what clinicians are looking for - is it consistency? What exactly is the expectation? Five parents have also mentioned that they received unclear instructions in terms of how often to do it (timeline, i.e., 1 week? 1 year?) and again, when to take measurements. Unclear instructions can lead to discrepancies in recordings. Overall, there should be a standardization of the teaching process and clarification in terms of what is expected of the families. This may help to not only improve accuracy, but also increase compliance and enhance understanding of the procedure.

- The final code that fit within this theme was **complex procedure**. Over half of the nurses and clinicians have acknowledged that home manometry is a complex procedure that involves too many variables, requires new equipment, is not a set system, and presents different challenges to the individuals performing it. Parents have also agreed that it's a process that has a lot of "moving parts" that you have to "juggle" at once (P8, P6). It's important to note that 3 clinicians and 1 mom of a young daughter describe home manometry as an "additional task." On top of being something that deviates from the family's norm and requires multiple steps and materials, it may also be seen yet another task to complete for families who already have so many other issues to monitor and treatments to give to their child not only with urology, but the other specialties that they see because of the child's primary diagnosis. These kids can a complex diagnosis that must be monitored throughout their entire lives, and it's important to realize that adding on another chore to their list of things to do may seem feel like a burden if the process isn't simple. It may be beneficial to devise a plan to simplify the process.

Overall, nuances of technique and the uncertainty of accuracy that are associated with this complex procedure may be addressed by standardizing the process of home manometry. With the help of the entire clinical team (both clinicians and nurses), a simplified process with clearer instructions show be created and made transparent to those who are expected to do it.

MATERIALS/TECHNOLOGY - What materials are provided and/or used for home manometry?

This theme aims to address the different types of equipment that patients and their families use for home manometry and how accessible they are to obtain. Some of these materials are provided by the clinic and may not be as user friendly as we assume they are. Other materials are not provided by the clinic, rather are supplied by the families themselves and used for this process. Each material will be discussed further.

- The one piece of equipment that was discussed more than the others was **extension tubing**. Every single clinician and nurse expressed issues and concerns with extension tubing - mainly revolving around the catheter-to-extension attachment, and some with regards to having access to this material. Six parents, 5 parents of girls and 1 of a young boy, discussed their experiences with the tubing. While the mother of the male mentioned that there were no issues with the extender, mothers of females had other experiences. Two moms had issues with connecting the tubing to the catheter (part of the process of their technique), 2 moms were not offered extension tubing even though they needed it, and 1 mom was given extension tubing but did not attempt to use it because it seemed too difficult. For the moms who had issues with connecting tubing, they did not fit or attach correctly to the catheters they were using. These moms, in addition to 1 other mom, had to figure out when exactly to connect everything to ensure that the urine would actually flow up. It was also difficult to hold the tubing up to measure. For the two moms who were not offered extension tubing the first time around, 1 mom was okay with doing home manometry without, however the other seemed frustrated about not being provided with it. For the 1 mom who did not attempt to use the tubing, her daughter was 1 at the time. This is the same mother that expressed concerns about all her daughter's other health issues, and it seemed as if adding on an additional material to a brand-new process was too complex to even attempt. Overall, extension tubing seems to be an issue mainly for girls. This is because, by nature, they don't require longer catheters and will therefore require extension tubing that connects to their catheters to measure the home bladder pressure. Clinic staff have acknowledged that only some of our catheters actually fit and lock into place with the extension tubing. It may be worthwhile to find a universal extension tube or universal connector (Damaser et. al) to provide to patients who require the extender. Possibly even giving a male length catheter to these kids to eliminate the extension tubing overall?

- **Catheters** were discussed in all FG's and interviews except one (A4). This is the main material that is required for home manometry because it is what's used to obtain pressure measurements and then drain the urine to obtain

volumes. According to clinicians and nurses, catheters are an issue for some patients because their normal CIC cath may not work for home manometry. For example, girls may require a different catheter specifically for home manometry because their normal cath doesn't attach to the extension tubing well. On top of that, it may be difficult to obtain the catheter brand/size/length that each individual patient needs to be able to do home manometry. Some parents have mentioned that the catheter deviates from their norm because it's lubricated (while their typical cath is non-lubricated) or it's flimsy (while their typical cath is stiffer). Most parents used their normal CIC cath (please refer to cases for this information). Spanish mom of a girl had issues with her regular catheter because it's too slippery to hold up and take measurements. She recommended using a foley. One mom of a young son had to use male catheters because his regular CIC cath was too short: the office did not provide enough for her to be able to do as many measurements as were requested of her. Overall, regardless of whether it's their usual catheter or not, 4 parents seemed to have issues with the catheters they were provided. 3 were girls and 3 used catheters that deviated from their norm. One mom mentions that parents who are used to catheterizing should be able to adapt to any new kind of catheter, however it seemed like other factors such as extension tubing and overall experience with CIC made it difficult to use the catheters. Overall, it is important to ensure that the catheters connect properly to the tubing and that parents are comfortable using these materials to take measurements before setting expectations for them.

- All except 1 nurse and 1 clinician acknowledged that **accessibility** of require materials is an issue within the clinic. This is mainly with regards to patients who require different catheters and/or extension tubing; however, some clinicians have noted that this issue has been remedied as of recent. Interestingly, only two parents faced barriers to receiving materials. The Hispanic mother of girl was not offered the extension tubing when she needed it the first-time doing home manometry. The mother of a young boy was not given enough male length catheters for the number of times the clinician asked her to do home manometry. It is important to note that although only 2 families had issues with receiving supplies, almost all the clinic staff acknowledged that it is an issue. Overall, it will be important to ensure that all the correct supplies are accessible and made available to families who need it when they are being asked to do home manometry.

- **Urine collection container** refers to the material used to drain the urine into for volume measurements. Although the clinic typically provides a urine basin/hat, some parents mentioned using their own materials for this. This code solely includes excerpts from the parent interviews. Everyone except the Spanish mother was provided with a urine basin. Three parents opted out of using this and used a small cup, 1 used urine bags attached to the catheter, and 1 used a tall handheld urinal. Four were girls and 1 was a boy. Additionally, 2 parents (1 girl, 1 boy) mentioned that they had to make sure their child didn't kick the urine basin, or it didn't tip over during the process. The remaining 3 did not express any issues with this. Responses for this category seemed to be all over the place, with no particular group having issues with the provided basin. What are ways to improve this area?

- A **measuring tool** was another material required to take pressure measurements. Patients are typically provided with a paper ruler. NP2 and N2 mentioned that these are hard to use because they are flimsy, thus requiring more personnel to help hold everything. Four parents opted out of using the paper rules and used their own, either plastic or wooden, rulers. One mom mentioned that although the clinic provided them with multiple paper rulers, they get urine all over them. She suggested that something more durable should be provided for pressure measurements. The ruler also makes the technique more difficult because, again, it's flimsy and requires multiple people to help. Overall, the clinic should switch out these paper rulers for more durable, perhaps plastic rulers. If this isn't possible, they can instruct parents to use a normal ruler at home to take these measurements. Most of if not all households typically have at least 1 ruler.

- The final code was **additional materials**. Only two parents (1 boy 1 girl) mentioned the use of additional materials outside of what was provided and is required. The mom of a daughter used chux just in case the urine overflowed or spilled out, and the mom of a son used gloves and wipes. The mother of the daughter suggested supplying families with baby wipes or betadine. Although only two parents mentioned using additional materials, this was not a specific that was asked throughout the interviews. Other families may potentially require these materials and just did not mention them. Although not a major concern, it may be worthwhile to consider providing patients with these materials if possible and if needed.

HOME ENVIRONMENT/CONTEXT - What is the patient's home and family life like, and what should we consider with regards to these factors?

This theme discusses considerations to take with regards to the patient's home environment and family context. Codes included in this theme are important to consider when setting expectations for home manometry.

- **Personnel** are required to assist with home manometry because the child is not physically able to do it themselves. This was discussed in every interview/FG. Almost all clinic staff have mentioned that a second person is required to perform home manometry. Few clinicians and nurses mentioned that in their experience, some families have expressed concerns as to whether this would be feasible to do with just 1 person and that they do not have any additional help at home.

Only two mothers of girls were able to do home manometry independently and without any additional help. For the first mom, this may be because she had experience with not only catheterizing her daughter, but with home manometry in general because her eldest daughter had done it before. Her daughter also was able to self-catheterize the first time they were asked to do home manometry. Second mom did not have anyone to help her, so she had difficulty doing this alone but just learned to do it because she had to. One Hispanic father of a boy mentioned that him and mom were able to do home manometry without the other, however this was much more difficult compared to having two people to help. Using a durable, wooden ruler helped ease the process when only 1 person was available.

The remaining 6 parents emphasized the need for having an additional person there. One mom said her and dad work from home and have adjusted their lives to their son's needs, however not everyone is fortunate to do that. Another single mother had to do home manometry on the weekend and make sure his father or mom's sister were present for a few days to help. One mom of a daughter mentioned that she "ended up in tears" when trying to do this independently. Overall, it's crucial that families have two sets of hands available to help with home manometry, at least for the first time. Other factors such as the measuring tool and child cooperation are what required an additional person to help.

- How well does home manometry fit into each patient's **everyday routine**? This was brought up in most clinician interviews and all parent interviews. In general, based on their personal experiences, clinicians do not ask families to do home manometry during school, some ask families to do it over the weekend or whenever there is downtime and they are free. They've also acknowledged that this isn't an everyday thing, it's only to be done over a short period of time in preparation for a visit or UDS test. A4 and NP1 mention that it fits into their regular CIC schedule. In response, parents have said they dedicate specific days/times to do home manometry (ex. over the weekend, at night when there's more downtime), but it generally does not interfere with their everyday schedules because these kids are already catheterizing. It's just a few more steps that requires a little more time and ensuring that another person is there to help. One single mother did say that the additional time it takes changes the routine for them and disrupts the day. This may be related to her overall home environment and the fact that she does not have additional people available to help 24/7. Overall, home manometry doesn't seem to be much of an issue in terms of everyday routines.

- Home manometry takes **time** and effort from the family's end - are they able to set aside time to perform this? Three clinicians have acknowledged that home manometry takes additional time, and compliance may be dependent upon the family's ability to find the time to do it. Refer to case classification for times. According to 6 families, in general, home manometry takes an average of 5 more minutes than regular catheterizations. One mom mentions that home manometry is not a quick process - it's time consuming. While parents do not express any major concerns or frustrations with it taking longer, they do see it as time consuming. Clinicians should warn families of this when they are being instructed to do home manometry. No families expressed concerns with finding the time to do home manometry because catheterizing is already part of their regular routine, taking measurements just takes a few extra minutes.

EDUCATION/LEARNING EXPERIENCE - What are the different ways that families are taught to do home manometry?

The final theme aims to discuss the different forms of education available within the clinic and the experiences that parents/caregivers have had with each. Some parents received only one form of education while others received multiple. It is important to identify the pros and cons of each type of education process.

- **Hands-on demonstration** seems to be the current method of education as expressed by clinicians the nurses teaching home manometry themselves. Typically, an appointment is set up, nurses demonstrate how to do home

manometry *on the child* with the parent's help and get the first measurement done in the office. Some clinicians express that those who receive hands-on demonstrations seem to understand better and bring back more accurate numbers. Only 3 parents (P1, P3, P5) were taught how to do home manometry using this method. The similarity between these patients is that they are all TK patients. All 3 kids were 4 years old at initial introduction, but the initial teaching ranged from 4 to 8 years ago. P6 mentions that she had already performed home manometry before a demonstration was done. This is also one of TK's patients. For the remaining 6 kids, they had all initially been taught home manometry over 2 years ago. Hands-on demonstrations in the clinic may not have been implemented at the time. Overall, almost all parents recommended hands-on demonstrations. This would help because some people are visual learners. Please see more in justifications and reasoning for hands-on demonstrations preceding sections.

- **Video** is the second form of education that is shown preceding hands-on demonstrations and is currently in place in the clinic. Videos were created using the One Wish Grant received in 2018. Only one mom of a daughter "thinks" she was shown a video the first time (P5). The remaining parents were not shown a video. This is likely because the video was not finalized or in place until more recently. Clinicians believe that the videos are a great source of teaching, that families enjoy them (F3), and that those who see them have a better understanding (F2), however NP2 expresses that the videos are a great additional tool but should not substitute the hands-on demonstrations. Three parents have mentioned that it would have been helpful to have access to/knowledge about the videos while first learning about the process.

-7 parents received **verbal explanations** on the steps of home manometry and how it should be done. Generally, the verbal explanations were simple and self-explanatory, but actually executing it themselves was a different story. One mom needed additional help later. One mom said the explanation was not detailed enough because the nurses seemed in a rush to get to the next patient, while another mentioned that the nurses were good about making sure she understood the process before leaving the clinic. These differences in perspectives may be due to the fact that nursing staff changed over the years, and they may not have had interactions with the same nurses. Although verbal explanations are descriptive, these should not be the only forms of education that are available for families learning a novel technique.

- All parents received a **pamphlet** with instructions, pictures, and a log to record measurements on. One mom did not receive a pamphlet the second time she did home manometry, and therefore no log to record on - she used a random piece of paper instead. No one seemed to have issues with this form of education.

- 3 parents had nurses who were **offering additional support** after their initial instructions. These parents seemed comfortable leaving the office knowing that they had the opportunity to contact nurses if they had any additional questions.

- Two parents received **non-physical demonstration**, and one patient's physician was **drawing diagrams** of the process for her. The former parents did not have any issues with the non-physical demonstration; however, the latter was "a little bit uncomfortable and frustrated by it" (P8). In addition to drawings, P8 received verbal instructions and the pamphlet. This learning experience may have been frustrating because if the procedure is novel and difficult, less hands-on and visual instructions may be hard to replicate at home.

Appendix G. Codebook

Code Name	Child/Grandchild Code	Definition	Files	References
Evaluative			18	259
Understanding		1. Personal thoughts/opinions on home manometry 2. Interpretations of how well patients and families understand home manometry and its importance	17	63
Recommendations		2. Suggestions on ways to improve home manometry/its related experience	16	61
Clinical Utility		2. Thoughts/perceptions on the benefits and usefulness of home manometry	17	53
First impressions		2. Initial reactions, questions, and perceptions during initial introduction	18	49
Home manometry vs. Urodynamics		2. Comparisons and contrasts between the novel and gold standard methods of measuring bladder pressures/volumes	17	38
Child feelings		2. Child's thoughts/feelings towards home manometry	11	29
Control/Independence		2. Feelings of control, self-empowerment, and independence in the patient's care	8	18
Maturity/Patient-Specific Characteristics			18	141
Experienced vs. non-experienced		1. Differences in perspectives surrounding home manometry with respect to maturation and patient-specific attributes 2. Differences between CIC and home manometry experience levels	13	36
Practice makes perfect		3. The idea that the more you do home manometry, the better/easier it gets	7	8
Older vs. younger		2. Differences between younger children (babies/toddlers) and older children	11	32
Child cooperation		3. The child's ability to physically stay still and cooperate with the parent throughout the home manometry procedure	17	49
Self-catheterizing children		3. Considerations for children who are able to perform CIC independently	12	18
Girls vs. boys		2. Behavioral and physical attributes between boys and girls that affect the home manometry process	8	19
Pathology		2. Ideas regarding spina bifida pathology and its effects on the child	7	10
Sources of Error			18	122
Nuances of technique		1. Factors surrounding and contributing to erroneous measurements	11	37
Uncertainty of accuracy		2. Difficulties with technique that are identified during home manometry execution	12	31
Complex procedure		2. Thoughts/perceptions/concerns on the accuracy of pressure and volume measurements	10	20
Materials/Technology			18	119
Extension Tubing		1. Discussions, experiences, and thoughts surrounding the materials used for home manometry	14	58
Catheter		2. Extension tubing provided specifically for home manometry, experiences with the catheter-to-extension attachment	16	44
Accessibility		2. Descriptions of the catheter used during home manometry and comparisons with the CIC catheter (if applicable)	13	33
Urine collection container		2. How accessible these materials are to families and barriers that the clinic faces to get them	9	21
Measuring tool		2. Container used to collect urine during home manometry	10	18
Additional Materials		2. Measuring tool used for home manometry pressure	2	3
Home Environment/Context			18	98
Personnel		2. Any additional materials used outside of what is typically provided and required to do home manometry	17	55
Everyday Routine		1. Considerations regarding the patient's home environment and family dynamic	16	30
Time		2. Availability of and need for additional hands/personnel to help with home manometry	10	17
Education/Learning Experience			18	59
Hands-on demonstration		2. How this fits into the patient/parents everyday routine with respect to work, school, etc.	13	28
Video		2. Time requirement for home manometry and the amount of time available to families	14	21
Verbal Explanation		1. Information regarding the home manometry education process and the pros/cons involving each 2. In-person, hands-on demonstration with nurse + family	8	21
Pamphlet		2. Playing the instructional video from YouTube for the respective child (M vs. F, English vs. Spanish, urethra vs. monti/mitrofanoff)	11	16
Offering Additional Support		2. Verbal explanation of the steps of the process	4	4
Non-physical demonstration		2. Paper handouts with instructions, images, and a log to record at-home measurements	2	3
Drawing diagrams		2. The option to call the nurses after initial teaching if any additional questions arise 2. Demonstration using materials but not performed directly on the child 2. Drawing diagrams of what the process should look like	2	3