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The Impact of Pelvic Floor Therapy on Adult Women with Interstitial Cystitis/Painful Bladder Syndrome

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THE IMPACT OF PELVIC FLOOR THERAPY ON ADULT WOMEN WITH
INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME

By

Christina Marie Shuker, RN, MSN, CRNP

Submitted In Partial Fulfillment of the Requirements

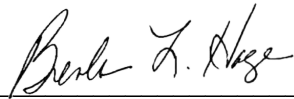
For the Degree of

Doctor of Nursing Practice

Misericordia University

July 2015

Signature of Faculty Reader



Signature of Director of DNP Programs

Date

8/24/2015

Date

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Abstract

Interstitial cystitis/painful bladder syndrome is a major source of chronic pelvic pain and disability affecting women of all ages, predominantly age 18 years and over. Estimates of prevalence among US women range from 2.7% to 6.5% translating to 3.4 and 7.9 million women who have symptoms consistent with this debilitating condition (Kerr, 2009). The bladder epithelium has been the focus for diagnosing and treating symptoms of IC, however taking focus away from the bladder has opened the door for clinicians to explore pelvic floor dysfunction indicating that pelvic floor therapies should be a first line treatment for those women with IC/PBS (Peters & Carrico, 2006).

In this evidence based practice change project, the problem of IC/PBS has been identified in a Urology/Gynecology practice in Northeastern Pennsylvania. Based on the clinical problem, a thorough literature review emphasized the solution of pelvic floor therapy as part of usual care to improve symptoms associated with IC/PBS. The evidence based change project was based on the Rosswurm and Larrabee Model. Several meetings were held with the office staff along with a local pelvic floor therapist to discuss details of the EBP change project including the effects this may have on the practice and patient centered care. The project was submitted to Misericordia University's Internal Review Board and IRB approval was obtained for this project to move forward.

Women who were 18 years or older who presented with symptoms of IC/PBS receive a complete history and physical examination, voiding diary, post void residual, full gynecological examination, urinalysis with culture, urine cytology if the patient had a smoking history, and a pain evaluation was performed. These women were invited to

participate in the EBP change project. The O'Leary-Sant questionnaire which measures urinary and pain symptoms as well as how problematic these symptoms were to quality of life was performed for a baseline measure. The patient was then educated on usual care in conjunction with pelvic floor therapy. The EBP change project was explained and informed consent was reviewed. If the patient chose to be a part of the project, 8 to 12 sessions of pelvic floor therapy was provided by a trained physical therapist at a local rehabilitation center. The patient then returned to the practice setting at 4 weeks and 8 weeks for follow-up evaluation at which time the O'Leary-Sant questionnaire was re-administered.

The pre-test and post-test data was compiled to determine if women showed improvement of symptom and problem indices related to IC/PBS. All of the women in the project reported symptom and quality of life improvement.

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Chapter One: Overview of the Problem of Interest

According to the Interstitial Cystitis Association (2014), Interstitial cystitis (IC) is a chronic, severely devastating urinary bladder disease characterized by symptoms of pelvic pain, excessive urinary frequency, urgency and nocturia that affects between four and 12 million people in the United States. Although children and adult men can get IC, women account for 90 percent of the cases with the average age of onset of 40 years. Twenty-five percent of these women are under the age of 30 years. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) 2011, developed inclusion and exclusion criteria for patients who were being evaluated for Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS) with inclusion criteria consisting of bladder pain, urinary urgency and frequency, bladder capacity of less than 350 mL and cystoscopic evidence of a Hunner's ulcer. However this criteria would have misdiagnosed more than 60% of patients diagnosed by researchers as definitely having or likely to have IC/PBS (Metts, 2001). The NIDDK (2011), has expanded its definition to include not only those with pinpoint hemorrhages or bladder ulcers identified on cystoscopy and hydrodistention, (which is a procedure performed under general anesthesia that stretches the bladder by filling it with water), but to also include those with only symptoms of urinary urgency, frequency, and pelvic pain who had identifiable causes ruled out, such as urinary tract infections, bladder cancer, and endometriosis. Researchers have recently started to use the term "painful bladder syndrome" (PBS) to describe such cases as well (Khoudary, Talbott, Bromberger, Chang, Sonder & Davis, 2009).

Although IC/PBS accounts for a small percent of health care visits, it's economic burden is significant. According to Payne, Joyce, Wise & Clemens, (2007) the rate of hospital outpatient visits between 1992 and 2001 for IC increased two-fold with physician office visits increasing three-fold. The annual rate was 102 office visits per 100,000 of the population with the diagnosis of IC being associated with a two-fold increase in direct medical costs. Between 1994 and 2000 the annual national expenditures for IC were stable at \$37 million however the annual costs for painful bladder syndrome increased from \$481 million to \$750 million.

IC/PBS symptoms have shown to result in poor quality of life involving sleep dysfunction, depression, anxiety, and stress, which also affect family relationships and responsibilities. The need for innovative ways to treat IC/PBS has become a public health goal to help decrease health issues and improve quality of life (Bosch & Bosch, 2014). Because of misdiagnosis, the accurate burden of IC/PBS on the health care system in the United States is undoubtedly underestimated in relation to administrative data that rely on physician coding to identify this disorder (Payne, Joyce, Wise & Clemens, 2007).

The purpose of this evidence-based practice change project is to evaluate the impact of pelvic floor therapy as usual care on improvement and reduction of IC/PBS symptoms. According to guidelines offered by the American Urological Association (2013), usual care of IC/PBS includes first-line treatment, which involves patient education, self-care practices and behavior modification such as diet modification to include the elimination of caffeine, alcohol, acidic or spicy foods, bladder retraining, self-hypnosis, gentle, non-jarring exercise/stretching, wearing comfortable, non-binding

clothing, shoes, hosiery and underwear as well as stress management and coping techniques to include relaxation and visual therapy. Second line treatments include manual maneuvers that resolve pelvic, abdominal and/or hip muscular trigger points as well as Kegel exercises and multimodal pain management approaches to include pharmacological interventions such as oral and intravesical therapy. Further treatment guidelines include surgical options, which will not be addressed as usual care in this practice change project.

Unfortunately, even in conjunction these therapies are often suboptimal in alleviating IC symptoms perhaps in part because many of the patients also suffer from pelvic floor spasms, which cause pelvic pain. Women with IC and pelvic pain were referred to the Beaumont Women's Initiative for Pelvic Pain and Sexual Health program where a comprehensive patient history and pelvic examination were completed by a certified women's health nurse practitioner. Seventy women were evaluated with the mean age of 45 and standard deviation of 12 years. The majority (87%) of the sample had levator pain. The levator ani muscle or pelvic floor muscle is a broad, thin muscle situated on the side of the pelvis. The average levator pain score was 4.48 out of 10. If pelvic floor dysfunction is diagnosed in IC patients, then current literature supports that appropriate manual physical therapy techniques by properly trained clinicians should be offered to patients who present with this disease (Peters, Carrico, Kalinowski, Ibrahim, & Diokno, 2007).

Background

An 1836 textbook by a Philadelphia surgeon Joseph Parrish documented a

syndrome of chronic frequency, urgency, dysuria and pelvic pain, which he coined “*tic dolooureux* of the bladder”. This diagnosis was used to describe painful, idiopathic nerve disorders. Parrish accredited this term to his mentor, Dr. Phillip Syng Physick who applied it to patients with severe lower urinary tract symptoms with the most common etiology being bladder stones. By 1808, Physick had developed the concept of bladder inflammation, or bladder ulcer in the absence of bladder stones (Parsons & Parsons, 2004).

According to Peters and Carrico, (2006), more than ninety years ago, interstitial cystitis was described as a distinct ulcer clearly seen on cystoscopy. Therefore the bladder epithelium had been the single focus of the pathogenesis of IC. Another assumption was that the bladder stores toxic urine, and for the bladder to function as a storage organ, it must protect itself from irritants and toxins in the urine. If this protective layer is compromised, the urine will act as an irritant and, penetrate into the detrusor muscle leading to proliferation of mast cells, which causes nerve upregulation, and ultimately causes urinary urgency, frequency and pain. Therefore treatment had been directed at treating the bladder epithelium. However, only 10% to 20% of patients with symptoms of IC have ulcers within their bladder.

Therefore the clinician must first consider the patient to have chronic pelvic pain thus using the term IC or PBS for only those patients whose symptoms are identifiably of the bladder origin. Taking the focus away from the bladder has opened the door for clinicians to explore other causes and treatment for this complex syndrome. Myofascial pain which affects the muscles and the sheath of the tissue and hypertonic pelvic floor

dysfunction are present in as many as 85% of patient with IC. A noxious stimulus may trigger the release of nerve growth factor in the periphery causing the mast cells in the bladder to release pro-inflammatory substances therefore causing neurogenic inflammation of the bladder wall. This hypertonic state may result in decreased muscle function, increasing myofascial pain. The pelvic floor muscles then become a source of pain even when the bladder is treated (Peters & Carrico, 2006)

Significance

The RAND Interstitial Cystitis Epidemiology (RICE) study was an observational study from 2006 to 2009 that sought to develop a case definition for IC/PBS with known sensitivity and specificity and to estimate the prevalence of the disease, which at that time had never been done using a large-population model (Konkle et al., 2012). This study was lead by researchers from RAND Corporation measuring the prevalence of a constellation of symptoms that are consistent with those conditions in the population of U.S. women. The researchers conducted telephone interviews with a sample of nearly 600 women diagnosed by clinicians with IC/PBS and or other similar comorbidities to pinpoint questions that had identified women diagnosed with IC/PBS and differentiated them from women diagnosed with other conditions. A second phase of the study used a two-stage population screening tactic. First, a collection of telephone interviews was generated from nearly 100,000 households to screen for the presence of women with bladder symptoms. A second step of screening was conducted to identify women who met IC/PBS criteria. This study found that approximately 2.7% to 6.5% of American women age 18 years and over met symptom criteria for IC/PBS. When extra-populated to

the general population, these numbers translate to between 3.4 and 7.9 million women who have symptoms consistent with this debilitating condition (Kerr, 2009).

The key to significant symptom reduction and improved quality of life includes early diagnosis and treatment. Yet this disease is often under diagnosed or misdiagnosed, both because of the many comorbidities found in patients with this disease and because symptoms overlap with those of other common conditions. These patients are turning to family practitioners first for help, yet recent surveys of clinician practices have found significant knowledge gaps with regards to IC/PBS among primary care practices (Theoharides & Whitmore, 2011). Although interstitial cystitis has been recognized since 1836, its etiology and pathogenesis are still unclear. Therefore it is not surprising that IC/PBS patients suffer on average five to seven years and often visit as many as eight clinicians before the correct diagnosis is made.

No infectious organism has been recognized as a cause for IC/PBS and symptoms associated with this disorder are similar to those of a number of conditions, including urinary tract infections, overactive bladder, allergies, chronic fatigue syndrome, endometriosis, fibromyalgia, and vulvodynia to mention a few. Therefore IC/PBS is largely a diagnosis of exclusion. When a patient presents with suprapubic discomfort or pressure related to bladder filling and increased urinary frequency lasting for several months, these other related conditions must be ruled out. Basic assessment should include a medical history, voiding diary, post void residual, full gynecological examination, urinalysis with culture, urine cytology if the patient has a smoking history, symptom questionnaire and pain evaluation (Theoharides & Whitmore, 2011).

Question Guiding the Inquiry

Evidence based practice is a problem-solving approach to the delivery of health care that links the best evidence from studies and patient care data with clinician expertise and patient preferences and values. When delivered in a framework of caring and in a supportive organizational culture, the highest quality of care and best patient outcomes can be achieved (Overholt, Melnyk, Stillwell, & Williamson, 2010).

The question guiding the inquiry for this evidence-based change practice is: *“In women 18 years and older with interstitial cystitis/painful bladder syndrome, does pelvic floor therapy as part of usual care improve symptoms as indicated by a reduction in the patients O’Leary-Sant Interstitial Cystitis Symptom and Problem Index (ICSI) score over an 8 week period?”*

The patient population (P) represents the population or topic of interest. This evidence-based project has focused on women aged 18 years and older with interstitial cystitis/painful bladder syndrome. The population of interest was chosen because the RAND interstitial cystitis epidemiology study aimed at estimating the national prevalence of interstitial cystitis/painful bladder syndrome has indicated that between 3.3 and 7.9 million American women older than 18 years of age as having bladder symptoms associated with IC/PBS (Konkle, et al., 2012).

The intervention, (I), included pelvic floor therapy as part of usual care to improve IC/PBS symptom and problem index. According to Bosch and Bosch (2014), the management of IC/PBS includes first-line treatment, which includes patient education, self-care practices, behavior modification, stress management and coping techniques.

Guidelines offered by the American Urological Association (AUA, 2013) discuss second-line treatments to include manual maneuvers that resolve pelvic, abdominal and/or hip muscular trigger points, lengthen muscle contractures, and release painful scars and other connective tissue restrictions, as well as Kegel exercises and multimodal pain management approaches to include oral and intravesical pharmacological interventions. These guidelines provided by the AUA included an additional systematic review conducted July 2013 to maintain guideline currency with newly published relevant literature. A high evidence strength rating demonstrates appropriate manual physical therapy techniques available by appropriately trained clinicians should be offered to patients who present with pelvic floor tenderness.

A physical therapist who is experienced in treating people with pelvic pain or women's health problems, having completed a residency or fellowship in women's health physical therapy and having the advanced knowledge, experience, and skills that apply to this condition was recommended. The initial visit consisted of an assessment that may include looking for both external muscle problems and an internal exam if tolerated. If the internal exam could not be tolerated it would be postponed until it can. The physical therapist would then evaluate the patient while standing, walking and sitting in order to judge whether their joints or posture may affect the pelvic floor as muscle problems in the lower back, hips, buttock or thighs can stress the pelvic floor muscles contributing to pain.

The foundation of physical therapy for pelvic pain is hands on treatment, which should include both external and internal techniques, however therapists will not use

internal techniques until the patient is comfortable with them. External techniques may include; skin rolling, deep tissue massage (myofascial release), trigger-point therapy to release tight spots, nerve release and joint mobilization. To treat the pelvic floor internally, the therapist may insert a finger or an appropriate instrument in the vagina or rectum to massage the muscles and connective tissue to release trigger points. A common trigger point release technique includes pressure on the spot until it relaxes. Internal massage is also used to release nerves. Pelvic floor therapy is normally covered by the patients insurance (ICA, 2013).

The comparison group or (C) included multimodal therapy and consist of patient education in regards to dietary modification to include elimination of bladder irritants, bowel function, sexual activity, stress management, self-care and emotional support which is deemed usual care (Bosch & Bosch, 2014).

According to Peters and Carrico (2006), despite many studies evaluating the multiple therapies directed at treating the epithelium for IC/PBS, few have proven effective when studied in a rigorous approach using a placebo-controlled trial. As many patients have not found symptom relief with these therapies alone, pelvic floor dysfunction is frequently believed to be present in these patients.

The intended outcome (O) for this capstone project was to improve symptom management. Barkin (2002) reports the importance of quantifying the patient's symptoms such as pain and voiding complaints as well as how bothersome they are. He discussed the O'Leary-Sant Interstitial Cystitis Symptom and Problem Index, which was developed to do just that. Results of this self-administered questionnaire provide a way to grade the

patient with respect to urinary and pain symptoms, and how problematic the symptoms are for the patient.

A study by Bogart, Suttorp, Elliott, Clemens, and Berry (2012) evaluated a quality of life scale adapted from the RICE BSE-6 scale which was used to assess the impact of IC/PBS on life and sexuality, and was modified based on expert opinion and focus group work to specify items valuable to IC/PBS to validate scales of symptom severity, mental and physical health related to quality of life, such as depression, coping, and perceived control. The RICE BSI-6 showed excellent internal consistency and strong validity. It will also be used to examine effects of psychosocial and treatment interventions on Quality of life among women with IC/PBS. These outcomes would be measured at the initial visit, 4 weeks and 8 weeks.

In order to properly apply the intervention, an appropriate time (T) had to be established. This evidence-based practice change project occurred over an 8-week period. Fitzgerald, et al. (2012) have noted improvement of IC/PBS symptoms after patients received up to ten, 60-minute treatment sessions over a 12 week period of time however due to time constraints, evaluation for this EBP change project would evaluate symptom and problem management over an 8 week time period.

System and Population Impact

IC/PBS symptoms are associated with pain; causing poor quality of life with sleep dysfunction, sexual dysfunction, depression, anxiety, and stress. Employment is problematic or impossible in 84% of those affected and family relationships and responsibilities are negatively affected in 70% of these patients. The cost of medical care

for an IC/PBS patient is more than \$11,000 per year with narcotics being the most commonly prescribed class of medication. IC/PBS is a chronic condition that can be controlled, but not cured. Aside from causing physical suffering, chronic diseases place an immense economic burden on our society. Psychological factors include chronic pain, misdiagnosis, multiple trips to the bathroom causing lack of sleep, multiple doctor's visits, various diets and unnecessary antibiotics (Bosch & Bosch, 2014).

The RAND Interstitial Cystitis Epidemiology Study (RICE) group administered a questionnaire to 599 women with IC/PBS, overactive bladder, endometriosis or vulvodynia. The sensitivity and specificity of each definition was calculated using physician assigned diagnosis as the standard reference. No single epidemiological definition had high sensitivity and high specificity. The findings indicated that 6.5% of American women met the high sensitivity IC/PBS criteria and 2.7% met high specificity IC/PBS criteria, indicating that painful bladder symptoms are common in the US. This study compared basic clinical and demographic characteristics of all women meeting the criteria with those of previously described IC/PBS in a clinical cohort. Some differences were observed among these clinical and community groups, however overall IC/PBS samples were strikingly similar with the most demographic difference observed being the lower rate of health insurance. These findings strengthen the body of evidence that suggests that this disorder is significantly burdensome, and likely under-diagnosed and undertreated in the United States.

IC/PBS must be viewed as a chronic disease requiring a long-term health care plan. Validation of this disease is important to patients, as many have been living with

IC/PBS symptoms for years. Patients need to be reassured that they are not the only persons with these symptoms and that they are experiencing a well-described syndrome that is not life threatening and is treatable. According to Bosch and Bosch (2014), both medical and social treatment options should be utilized in the care of this disease, as there are social and environmental factors involved.

Purpose, Aims/Objectives

Interstitial cystitis/painful bladder syndrome is a visceral pain syndrome with a significant impact on quality of life. The main aims of this project were as follows: (1) to determine the presence of pelvic floor dysfunction in women within a women's health practice diagnosed with interstitial cystitis, painful bladder syndrome; (2) to evaluate the impact of pelvic floor therapy as part of usual care in adult women age 18 years and older with interstitial cystitis/painful bladder syndrome; (3) to promote symptom reduction with pelvic floor therapy over an 8 week period. If pelvic floor dysfunction is found in IC/PBS patients, then therapy targeting the pelvic floor musculature should be considered a part of a first line approach to treating this disorder.

Chapter Two: Review of Evidence/Literature

Methodology

An extensive search of current literature was first conducted to answer the PICO-T question; In women 18 years and older with interstitial cystitis/painful bladder syndrome, does pelvic floor therapy as part of usual care improve symptoms indicated by reduction in the patients O’Leary-Sant Interstitial Cystitis Symptom and Problem Index (ICSI) score over an 8 week period.

Initially a search was conducted through databases such as Cochrane database of systemic reviews, National Guideline Clearing House, Sigma Theta Tau, Evidence Based Nursing, and Health Information Resources. Unfortunately, a search of these databases yielded very little results. One guideline published by the American Urological Association on the diagnosis and treatment of IC/PBS was found. The search was then broadened to include a thorough search of CINAHL Complete, MEDLINE, and Health Source: Nursing/Academic Edition. Articles included were published after the year 2004 to ensure recent literature as well as sufficient quality studies.

Key terms used in the search included: title, keywords and abstracts of interstitial cystitis, painful bladder syndrome, pelvic floor tenderness, pelvic floor dysfunction, pelvic floor therapy, management, oral management, oral therapy, behavior management, assessment, diagnosis, treatment, complementary therapies and evaluation of symptoms. “Interstitial Cystitis” and “Painful bladder syndrome” yielded 498

- Years 2004 -2014 yielded 472
- Academic Journals yielded 414

- Females yielded 226
- Adults 19+ years yielded 122

“Interstitial Cystitis” and “Pelvic Floor Tenderness” yielded 2 including academic journals.

“Interstitial Cystitis” and “Pelvic Floor Dysfunction” yielded 13; included years 2004-2014

- Academic Journals yielded 14
- Females / NA
- Adults 19+years yielded 5

“Interstitial Cystitis” and “Pelvic Floor Therapy” yielded 28; included years 2004-2014, all Academic Journals

- Females 28
- Adults 19+ years yielded 10

“Interstitial Cystitis” and “Management” yielded 225; included years 2004-2014

- Academic Journals yielded 208
- Females yielded 103
- Adults 19+years yielded 37

“Interstitial Cystitis” and “Oral Management” yielded no results

“Interstitial Cystitis” and “Oral Therapy” yielded 5; included years 2004 -2014

- Academic Journals yielded 5
- Females /Adults 19+ years /NA

“Interstitial Cystitis” and “Behavior Management” yielded no results

“Interstitial Cystitis” and “Assessment” yielded 162; included years 2004-2014

- Academic Journals yielded 155
- Females yielded 107
- Adults 19+years yielded 83

“Interstitial Cystitis” and “Diagnosis yielded 686; included years 2004-2014

- Academic Journals yielded 628
- Females yielded 429
- Adults 19+years yielded 256

“Interstitial Cystitis” and “Complementary Therapies” yielded no results

“Interstitial Cystitis” and “Evaluation of symptoms” yielded 2; included years 2004-2014 and academic journals

Articles were included if they were published after 2004 to ensure recent literature and sufficient quality studies. All articles included those published in English; however, articles from countries other than the United States were included as long as they were available in English. Articles were limited to the care of adults. Articles that pertained to interstitial cystitis in men were excluded because the PICO-T question specifically addressed the management of IC/PBS in women. However, studies that included both men and women could not be excluded, due to findings being pertinent to the management of IC/PBS in women. The search was not limited to nursing literature as other disciplines such as physical therapy have contributed extensive research on the topic of interstitial cystitis/painful bladder syndrome and pelvic floor therapy.

An advanced search aimed at selecting articles with a high grade of evidence with

special limitations to include Randomized Controlled Trials, Systematic Reviews, Practice Guidelines, Meta Analysis and Journal Articles. A comprehensive review had determined that the AUA Guidelines are the most comprehensive guideline currently available. The search for unpublished studies included: Google scholar and dissertation abstracts.

Findings

The priority in selecting articles was to choose articles with a high grade of evidence whose content most specifically addressed the PICO-T question. When choosing which articles to evaluate, the hierarchy of evidence that was used to select articles for inclusion, and to evaluate those articles, was presented by Fineout-Overholt, Melnyk, Stillwell, and Williamson (2010). The levels of hierarchy are as follows from the lowest level of evidence to the highest: 1 expert opinion, 1 cohort study with high risk of bias, 2 randomized control trials (RCT's) and 2 systematic reviews.

The American Urological Association (AUA) Guidelines for the Diagnoses of and Treatment of Interstitial Cystitis/Painful Bladder Syndrome by Hanno et al. (2011), was analyzed as part of the review by using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument. The AGREE instrument was rated by this author on its performance in the following six categories: scope and purpose 75%, stakeholder involvement 70%, rigor 70%, clarity 88%, applicability 30%, and editorial independence 75%. The AUA guideline was developed by a committee of urologists, nurses, and other clinicians with specific expertise on IC/PBS.

The Committee conducted a systematic review of MEDLINE, of publications in English published between 1983-2009. Meta-analysis of randomized controlled trials and systematic reviews were used to identify peer-reviewed publications relevant to the diagnosis and treatment of IC/PBS. The review yielded an evidence base of 86 treatment articles after application of inclusion/exclusion criteria. Inclusion criteria consisted of the terms, “interstitial cystitis”, “painful bladder syndrome”, “bladder pain syndrome”, and “pelvic pain” as key words capturing the various diagnostic procedures and treatments known to be used for such syndromes. Preclinical studies (animal models), pediatric studies, commentary, and editorials were excluded. An additional systematic review was conducted in July 2013 to maintain guideline current with newly published relevant literature. This review identified an additional 31 articles relevant to treatment. When sufficient evidence was present the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate), or C (low). Additional treatment information was provided as clinical principles and expert opinion when insufficient evidence existed.

Treatments that may be offered are divided into first line treatments to include general relaxation and stress management, pain management, education and behavior modification. Second line treatments include pelvic floor therapy, multimodal pain management, oral medications and intravesical treatment. Third line treatment recommends cystoscopy with hydrodistention, which is a procedure performed under general anesthesia that stretches the bladder by filling it with water. If Hunner’s lesions are present then fulguration, which is electrocautery of the lesions, should be performed.

Fourth line treatment includes injections of abotulinum toxin A into the detrusor muscle, fifth line treatment oral cyclosporine and sixth line treatment major surgery to include substitution cystoplasty which is excision of the symptomatic bladder with reconstruction to produce a low pressure reservoir using a segment of remodeled intestine anastomosed to the bladder remnant or urinary diversion with or without cystectomy which includes rerouting urine flow from its original pathway.

The chief weaknesses of this guideline are essentially due to the lack of available scientific research to support the guideline and disease process of IC/PBS. The medical community wrote the guideline for healthcare providers and patients based on subjective evidence from experts caring for patients with IC/PBS. The authors did not address the cost of treatments or consider any contributions from patients with IC/PBS. There is little evidence supporting a single treatment of choice for the majority of IC/PBS patients. Limitations include poorly defined patient groups, small sample sizes, lack of placebo controls for many studies likely overestimating efficacy, short follow up durations and the use of a variety outcome measures.

Anderson and Perry (2006) completed a MEDLINE, EMBASE and AdisBase search to examine Pentosan Polysulfate (Elmiron) use in the relief of bladder pain or discomfort in IC vs. placebo and other therapies such as hydroxyzine and cyclosporine's. A randomized, double blind, multicenter, dose ranging, 32-week study (n=380), compared the efficacy of 300, 600, and 900 mg per day dosages of oral Elmiron in IC patients with no dose-response relationship seen. According to O'Leary-Sant Interstitial Cystitis Symptom Index scores, there was a significant ($p < 0.001$) improvement from

baseline at the 300-mg/day dosage (n = 128). In addition, improvement in the patient's overall rating of symptom index of $\geq 50\%$ increased from 21.1 % after 4 weeks of treatment to 49.6% after 32 weeks of therapy.

Elmiron was significantly more effective than placebo in relieving symptoms of patients with moderate or severe IC in two placebo-controlled trials: Mullholland et al. (1990), (n = 110), and Parsons et al. (1993), (n=148). In both studies, significantly larger proportions of patients with IC showed improvement of their overall condition when treated with Elmiron versus placebo. Assessment of pain and urgency were similar across both studies with a larger proportion of patients experiencing a substantial relief in pain and urgency when treated with Elmiron compared to placebo. The mean reduction from baseline in the pain score was not significantly different between Elmiron or placebo recipients in the trial reported by Mullholland et al. (1990); although, the reduction in the mean pain score for patients receiving Elmiron was significantly ($p = 0.05$) different from zero or no change.

In a six month Finnish urology clinic study comparing the efficacy of Elmiron with cyclosporine in patients with IC, the proportion of patients reaching the anticipated primary end point of 50% reduction in frequency in 24 hours in Elmiron versus cyclosporine recipients was 0% versus 34% ($p < 0.0001$). Cyclosporine may show to be beneficial for patients who have not benefited from other IC therapies; however the tolerability profile suggests that patients treated with this drug need to be regularly monitored for blood pressure and serum creatinine. Over half of the patients in this study had at least three previous unsuccessful treatments and the mean patient age, at 58 years,

was higher than in most of the studies discussed.

The long-term efficacy of oral Elmiron 100 mg three times daily for up to 35 months has been evaluated in a large, multicenter, physician's trial with (n = 2809). Improvement in symptoms of IC were reported and patient evaluation demonstrated that the proportion of patients completing at least 3 months of Elmiron therapy (n=1416) with at least moderate improvement in their overall assessment of IC symptoms. The majority of patients in this trial had moderate or severe symptoms with the average patient age being 46.9 years. Over half of the patients had been treated with at least one course of intravesical dimethyl sulfoxide.

Primary efficacy outcomes included patient rated evaluation questionnaires targeting overall improvement of conditions; daily micturition frequency and patient reported 7-point global response assessment (GRA). Secondary efficacy outcomes included evaluation of overall improvement by pain and urgency scale rating, changes in O'Leary-Sant symptom problem indexes and a six point scale GRA. Weaknesses include possible bias due to withdrawals, study design limitation and limited statistical power due to low rates of recruitment. Although this study had limitations as noted above, it is still considered to be valid as current literature supports Elmiron use as an important option in treatment of IC (Anderson & Perry, 2006).

Khoudary et al. (2008) is a cross-sectional analysis of 41 subjects age 20 -71 years with moderate to severe IC enrolled in an 18 week, randomized, double-blind, placebo controlled clinical trial to assess the efficacy and safety of a combination of intravesical and oral Elmiron compared to placebo as a new therapeutic selection for IC

with the objective of determining possible factors that may increase the severity of symptoms and decrease quality of life in women diagnosed with IC; how symptom severity affects quality of life adjusting for these factors; and to investigate which symptoms would be most likely to impair IC patients' physical and mental quality of life.

Females 18 years and older who recently met the NIDDK criteria for IC and were previously untreated with Elmiron were recruited from IC patients of Citrus Valley Medical Research Inc. Women were required to have a negative urine culture, a score of at least four on a nine-point pain scale and five on the O'Leary-Sant Interstitial Cystitis Symptom Index at baseline. All subjects signed an informed consent, and the study design was approved by the IRB of Foothill Presbyterian Hospital in Glendora CA and the IRB of the University of Pittsburgh.

The conclusion of the parametric technique is based on the large sample properties. With a sample size of 41, the properties may not be applied. Therefore the authors used a non-parametric approach to assess the study aims. Continuous variables were presented as median, 25th and 75th percentiles while categorical variables were presented as percentages. Spearman correlations, Mann-Whitney U-tests, and Kruskal-Wallis tests were used to assess univariate relations. All statistical tests were two sided and used a significance level of 5% and all analyses were conducted using STATA version 10.0.

The results demonstrate that patients with IC reported a significantly poorer quality of life than controls across all SF-36 domains ($p < 0.01$). Weaknesses includes a cross sectional design which limits the ability to determine the direction of causality

between symptom severity and quality of life. A small sample size and strict application of NIDDK criteria resulted in exclusion of mild cases. Patients with IC reported significantly poorer quality of life than controls across all SF 36 domains. Therefore it may be postulated that managing pain and nocturia in particular may improve the patients overall physical and mental quality of life.

FitzGerald, et al. (2012) present a randomized, single-blind, randomized clinical trial comparing pelvic floor Myofascial Physical Therapy (MPT) vs. Global Therapeutic Massage (GTM). This study was performed at 11 clinical centers located in North America. Recruitment consisted of women with IC/PBS who demonstrated pelvic floor tenderness on physical examination and had a limitation of no more than three years of symptom duration. Primary outcome was the proportion of responders defined as moderately improved or markedly improved in overall symptoms compared to baseline on a 7-point Global Response Assessment scale. Secondary outcomes included ratings of pain, urgency and frequency on the O'Leary-Sant IC Symptom index. Response rates were compared between treatment arms using the exact conditional version of the Mantel-Haenszel test to control for clustering by clinical center. For secondary efficacy outcomes, cross-sectional descriptive statistics and changes from baseline were calculated.

Recruitment was at a rate slower than expected with limited funding therefore the study was closed prior to reaching the recruitment of 88 patients. A total of 81 patients were recruited between July 2008 and May 2009. The majority were white women with a median age of 43 years. Ages ranged from 18-77 years. There were no statistically

significant differences between the two treatment groups in demographic characteristics. This study was still adequately powered to identify significant differences in the primary outcome of the study. Overall 59% in the MPT group and 26% in the GTM group reported moderate or marked improvement ($p=0.0012$) with 43% in the GTM group reporting no improvement. This study supports the concept of pelvic floor MPT for the treatment of IC/PBS as a significantly higher proportion of women with IC/PBS responded to treatment with MPT. The population includes female aged 18-77 years to support PICO-T criteria.

Berry et al. (2010), used an adaptation of risk assessment methodology (RAM), which is a methodology used to determine the appropriateness of various symptom indicators to diagnose IC/PBS compared with indicators of conditions with overlapping symptoms, such as overactive bladder, endometriosis and vulvodynia. Nominations were solicited from relevant medical societies, including the American Urological Association, American College of Obstetrics and Gynecology, and American Urogynecology Society as well as recognized IC/PBS experts. Nine experts were chosen for the final multidisciplinary panel, including five in urology, two in gynecology, one in nursing and one in case definition methodology.

A comprehensive literature review of the best scientific evidence in regard to IC/PBS and related conditions with overlapping symptoms using the PubMed database and predefined search terms was performed. The final review involved a history of the case definition of each disease and a description of the prevalence of patient reported symptoms both within and across diseases.

Forty-two urologists and gynecologists around the United States were contacted with eight urologists and 16 gynecologists accepting participation. A total of 673 participants were recruited of whom 599 were interviewed. The diagnosis was IC/PBS only in 236, IC/PBS plus one of the other conditions in 101, overactive bladder in 124, endometriosis in 58, vulvodynia in 44 and more than one non IC/PBS condition in 36. These participants completed a comprehensive 90-minute computer assisted telephone interview conducted by trained interviewers from the RAND Interstitial Cystitis Epidemiology telephone survey center. Physician clinical diagnoses served as the reference standard to define IC/PBS. A repeated approach to construct and test different combinations of the RAND Interstitial Cystitis Epidemiology study items were used to predict the IC/PBS diagnosis (sensitivity) and differentiate IC/PBS from other conditions (specificity).

The findings conclude that no single definition is associated with high sensitivity and specificity, which may be related to the true overlap of symptoms across these conditions, or to the accuracy of measurement and clinical diagnoses of these conditions demonstrating that more meaningful comparison across samples is required. Previous measures used to identify patients with IC/PBS were developed to track the course of the conditions. The RAND Interstitial Cystitis Epidemiology cohort (RICE) measures are designed to identify women with IC/PBS and describe their symptoms. These measures along with other means will be used in this evidence-based project for symptoms evaluation.

Chung, Liu, Li and Lin (2014), performed a cross-sectional study to compare the

difference in the utilization of healthcare services between patients with IC/PBS and patients without using a population-based database in Taiwan. The study comprised of 350 patients with IC/PBS and 1,750 age-matched controls. Data on the sampled subjects and their utilization of healthcare services were recovered from the Longitudinal Health Insurance Database. This database contained complete medical claims and registration files for 1,000,000 enrollees, who were randomly selected from all enrollees listed in the 2000 registry of beneficiaries under the National Health Insurance program.

This study first identifies 512 female patients who had received a first-time diagnosis of IC/PBS during an ambulatory care visit between January 2006 and December 2010. Due to stringent oversight of peer reviews for the prescription of Cystistat, it is unlikely that misdiagnosed cases were included in the study group. In order to increase the validity of the IC/PBS diagnoses, this study only included patients who had received a prescription for Cystistat. Those patients <18 or >80 (n=11) years of age were excluded leaving an overall number of 350 IC/PBS patient cases in the study group. For controls, the data was also retrieved from the Longitudinal Health Insurance Database. Female subjects between 18 and 79 years old were identified. Those who already had prior history IC/PBS were excluded from the study. Then 1,750 were randomly selected who matched to the study cases by age and index year through a survey select program.

An SAS system for windows statistical analysis package was used to conduct the statistical analyses. Descriptive statistical analysis, including frequency, percentage, mean and standard deviations were performed on all outcome variables. Student's t-tests

were carried out to examine the relationships between outcome variables for patients with IC/PBS and controls. Additionally, a multivariate-regression-analysis was used to model the logarithm of mean costs as a liner function of a set of independent variables. The difference was considered significant if a two-sided p value was ≤ 0.05 . Of the 2,100 female study subjects, the mean age was 48.4 years old and approximately 50% were older than 50. There was no significant difference in the geographic region between the IC/PBS and controls ($p=0.159$).

This study found that female patients with IC/PBS had significantly more outpatient visits for urological services than controls (mean value 2.5 vs. 0.2) during follow up period. Of the 350 female patients with IC/PBS, 159 (45.4%) had ever used an outpatient visit during follow-up period. This study reveals that female patient with IC/PBS had significantly more outpatient visits (35.0 vs. 21.3) for non-urological reasons as well as significantly higher total costs (\$US 1149 vs. \$US 900) than controls.

The principle strength of the study was in the use of a population-based dataset, which mitigates the effect of selection bias inherent in voluntary registries. The database used in the study also enabled the authors to trace the healthcare utilization of all study subjects, which can reduce the potential recall bias present in a survey study. A noted decreased cost and outpatient visits in quality of care along with population criteria are both strengths noted in this study.

Limitations of Search and Review

In reviewing literature, limitations were encountered. Current research lacked studies on the effectiveness of a multimodal approach to treatment of IC/PBS. A few

studies showed benefits to stress reduction, behavior modification, improved coping mechanisms, and diet modifications as first line treatment. The strongest evidence in the form of RCT's, meta-analysis, cohort studies and case studies addressing the management of IC/PBS available focused on treatment with pharmacological measures. The AUA clinical guideline did provide information in regards to manual physical therapy as being second line treatment, however no studies were found to include manual physical therapy as a first line treatment option.

Therefore a further search of PubMed to include the terms “Interstitial Cystitis”, and “ Pelvic Floor Dysfunction” yielded 48

- Publication dates of 10 years yielded 26
- Humans 25

“Pelvic Floor Therapy”, and “Interstitial Cystitis” Publication dates of 10 years, humans yielded 47.

Lukban, et al. (2001) performed a pilot study, which consisted of 16 female patients with the mean age being 42.5 years who were diagnosed with IC, and high-tone pelvic floor dysfunction, which was detected by trigger-point palpation on digital examination by a Urologist. These patients were referred to physical therapy for suspected sacroiliac dysfunction and were then issued an O’Leary-Sant Interstitial Cystitis Symptom Questionnaire and Modified Oswestry Disability Scale prior to evaluation. These questionnaires evaluate urinary frequency, nocturia, urgency, suprapubic pain, and dyspareunia. Evaluation performed by a certified manual physical

therapist identified sacroiliac dysfunction in all 16 cases. Manual therapy and an extensive home exercise program for a mean of 8.72 (range, 2 to 15) visits. A comparison of pre- and post treatment Modified Oswestry and O'Leary-Sant scores revealed 94 % improvement in symptomatology with the greatest improvement seen in the incidence of frequency and suprapubic pain, further suggesting support of this evidence based practice change.

Conclusions

The evidence has shown that addressing the pelvic floor in patients demonstrating IC/PBS symptoms has great importance. Findings revealed statistically significant correlations between usual care and pelvic floor therapy related to both cost benefits and quality of life to the patient. Utilizing the findings in practice and implementing coordination of care between a practitioner and professionally trained physical therapist would prove to be beneficial in the treatment of IC/PBS.

Chapter Three: Framework of Theory

The Rosswurm and Larrabee Model was chosen for this evidence based practice change. This model guides nurses and other healthcare professionals through a systematic process, which tremendously increases the accessibility to research findings to prepare the way for the paradigm shift from traditional intuition-driven practice to evidence-based practice (Gawlinski & Rutledge, 2008).

According to Gawlinski and Rutledge (2008), this model has six phases with aims for integration of evidence based practice into a care delivery system which includes; assessing the initial need for change in practice; linking the problem to standard interventions and outcomes; synthesizing best evidence; design of practice change; implementation and evaluation of change in practice and integrating and maintaining the practice change.

Gawlinski and Rutledge (2008), describes each of the six phases. The first step includes assessment of the need for change in practice by comparing internal data about a specific current practice and comparing it with external data in standard databases. Comparison of internal and external data may validate current practice or support the need for a change in practice. For this evidence based change project current practice includes dietary changes such as decreasing bladder irritants, timed voids, stress management, education and behavior modification. Approximately 50 to 75% of patients present with pelvic floor trigger points causing a somatovisceral response, which is pain shooting in the perineum, bladder or pelvic organs validating support for a change in practice.

The second step involves linking the problem with interventions and outcomes. Classification systems such as International Classification of Diseases (ICD) and Diagnostic and Statistical Manual of Mental Disorders (DSM) help to define concepts of a science, organize knowledge, facilitate communication among practitioners, provide standards for determining effectiveness and cost of care, and identify needed resources. According to the American Urological Association (2013), patients with IC/PBS were identified in the electronic medical record by the presence of ICD-9 code 595.1 (interstitial cystitis), and the prevalence of the diagnosis was found to be 197 per 100,000 women and 41 per 100,000 men.

In the third step is where interventions and outcomes are refined by synthesizing best research evidence and combining it with clinical judgment and contextual data to determine whether the strength of the evidence supports a change in practice. Evidence supports the issue of multimodal treatment approaches for IC to include pelvic floor therapy performed by a trained physical therapist for pelvic floor muscle dysfunction combined with usual care as noted above.

The fourth step involves the steps taken to design the change in practice. The practice environment, resources and feedback for stakeholders are crucial considerations when designing a change. Only activities addressed and population similar to those in the evidence base are used to guide practitioners in identifying anticipated outcomes of the practice change. For this EBP change project, individuals presenting to the Urology/Gynecology practice setting with symptoms related to IC/PBS were evaluated for participation in this project. A complete history and physical examination, voiding

diary, post void residual, full gynecological examination, urinalysis with culture, urine cytology if the patient has a smoking history, and pain evaluation was performed. Individuals who meet specified inclusion criteria were invited to participate in this project. The investigator then reviewed the informed consent (Appendix A) and administered the O'Leary-Sant index questionnaire (Appendix B) which measures urinary and pain symptoms, and how problematic these symptoms are for the patient. The patient was then educated on self-care practices and behavior modification such as diet modifications to include the elimination of caffeine, alcohol, acidic or spicy foods, bladder retraining, gentle, non-jarring exercise/stretching, wearing comfortable, non-binding clothing, shoes, hosiery and underwear as well as stress management and coping techniques to include relaxation techniques. Pelvic floor therapy evaluation and treatment of 8 sessions provided by a trained physical therapist at Allied Services was discussed with these patients. If they so choose to proceed with pelvic floor therapy in conjunction with usual care, pelvic floor therapy was ordered and scheduled.

Step five involves implementation and evaluation of the change in practice. This stage requires close monitoring of the implementation process for success. Follow up reinforcement of the practice change, which may include staff surveys and QI study for data analysis. Interpretation of these results will determine whether the protocol was implemented as intended and what affect it had on patient outcomes. The patient returned to the Urology/Gynecology practice setting at 4 weeks and 8 weeks for evaluation by the investigator at which time the O'Leary-Sant symptom and problem index questionnaire was assessed.

The sixth step includes integration and maintaining this change in practice. The change agents need to consider the cultural climate of the organizations as they attempt integration into practice innovations. Ongoing communication with stakeholders, adherence to the details and continuing education ensures a smooth and speedy integration of the change into the organization's standards of care (Gawlinski & Rutledge, 2008). At the conclusion of this EBP project, evaluation of its effectiveness in improved symptoms indicated by reduction of the patients O'Leary-Sant Interstitial Cystitis Syndrome index score was determined. Collaboration with ongoing stakeholders will ensure a smooth integration of the change into the organization's standards of care.

Relationship of Model to Project

Rosswurm and Larrabee's model is an evidence based practice approach to clinical care that incorporates the thorough use of current best evidence of well designed studies, clinician's expertise, and patient values and preferences. By using this problem solving approach to clinical care that integrates the conscientious use of current best evidence from well-designed studies, clinician's expertise and patient values and preferences, healthcare providers can provide care that leads to better clinical decisions and patient outcomes.

Chapter Four: Project Planning

Project Design

The management of IC/PBS is both frustrating and difficult as it is a diagnosis of exclusion. Consequently, both patients and healthcare providers tend to be dissatisfied with the quality of care. The American Urological Association (AUA, 2013) provides a guideline for the diagnosis and treatment of IC/PBS. Recommendations for first line treatment include patient education, self-care practices, behavior modification, and stress management. These usual care therapies are often suboptimal in alleviating symptoms related to IC/PBS. According to Peters and Carrico (2006), pelvic floor dysfunction demonstrated by levator pain upon examination is present in as many as 85% of patient with IC/PBS. This demonstrates the notion that pelvic floor therapy techniques performed by properly trained clinicians should be offered as part of standard of care as a first line approach.

The question guiding the inquiry for this evidence-based quality improvement project is: In women 18 years and older with interstitial cystitis/painful bladder syndrome, does pelvic floor therapy as part of usual care, improve symptoms indicated by reduction in the patients O'Leary-Sant Interstitial Cystitis Symptom and Problem Index (ICSI) score over an 8 week period.

The proposed evidence based practice change project was introduced in a gynecology/urology office located in a suburban area in the northeastern United States. The practice, located on the grounds of a large hospital, includes one doctor, and two

nurse practitioners. Additionally, the office employed one registered nurse, one LPN, two medical assistants, and 4 personnel in other clerical positions. The types of patients seen in the practice include adolescents through elderly women who presented to the office for well-woman examinations, acute gynecologic and urologic conditions, and chronic gynecologic conditions.

Prior to implementing the EBP change project, there were several collaborative meetings. The first meeting was with the collaborating physician and the other Nurse Practitioner to discuss the evidence and the problem, as well as, to obtain permission to perform the EBP change project. Both the physician and nurse practitioner were open to the idea of this practice change. These practitioners agreed that IC/PBS was a common problem among women that may go unaddressed at the annual visits. They were open to efficient ways of improving patient care and satisfaction. It was agreed, that implementation of this practice change should improve the overall diagnosis and management of IC/PBS in women within the practice.

The next meeting was with the medical assistants and nurses who are directly involved with initial intake of the patients problem. All questions were answered and any concerns were addressed in regards to the details of the EBP change project and the staff was satisfied.

The investigator also met with a local pelvic floor specialist to whom all referrals would be directed. This meeting included discussion in relation to the treatment plan, the use of the O'Leary-Sant Questionnaire, collaboration of care and follow up. There was also a follow up meeting to brief the medical staff on the details of the EBP change

project including the effects this may have on the practice, the project coordinator discussed various aspects of the project so the staff remembered that the project would begin in May 2015.

Individuals presenting to the Urology/Gynecology practice setting with symptoms related to IC/PBS would receive a complete history and physical examination, voiding diary, post void residual, full gynecological examination, urinalysis with culture, urine cytology if the patient had a smoking history, and pain evaluation was performed. Individuals who meet specified inclusion criteria were invited to participate in this project. The investigator then reviewed the informed consent (Appendix A) and administered the O'Leary-Sant index questionnaire (Appendix B) which measures urinary and pain symptoms, and how problematic these symptoms are for the patient. The patient was then educated on self-care practices and behavior modification such as diet modifications to include the elimination of caffeine, alcohol, acidic or spicy foods, bladder retraining, gentle, non-jarring exercise/stretching, wearing comfortable, non-binding clothing, shoes, hosiery and underwear as well as stress management and coping techniques to include relaxation techniques. Pelvic floor therapy evaluation and treatment of 8 sessions provided by a trained physical therapist at Allied Services was discussed with these patients. If they so choose to proceed with pelvic floor therapy in conjunction with usual care, pelvic floor therapy was ordered and scheduled. The patient would come into the Urology/Gynecology practice setting at 4 weeks and 8 weeks for follow-up evaluation at which time the O'Leary-Sant symptom and problem index questionnaire will be re-administered and added to the patients normal medical record. No experimental

procedures were used in this quality improvement project.

Before this EBP change project could move forward the approval process required submission to the Misericordia University's Institutional Review Board (IRB). The IRB has final approval of all academic projects. This approval was obtained on May 11, 2015 (Appendix C). There was no other formal approval process for projects required by the clinical practice site, however verbal consent and approval from the office manager and clinical practice preceptor was obtained prior to implementation.

Data Collection Tools

Data collection was maintained by the investigator within the Medent electronic medical record, which is HIPAA and password protected. At the end of the 8 week period, data was extracted from the patients' normal medical files, reviewed retrospectively, de-identified, and reported in aggregate form with no patient identifiers used. In this EBP change project, data reviewed is a function of the patient's normal medical care.

Resources Needed

Plain white 8x11 inch paper and black ink were used to print the O'Leary-Sant index questionnaire and educational information in regards to bladder irritants. Brochures provided by the Interstitial Cystitis Association which had been obtained free of charge were also be given to the patient. These brochures discuss standard of care, which includes information regarding bladder irritants, stress management, and pelvic floor therapy. Approximately, 30 copies of each of the participant consent, and bladder irritant

sheet were produced for distribution to participants. Additional project documents were printed as needed.

Budget Justification

No rewards or compensation was offered. Participants were allowed to withdraw at any time with no penalty or impact on their medical care. No travel or lodging expenses were acquired. This EBP change project was carried out in the investigators clinical practice site, therefore examination and testing materials were implemented as usual care practice therefore no expense were incurred. The investigator provided materials needed to complete the EBP change project. These materials included paper and ink, which were of minimal cost.

Chapter Five: Implementation Procedures and Processes

IC/PBS has shown to result in poor quality of life involving sleep dysfunction, depression, anxiety, and stress, affecting family relationships and responsibilities. The need for innovative ways to treat IC/PBS has become a public health goal to help decrease health issues and improve quality of life (Bosch & Bosch, 2014). The intent of this evidence based change project was to evaluate the impact of pelvic floor therapy on adult women with interstitial cystitis/painful bladder syndrome by symptom reduction. This chapter discusses the project setting, participants, and implementation process to include task list and time line.

Setting

The EBP change project was implemented in a corporation run Urology/Gynecology (URO/GYN) practice in Scranton, Pennsylvania. The Interstitial Cystitis Association, calculated estimates of people affected by IC/PBS by state based on the US census bureau. According to these statistics, Pennsylvania likely has 163,793 - 497,931 men and women affected by IC/PBS (ICA, 2010). The practice site for the EBP change project has 1 URO/Gynecologist, 2 Certified Registered Nurse Practitioners, and 8 support staff to include nursing, medical assistants and office personnel.

Participants

Participants that were included in this EBP change project were adult female patients age 18 years or older, of all ethnicities, proficient in speaking, reading and writing English, seen at the practice site requiring care for IC/PBS. Patients that were excluded from this EBP change were males, females younger than age 18, patients that

were cognitively impaired, and those that had a hysterectomy or pelvic floor prolapse repair within the past 6 months. Patients were recruited by an interdisciplinary team to include the nurse practitioners, physician, nursing staff along with the office manager who had access to the daily schedule and was educated on inclusion and exclusion criteria for this project.

Implementation Process

According to the University's requirements for implementing this evidence based practice change project, the Institutional Review Board (IRB) approval process was initiated. An EPB protocol was submitted and the EBP change project was granted permission for implementation on May 11, 2015. The organization where the EBP protocol was conducted did not require IRB approval.

Participation recruitment commenced on May 13, 2015 and was scheduled to terminate on July 31, 2015 (10 weeks) according to IRB approval. The investigator projected to enroll 15-20 participants. A modification due to unforeseen circumstances prevented participation enrollment for 3 days. Participants were identified through the Medent electronic medical record of patients who have been seen within the past 6 months for symptoms related to IC as well as any new patients with symptoms related to IC. Established patients were contacted by either the investigator or the office manager to assess symptom management. If the patient did not feel as though their symptoms were being controlled, they were asked if they would like to come into the office for follow up evaluation. Through the evaluation process, some participants did not wish to proceed with pelvic floor therapy due to time or travel constraints and were not included in the

study.

If the patient was established, a physical examination was performed and the O'Leary-Sant problem and symptom index questionnaire was completed. Eligible participants received a project consent form to participate in the EBP change intervention by the investigator. The investigator reviewed the consent form and participants were allowed the opportunity to ask the investigator any questions related to the consent process and EBP change project prior to agreeing to participate. Agreement to participate was established by signing the consent, however the participants were made aware that they may withdraw at any time without any repercussion.

New patients presenting with symptoms of IC received a complete history and physical examination voiding diary, post void residual, full gynecological examination, urinalysis with culture, urine cytology if the patient had a smoking history, and pain evaluation. Further evaluation to eliminate other conditions such as irritable bowel syndrome, fibromyalgia, vulvodynia, endometriosis, or vaginal infections were addressed prior to review of project and consent. After consent was signed, the patient was then educated on self-care practices and behavior modification such as diet modifications to include the elimination of caffeine, alcohol, acidic or spicy foods, bladder retraining, gentle, non-jarring exercise/stretching, wearing comfortable, non-binding clothing, shoes, hosiery and underwear as well as stress management and coping techniques to include relaxation techniques, and emotional support was given. The patient was then educated on pelvic floor therapy and a brochure from the Interstitial Cystitis Association was given along with information regarding bladder irritants and bladder training. Pelvic floor

therapy was ordered and the patient was scheduled for a 4-week follow up with instructions to call with any concerns in the meantime. One hour of appointment time was allotted for each patient. The patient understood that due to unforeseen circumstances, the conclusion of IRB approval was indicated as July 31, 2015 and the full 12 weeks would not be assessed for this EBP project, however the patient would still be followed the same as discussed according to the consent with follow up at 4 weeks, 8 weeks, and 12 weeks with final project evaluation at 8 weeks. The investigator received updates from the pelvic floor therapist throughout treatment. At the 4-week follow up visit, the O'Leary-Sant problem and symptom questionnaire was completed to determine continuity of care.

Information in regards to the patients pre-test O'Leary-Sant questionnaire scores and post-test scores were extrapolated and analyzed. The EBP intervention's next steps include dissemination of the findings. A power point presentation was created to overview the clinical problem, intervention and findings. The oral defense presentation was scheduled for August 14, 2015 with the final DNP project paper submission on August 16, 2015 for review by faculty. Recommendations for continued surveillance and implementation were discussed as well as opportunities to present findings at local and national conferences will be explored.

Chapter Six: Evaluation and Outcomes

Interstitial cystitis/painful bladder syndrome is a problem that has the potential to affect a woman in many aspects of her life to include social, emotional and economical areas. Pelvic floor therapy, when performed properly with collaboration of care with the patient's urologist/gynecologist, has been shown to be a more effective treatment for IC/PBS (FitzGerald, et al. 2012). This evidence-based practice (EBP) project sought to determine if PFT in conjunction with usual care would be an effective intervention among women in a Urology/Gynecology practice located within the northeastern United States.

Mean was used to characterize the participant population. Nine women volunteered to participate in the EBP change project. The participants in this evidence-based practice change project were females ranging in age from 26 to 82 years old, with a mean age of 51 years. No women under twenty-six years opted to participate in the project. Each participant suffered from IC/PBS symptoms. Only 9 of the expected 15 women were enrolled due to time constraints. However the study was still able to adequately identify significant differences in the primary outcome of the study. The average length of diagnosis ranged from newly diagnosed to 10 years, with a mean of 3 years.

The O'Leary-Sant voiding and pain indices measurement tool determining symptom index and problem index was to be utilized in a pre-test, 4 weeks, 8 weeks and post-test format to assess the effectiveness of the intervention of PFT among a group of participants over the age of 18 years. However, due to time constraints this utilization

tool was used as a pre-test, 4 week and 8 week format (Tables 1 and 2).

The Interstitial cystitis symptom index contains 4 items that measure symptoms demonstrated over the last month that consist of the strong need to urinate with little or no warning, the feeling of having to urinate 2 hours after finishing, number of nighttime urination, and pain or burning in the bladder. The ICSI index score is the sum of the item scores (range: 0-21).

Table 1

O'Leary-Sant Symptom Index Scores

IC Symptom Index	Before Treatment	4 Weeks	8 Weeks
Patient #1	14	11	7
Patient #2	18	7	3
Patient #3	15	9	4
Patient #4	14	10	6
Patient #5	11	7	3
Patient #6	14	9	5
Patient #7	10	9	6
Patient #8	16	11	4
Patient #9	15	12	8

The Interstitial cystitis problem index contains 4 items that measure how much of a problem the following had over the past month: frequent urinating during the day, nighttime urination, the need to urinate with little warning, and burning, pain, discomfort, or pressure of the bladder. The ICPI score is the sum of the item scores (range: 0-16).

Table 2

O'Leary-Sant Problem Index Scores

IC Problem Index	Before Treatment	4 Weeks	8 Weeks
Patient #1	15	11	7
Patient #2	14	5	4
Patient #3	10	5	2
Patient #4	13	8	5
Patient #5	11	8	2
Patient #6	12	9	4
Patient #7	13	12	7
Patient #8	12	10	6
Patient #9	13	12	6

Data Analysis and Results

Pelvic Floor Therapy consisted of therapeutic exercises, manual therapy, neuromuscular reeducation, pain management, patient education and posture/body mechanics. Usual care consisted of education on self-care practices and behavior modification such as diet modifications to include the elimination of caffeine, alcohol, acidic or spicy foods, bladder retraining, gentle, non-jarring exercise/stretching, wearing comfortable, non-binding clothing, shoes, hosiery and underwear as well as stress management and coping techniques to include relaxation techniques. An average of 62% decrease in the O'Leary-Sant symptom index was reported over an 8-week period of pelvic floor therapy consisting of a 1-hour sessions once or twice a week dependent on

duration and severity of symptoms. An average of 63% decrease in the O'Leary-Sant problem index was reported over the same breadth of time. All patients met the criteria of completing the trial. The therapy was well accepted and well tolerated, and follow up was considered good. A paired t test was calculated which showed a symptom index p-value of 0.0010. The 95% confidence interval ranged from 2.53 to 6.81 as the mean of the pre test minus the post-test was equal to 4.67 (Table 3). The paired t test was also calculated for the problem index, which showed a p-value of 0.0001. The 95% confidence interval ranged from 6.78 to 8.78 as the mean of the pre test minus the post-test was equal to 7.78. Therefore the response rate was considered highly statistically significant (Table 4).

Table 3

O'Leary-Sant Symptom Index Statistics

IC Symptom Index	Pre Treatment	Post Treatment
Mean	14.11	9.44
Standard Deviation	2.42	1.74
Standard Error of Mean	0.81	0.58
Number	9	9

Table 4

O'Leary-Sant Problem Index Statistics

IC Problem Index	Pre Treatment	Post Treatment
Mean	12.56	4.78
Standard Deviation	1.51	1.92
Standard Error of Mean	0.50	0.64
Number	9	9

Relationship of Results to Framework and Objectives

IC/PBS is frequently associated with pelvic floor dysfunction. For this group of patients, it is obligatory to observe not only the bladder, but also all the other organs inside the pelvis. An optimal approach is a combined treatment oriented not only to treat the bladder, but also to include the other components responsible for this pain disorder. This evidence based change project has shown that pelvic floor therapy as part of usual care is helpful in managing pelvic pain and relaxing the pelvic floor. Treatment should continue until tenderness and tightness are minimized or resolved, which requires one or two visits per week for 8 to 12 weeks depending on the duration and severity of symptoms. As symptoms decrease in severity, frequency of therapy is decreased and the patient continues with home pelvic muscle stretches and relaxation techniques (Peters & Carrico, 2006).

Population: *In women 18 years and older with interstitial cystitis/painful bladder syndrome.*

The participants in this evidence based practice change project included females ranging in age from 26-82 years with a mean age of 51 years. N = 9 out of 11 as 2 patients declined to participate as they reported fear of pain with pelvic floor therapy or too far of a distance to travel. Two of the patients were established IC patients who had never received pelvic floor therapy with seven newly diagnosed patients.

Intervention: *Pelvic floor therapy as part of usual care.*

Pelvic floor therapy was ordered as evaluation and treatment of up to 12 weeks. The pelvic floor therapist provided evaluation updates throughout treatment. The two established patients indicated continued usual care. The seven new patients were educated on usual care as well as pelvic floor therapy. No pharmacological therapies were administered throughout this EBP change project.

Outcome/Time *Improve symptoms as indicated by reduction in the patients O'Leary-Sant Interstitial Cystitis Symptom Index (ICSI) score over and 8 week period.*

Results indicate that (n = 9), there was a significant (p <0.0010) improvement from baseline in the patients' O'Leary-Sant IC symptom index as well as (n = 9), there was a significant (p < 0.0001) improvement from baseline in the patients' O'Leary-Sant IC problem index over the 8 week time period.

Chapter Seven: Implications for Nursing Practice

Planning and implementing evidence-based practice (EBP) changes and quality improvement is the future of the profession of nursing begins with formative education and continues throughout the nurses' career. EBP implications should be explicitly valued by the nursing profession at all levels increasing healthcare environments needed to support EBP activities as part of career development. This chapter will discuss the clinical implications of this practice change project. It will focus on implications for nursing practice, review the strengths and limitations of this project and discuss its linkage to DNP Essentials.

In January 2011, the American Urological Association (AUA) recommended starting treatment of IC/PBS with the most conservative treatments to include stress management, patient education and self-care (Theoharides, & Whitmore, 2011). However, according to Cervigni and Natale, (2014), many patients with IC /PBS have concomitant pelvic floor hypertonicity estimating the prevalence ranging from 50% to 87% noting that pelvic floor dysfunction exacerbates IC/PBS symptoms. Therefore, pelvic floor therapy should be considered as a first line treatment in these cases.

Although the concept of applying "best evidence" in a clinical decision seems forthright, it is actually very complex. Skillful critical thinking is required to evaluate the evidence for its strength and scientific rigor. Moreover, it needs to be well thought out in light of the patient's concerns and preferences (Melnik & Finehout-Overholt, 2005). The impact from this EBP change project is influential. The results are an important aspect of bringing recognition to the complex roles of APNs and their impact on outcomes. The

findings demonstrated that providing best practice resources could lead to rapid interventions for women with IC/PBS. The collaborative work with trained pelvic floor therapists will influence the ability to integrate additional EBP changes.

Strengths of the Project

The quality of data is considered high. According to Burns and Grove (2003), quality data are best obtained from articulate, well-informed participants who are able to share more rich data in a clear and concise manner. The participants in this EBP change project were allotted more than the usual 15-minute time period to be interviewed at greater depth and breadth.

Reliability testing measures the amount of random error in the measurement technique, taking into account dependability, consistency, accuracy, and comparability. The same pelvic floor therapist measured patient outcomes through the same biofeedback and reported to the investigator throughout care of each patient, therefore reliability is considered to be high.

The O'Leary-Sant Questionnaire used to assess symptom and problem index is considered valid. This instrument has been used by the American Urological Association (2013) to establish guidelines related to IC/PBS, and the RAND Interstitial Cystitis Epidemiology study (Konkle et al., 2012). This instrument measures all major elements relevant to the concept being measured.

Limitations of the Project

There were some limitations to this EBP change project. Current research lacked studies on the effectiveness of a multimodal approach to treatment of IC/PBS. A few

studies showed benefits to stress reduction, behavior modification, improved coping mechanisms, and diet modifications as first line treatment. Another limitation that was identified early in the project was the probability of a limited number of participants, although it was felt by the author that enough data was collected to show the projected outcomes were met. Limited participants were obtained due to time constraints related to delayed IRB approval and completion dates as well as two patients who refused to participate. Since the number of participants in this project was small, the results cannot be predicted to what may occur in a larger population setting. And, the outcomes data from the participants was based on self-report in a pre and posttest format therefore results may have been more biased than what this investigator would have preferred.

Linkage to DNP Essentials

The mandate for evaluation is integral to professional nursing practice. The DNP Essentials serve as a blueprint for the education of Advanced Practice Nurses at their respective levels of competencies (Hickey & Brosnan, 2012). Recommendations that nurses practicing at the highest level should receive doctoral level preparation acquiring knowledge required for safe nursing practice and growing concerns regarding the quality of patient care delivery and their outcomes (American Association of College of Nursing, 2006).

Essential I: The DNP prepared nurse integrates nursing science with knowledge from ethics, the biophysical, psychosocial, analytical, and organizational sciences as the basis for the highest level of educational preparation in nursing (AACN, 2006). Science-based theories and concepts are used to determine the significance of health and the

healthcare delivery phenomena, describe actions and strategies to enhance, alleviate, and improve health care delivery as appropriate and develop new approaches based on theory (AACN, 2006).

Analytical reasoning provided the framework for scientific knowledge of the IC/PBS practice change project. This project focuses on symptom and problem index related to experience, management strategies and outcomes, which is applicable to advanced nursing practice and research in addition to providing direction for selecting the delivery of clinical interventions for successful outcomes.

Essential II: Organizational and Systems Leadership for Quality

Improvement and Systems Thinking. Organizational and system leadership are critical for improving patient and health care outcomes (AACN, 2006). Development and evaluation of care delivery approaches that meet the needs of health disparities, patient safety, and excellence in practice comprises this essential. Ensuring accountability to clinical policy, process improvement and facilitation in organization-wide changes in health care describe components of the DNP prepared nurse. A major goal of the IC/PBS practice change project was to provide evidenced-based care and to decrease this disease disparity while upholding patient safety.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice. The vigorous nature of health care requires that the DNP prepared nurse be current on new information while disseminating findings into clinical practice. Using analytical methods to critically appraise existing literature and other evidence pertinent to practice, the DNP prepared nurse employs evidence-based practice to improve patient

and population outcomes. An extensive review of the literature was conducted to identify the best evidence-based practice application to achieve symptom and problem management of IC/PBS.

Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care. DNP prepared nurses are characterized by their abilities to use information systems and technology to support and improve patient care and healthcare systems as well as provide leadership within healthcare systems and/or academic settings (AACN, 2006). The IC/PBS change project required technological data extraction from the O'Leary-Sant voiding and pain indices questionnaire to measure outcomes. A Power Point presentation was developed for doctoral defense as well as presentation at local and national conferences.

Essential V: Health Care Policy for Advocacy in Health Care. Health care policy creates a framework that can facilitate or obstruct the delivery of health care services or the ability of the provider to engage in practice to address health care needs. DNP graduates are equipped to design, influence, and implement health care policies that frame health care by proactively developing and implementing policy at all levels, including institutional, local, state, regional, federal and international (AACN, 2006). The IC/PBS change project influences future implications to improve IC/PBS guidelines for first line therapy.

Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes. DNP prepared nurses employ effective team leadership and are prepared to play a central role in established collaborative teams, participating in the

work of the team and assuming leadership of the team when appropriate (AACN, 2006). The collaboration between pelvic floor therapy specialists, nurse scholars, peers, and other health care professionals allowed for effective communication in the development and implementation of this practice model.

Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. Implementation of clinical prevention and population health activities is essential to achieving the national goal of improving the health status of the population of the United States (AACN, 2006). Consistent with the national calls for action, DNPs must serve as leaders in affirming quality care to achieve greater levels of excellence. Current concepts of public health such as health promotion, evidence-based practice recommendations, determinants of health, environmental and occupational health, and cultural diversity and sensitivity guide the practice of DNP graduates (AACN, 2006).

IC/PBS imposes an increasing burden in the United States in terms of quality of life, and healthcare costs (Payne, Joyce, Wise & Clemens, 2007). This EBP change project emphasizes the collaborative roles of the health care team and the patients demonstrating positive outcomes, which are essential to influence population health.

Essential VIII: Advanced Nursing Practice. The foundational practice competencies that connect specialties are seen as obligatory for the DNP prepared nurse practice, which is specified in Essential VIII. DNP prepared nurses are projected to demonstrate refined assessment skills and base practice with the application of biophysical, psychosocial, behavioral, sociopolitical, cultural, economic, and nursing sciences as appropriate in their area of specialization (AACN, 2006). The IC/PBS project

is an example of implementing evidence-based practice built on the premise of national and international findings to advance nursing practice.

Conclusion

Activities that analytically advance the teaching, research, and practice of nursing through rigorous inquiry are significant to the nursing profession (AACN, 2006). DNP prepared nurses project quality and safety interventions that are evidence based and population appropriate to reduce underlying causes and promote appropriate treatment of chronic diseases (Cupp Curley & Vitale, 2012). Employing the AACN Essentials for this evidence-based practice change project allowed the investigator to identify specific competencies that were demonstrated to advance nursing practice.

Chapter Eight: Summary of Project and Conclusions

Evidence-based practice is an approach that enables health care providers to deliver the highest quality of care in meeting the multifaceted needs of patients and families. When healthcare providers know how to find, critically appraise, and practice the best evidence, and when patients are confident that their healthcare providers are using evidence-based care, ideal outcomes are achieved for all (Melnyk & Fineout-Overholt, 2005). The literature indicates that approximately 2.7% to 6.5% of American women age 18 years and over met symptom criteria for IC/PBS. When extrapolated to the general population, these numbers translate to between 3.4 and 7.9 million women who have symptoms consistent with this debilitating condition (Kerr, 2009).

Change in Clinical Practice

An extensive search of current literature was first conducted to answer the PICO-T question; *“In women 18 years and older with interstitial cystitis/painful bladder syndrome, does pelvic floor therapy as usual care improve symptoms indicated by reduction in the patients O’Leary-Sant Interstitial Cystitis Symptom Index (ICSI) score over an 8 week period”*. The evidence had shown that addressing the pelvic floor in patients demonstrating IC/PBS symptoms had great importance. Current literature supports statistically significant correlations between usual care and pelvic floor therapy related to both cost benefits and quality of life to the patient. Utilizing the findings in practice and implementing coordination of care between a practitioner and professionally

trained physical therapist would prove to be beneficial in the treatment of IC/PBS.

The health issue addressed in this EBP change project was the effectiveness of implementing standard of best care practices including pelvic floor therapy in the management of women years 18 and older with interstitial cystitis/painful bladder syndrome. This project provided the investigator an empirical learning opportunity to develop the knowledge and skills necessary to provide patient-centered care, work with an interdisciplinary team, utilize informatics, and apply research findings in practice.

The support of the clinical practice setting and their commitment to excellence made the project very adaptable. The Rosswurm and Larrabee Model served as the guide to integrate research into daily practice. Members of the interdisciplinary team devoted considerable efforts to facilitate the implementation of this evidence-based practice change project. Without this level of support, success would have been hard to achieve. (Gawlinski & Rutledge, 2008).

After obtaining support from the Advanced Gynecology Practice site, an application to the Misericordia University IRB board was submitted and approval for this EBP change project was obtained on May 11, 2015. Several office meetings were then held with the clinical office staff to review the EBP change project as well as include logistics in approaching potential participants. The investigator obtained and developed documents such as consent form, O'Leary-Sant Questionnaire, bladder irritants, timed voids and brochures provided by the ICA association in regards to stress reduction, self help and pelvic floor therapy.

The investigator approached 11 potential participants with 9 females age 26-82

years who consented to participate. There were several reasons that potential participants chose not to participate. These included time constraints, travel distance to physical therapy and fear of therapy due to pain. The desired outcome of this project was a decrease in the O'Leary-Sant symptom and problem index scores reported by a pre test, 4 week and post test. The results indicated that all participants reported an improvement in symptom and quality of life following the intervention. The analysis of pre test and post test data showed that an average of 62% decrease in the O'Leary-Sant symptom index and a 63% decrease in the O'Leary-Sant problem index was reported over the 8 week time period with a statistically significant symptom index p-value of 0.0010 and problem index p value of 0.0001.

Conclusion

The EBP change project of implementing standard of best care practices including pelvic floor therapy as usual care in the management of women years 18 and older with interstitial cystitis/painful bladder syndrome was shown to be effective for symptom and quality of life improvement. Many of the equivalent findings that were present in the literature review were also revealed in the project. The age ranges of the majority of IC/PBS sufferers were similar. Despite the small sample size, the EBP project was successful and met the standards of improvement in symptoms and quality of life from this disease. Analysis of the pre-test and post-test measurement tool scores showed that the project was statistically significant for improvement of IC/PBS symptoms.

The EBP project flowed well and the intervention of practice to include pelvic floor therapy as first line treatment for IC/PBS will be implemented in the

Urology/Gynecology practice on a regular basis. An EBP project such as this has the ability to significantly impact women who suffer from this condition by allowing them to improve their health-related quality of life.

Dissemination Plans

The doctor of nursing practice (DNP) degree has created opportunities for nurses to implement their EBP projects in collaboration with academic and clinical teams. Findings from such innovative efforts have unique dissemination presentation venues. Approaches for dissemination of such projects include most importantly, the oral defense presentation followed by power point or poster presentations at local or national conferences, journal clubs and seminars as well as disseminating evidence through publication (Melnyk & Finout-Overholt, 2005).

Future Implications for Practice

Applying the EBP change project to all patients presenting with this disease will determine the significance of health and delivery of healthcare to alleviate symptoms related to IC/PBS while continuing to evaluate care delivery approaches that meet the needs of health disparities, patients safety and excellence in practice. Continued collaboration with pelvic floor therapists, peers, nurse scholars and other healthcare professionals to critically appraise existing literature and other evidence pertinent to practice will improve patient and population outcomes and advocate for healthcare policy change in IC/PBS guidelines for first line therapy (AACN, 2006).

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Appendices

Appendix A: Informed Consent

Informed Consent:

The effectiveness of implementing standard of care best practices including pelvic floor therapy in the management of in women with interstitial cystitis/painful bladder syndrome

You are being asked to take part in a quality improvement project to evaluate the outcomes of best practices which includes a comprehensive physical examination, laboratory/diagnostic studies, medication, and pelvic floor therapy (and evaluation and strength assessment of pelvic floor muscles). you will be asked to complete a symptom index (the O'Leary-Sant Interstitial Cystitis Symptom Index- ICSI) four times in the course of your treatment (initially, at 4 weeks, 8 weeks, and 12 weeks into treatment). This index allows us to evaluate the level of symptom relief you experience as part of your treatment plan.

You are being asked to take part in this quality improvement project to help us evaluate the effectiveness of the care of patients with IC/PBS. Please read this form carefully and ask any questions that you have may have before agreeing to take part in this project.

What is the project about: The purpose of this project is to evaluate the effectiveness of implementing standard of care best practices including pelvic floor therapy in the management of in women with interstitial cystitis/painful bladder syndrome.

What will you be asked to do: There are no special activities you will be asked to do. If you agree to participate in this project, at the end of your 12 week treatment period, a retrospective chart review of your medical record will be conducted. All information will be reported anonymously using de-identified information. No identifying information will be used.

Risks and benefits: Risks for participation in this project are no more than the normal risks of any standard treatment for IC/PBS. Benefits may include symptom relief.

Compensation: There is no compensation for participating in this quality improvement project. The treatment for IC/PBS should be covered by your insurance.

Your information will be confidential: Privacy and confidentiality of your medical information will be maintained. No identifying information will be used when reporting the outcomes of the quality improvement project.

Taking part is voluntary: Taking part in this quality improvement project is voluntary. If you decide not to take part in this study, it will not affect your current or future relationship in our practice. If you decide to take part, you are free to withdraw at any time.

If you have questions: the investigator conducting this quality improvement project is Christina Shuker, MSN, CRNP, DNP student. Please feel free to ask any questions you have now. If you have and questions later, you may contact Christina Shuker at 570-344-9997 or Dr. Brenda Hage, Director of DNP Programs at Misericordia University, Dallas, PA at 570-674-6760 or at bhage@misericordia.edu If you have any questions or concerns about you rights as a participant in this project, you may contact the

Misericordia Institutional Review Board Chairperson at 570-674-8108. You will be given a copy of this form for your records.

The effectiveness of implementing standard of care best practices including pelvic floor therapy in the management of in women with interstitial cystitis/painful bladder syndrome

Statement of Consent: I have read the above information, and have received answers to any questions I have asked. I consent to take part in this quality improvement project.

Your signature _____ Date _____

Your name (printed) _____ Date _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____ Date _____

This consent form will be maintained by the researcher for at least three years beyond the end of this project.

Investigator Name (printed) _____ Date _____

Investigator's signature _____ Date _____

APPROVED UNTIL
JUL 31 2015
MISERICORDIA IRB

Appendix B: O’Leary-Sant Interstitial Cystitis Symptom Index

To help your physician determine if you have interstitial cystitis, please put a check mark next to the most appropriate response to each of the questions below. Then add up the numbers to the left of the check marks and write the total below.

Symptom index

During the past month:

Q1. How often have you felt the strong need to urinate with little or no warning?

- 0. Not at all.
- 1. Less than 1 time in 5.
- 2. Less than half the time.
- 3. About half the time.
- 4. More than half the time.
- 5. Almost always.

Q2. Have you had to urinate less than two hours after you finished urinating?

- 0. Not at all.
- 1. Less than 1 time in 5.
- 2. Less than half the time.
- 3. About half the time.
- 4. More than half the time.
- 5. Almost always.

Q3. How often did you most typically get up at night to urinate?

- 0. None.
- 1. Once.
- 2. Two times.
- 3. Three times.
- 4. Four times.
- 5. Five or more times.

Q4. Have you experienced pain or burning in your bladder?

- 0. Not at all.
- 2. A few times.
- 3. Almost always.
- 4. Fairly often.
- 5. Usually.

Add the numeric values of the checked entries;
total score: _____

Problem index

During the past month, how much has each of the following been a problem for you?

Q1. Frequent urination during the day?

- 0. No problem.
- 1. Very small problem.
- 2. Small problem.
- 3. Medium problem.
- 4. Big problem.

Q2. Getting up at night to urinate?

- 0. No problem.
- 1. Very small problem.
- 2. Small problem.
- 3. Medium problem.
- 4. Big problem.

Q3. Need to urinate with little warning?

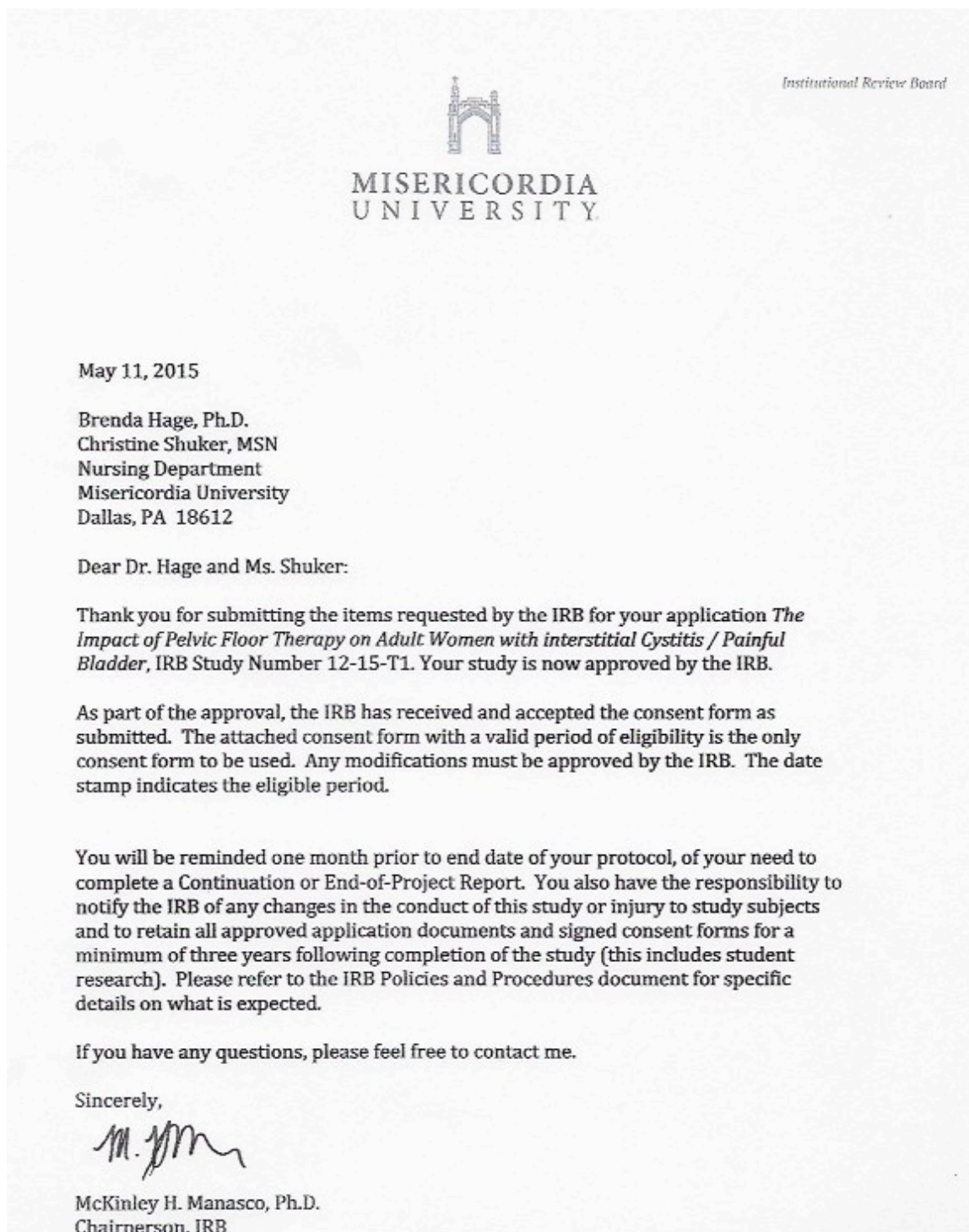
- 0. No problem.
- 1. Very small problem.
- 2. Small problem.
- 3. Medium problem.
- 4. Big problem.

Q4. Burning, pain, discomfort, or pressure in your bladder?

- 0. No problem.
- 1. Very small problem.
- 2. Small problem.
- 3. Medium problem.
- 4. Big problem.

Add the numeric values of the checked entries;
total score: _____

Appendix C: IRB Approval Letter



Appendix D: Misericordia University IRB Application

Protocol Number: _____

**MISERICORDIA UNIVERSITY
APPLICATION COVER SHEET FOR INITIAL IRB REVIEW**

Type 1 Review Type 2 Review Type 3 Review

Name of contact person: Christina Marie Shaker, MSN, CRNP, DNP Student

Department/Program: Nursing Department, Doctor of Nursing Practice Program

Address: 131 Simpson Street, Eyrone PA 18403

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Faculty Research Advisor (for student research): Dr. Brenda Hage, PhD, DNP, CRNP

Advisor's Telephone Number: (570) 674-6760

Advisor's email address: bhage@misericordia.edu

Project Title: The Impact of Pelvic Floor Therapy on Adult Women with Interstitial Cystitis/Painful Bladder Syndrome

Proposed Project Dates: from: Date of IRB Approval to July 31, 2015

PLEASE DO NOT INDICATE A START DATE ANY SOONER THAN THE MONDAY FOLLOWING THEIR MEETING DATE AT WHICH YOUR PROTOCOL WILL BE DISCUSSED.

NOTE: DO NOT BEGIN DATA COLLECTION UNTIL YOU RECEIVE NOTIFICATION THAT YOUR APPLICATION HAS BEEN APPROVED.

Type 1 Review:

Action:

Approved as submitted

Application disapproved as Type 1, resubmit as Type 2 Type 3

Signature of Reviewer(s) _____ Date _____

_____ Date _____

The reason(s) for disapproval are:

Type 1 Review:

Action:

- Approved as submitted.
- Approval withheld pending submission of revision and/or additional information.
- Application disapproved.

Signature of Reviewer #1 _____ Date _____

Signature of Reviewer #2 _____ Date _____

Type 3 Review:

Action:

- Approved as submitted.
- Approval withheld pending submission of revision and/or additional information.
- Application disapproved.

Signature of IRB Chair/Designee on Behalf of IRB _____ Date _____

Date of Submission:

TYPE I APPLICATION - JUSTIFICATION - ANSWER ALL QUESTIONS - RESPOND TO NARRATIVE QUESTIONS AT THE END OF THE FORM, IF APPLICABLE.

YES NO

 1. Will your research be conducted in an educational setting?

Y If you answered no, move to question #4.

 2. Will it be conducted in an existing setting? If yes, describe below.

 3. Is your study focused on a normal practice, such as normal educational practices? If yes, describe these below.

 4. Will you collect information that exists in a public forum, such as information in public records?

 5. Will the information you are collecting be recorded anonymously?

 6. Are you collecting data about adults through educational tests, surveys, interviews or observations of public behavior?

Y If you answered no, move to questions #9

 7. Are the data that you will collect from adults recorded anonymously OR considered benign information?

Y If you answered yes because you consider the information to be benign, answer the following questions:

 Individuals who provide information are at-risk of criminal or civil liability

 Individuals who provide information place their financial standing at-risk

 Individuals who provide information risk their current employment or future employability

 Individuals who provide information place their reputations at-risk

SKIP TO QUESTION #9, if your research DOES NOT include minors

 8. If you are collecting educational testing information passively from minors (no active engagement), will the information be recorded anonymously?

If you answered NO, answer the following questions:

 Minors who provide information are at-risk of criminal or civil liability

 Minors who provide information place their financial standing at risk

Date of Submission:

Minors who provide information risk current employment or future employability

Minors who provide information place their reputations at risk.

YES NO

9. Are you collecting data from public officials or candidates?

Y If you answered no, please proceed to question #11.

10. Does your data collection involve examining public benefit or service programs?

If you answered yes, is the work to be completed with or approved by a federal agency or department director?

11. Does your data collection involve food quality and consumer acceptance? If you answered NO, do not respond to item 12.

 12. Are the foods to be consumed *wholesome* AND without additives?

Y If you answered NO to Questions # 2, 3, 7, 8, 12 or if you responded YES to any of the sub-questions in #7 or 8, you must complete the application for TYPE II or III.

Response to Question #2 (if applicable):

Community Health Systems, Advanced Gynecology Associates

Response to Question #3 (if applicable):

The proposed project intervention is considered a standard of care. No patient identifiers will be disclosed.

In addition to this form, submit an abstract of your work which describes the purpose of the research, location(s) of data collection, individuals to be interviewed including age range, methods of data collection, instruments to be used to collect data, and the benefits of the research. Also attach a copy of your data collection instrument and a signed copy of the Application Cover Sheet and Assurance Form found in Section III. You may be asked to submit an informed consent depending on the risk to human subjects.

MISERICORDIA UNIVERSITY
RESEARCHER ASSURANCE STATEMENT

I understand Misericordia University's IRB policies and procedures concerning research involving human subjects and I agree to:

1. Accept responsibility for the ethical conduct of this research;
2. Obtain approval from Misericordia University's IRB prior to instituting any changes in this project;
3. Report to Misericordia University's IRB serious adverse reactions or unexpected effects on subjects;
4. Complete all required reports in a timely manner; and
5. Disclose any financial or personal conflict of interest.

a. Christina Marie Shaker, Nursing, Doctor of Nursing Practice Program
MSN, CRNP, DNP Student

Researcher's printed name	Department/Program
<i>Christina Marie Shaker</i>	
Researcher's signature	Date 1/24/15
<i>Christina Marie Shaker</i>	

b.

Researcher's printed name	Department/Program
Researcher's signature	Date

c. Brenda Hage, PhD, DNP, CRNP

Advisor's printed name	Department/Program
Researcher's signature	Date

d.

Researcher's printed name	Department/Program
Researcher's signature	Date

e.

Researcher's printed name	Department/Program
Researcher's signature	Date

For student research:
I have approved the procedures of the research project described in the attached application. I agree to assist the student with application of the policies and procedures involving human subjects' protection.

<i>Brenda L. Hage</i>	Department/Program
Faculty research advisor printed name	DNP Nsg
<i>Brenda L. Hage</i>	Date 4/25/15
Faculty research advisor signature	

Conflict of Interest Questions (each researcher must initial each statement):

1. Are you aware of any relationships between yourself and/or a member of your family that might affect the outcome of this study? NO CS
YES

If YES, please describe

2. Do you or a member of your family have any financial interests in the outcome of this study? NO CS

3. YES

If YES, please describe

Appendix E: Letter of Support

Advanced Gynecology Associates

Barbara Plucknett, M.D., F.A.C.O.G.
Christina Shuker, MSN, CRNP
743 Jefferson Avenue, Suite 203
Scranton, PA 18510
Phone: 570-344-9997 Fax: 570-344-3158

February 19, 2015

Ref: Christina Shuker
131 Simpson St.
Archbald, PA 18403

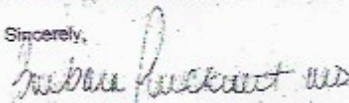
Dear Misericordia University IRB Chair,

On behalf of Community Health Systems and Advanced Gynecology Associates, I am writing to formally indicate my support of the Doctor of Nursing Capstone Project proposed by Christina Marie Shuker, MSN, CRNP, DNP Student at Misericordia University.

Christina has been employed by Advanced Gynecology Associates for 3 years and we have worked together in the Operating Room for several years prior. I am dedicated to mentoring Christina when assistance is needed with her project that is titled: "The Impact of Pelvic Floor Therapy on Adult Women with Interstitial Cystitis/Painful Bladder Syndrome" as there is a great need for this proposal in our practice.

I look forward to collaborating with Christina on this proposal. If you have any questions or concerns, please feel free to contact my office at (570) 344-9997.

Sincerely,



Barbara Lynn Plucknett, MD, F.A.C.O.G.

Appendix F: Investigators Curriculum Vitae

Christina M. Shuker, MSN, CRNP

Cell 570-983-5515

Home 570-876-2871

131 Simpson Street

Eynon, PA 18403

shukercrnp@gmail.com

Professional Experience

Advanced Gynecology Associates

Intermountain Medical Group (CHS)

MSN, CRNP

743 Jefferson Avenue, Suite 203

Scranton, PA 18501

09/2012 - present

Hematology/Oncology Associates

Dr. Martin Hyzinski

MSN, CRNP

743 Jefferson Avenue, Suite 205

Scranton, PA 18501

06/2011-09/2012

Bariatric Program Coordinator

Mercy Hospital

746 Jefferson Avenue

Scranton, PA 18501

06/2010 – 06/2011

Registered Nurse

Mercy Hospital

05/2007 – 06/2010

Served as and RN and Charge Nurse at Mercy Hospital on the Oncology floor from May 2007 to June 2008. Transferred to the Operating room to work as a circulator.

CNA

05/2005 – 05/2007

Prior to accomplishing my Degree in Nursing, I worked as a Certified Nurse's Aide on the Oncology floor at Mercy Hospital.

1987-2007

Past work experience included Student Accounts Coordinator at Marywood University and prior to this Position, Scranton-Temple Residency Program as an Administrative Assistant and Coordinator.

Education:

- Currently attending Misericordia University as a Doctor of Nursing Practice Student - Expected Graduation 2015
- ANCC, FNP-BC Accreditation December 2011
- Misericordia University MSN, FNP 2011
- Marywood University BSN May 2007, Board Certified 2007

Professional Memberships/Affiliations:

- Pennsylvania Coalition of Nurse Practitioners
- Nurse Practitioners of NEPA
- Fellow, American Academy of Anti-Aging Medicine
- Sigma Theta Tau National Honor Society
- Adjunct professor, Marywood University
- Active Clinical Preceptor, Nurse Practitioner, Medical Students

Appendix G: National Institutes of Health Web-based Training Certificate

