INTERSTITIAL CYSTITIS: ALGORITHM TO SIMPLIFY DIAGNOSIS OF CHRONIC URINARY SYMPTOMS

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Abstract

This before and after study was undertaken to determine if an algorithm constructed in an electronic health record (EHR) template in Centricity would assist in diagnosing interstitial cystitis. Data were collected from medical providers (MDs, DOs, PAs, NPs) in family practice, internal medicine, and OB/GYN specialties. A convenience sample of providers was used. Data were collected using The Post-Study Usability Questionnaire and Perceived Competence Scale. Twenty-three common bladder ICD-10 codes were compared before and after providers were introduced to the algorithm and EHR template. Data provided information on the usability of an algorithm and the Centricity EHR template for the purpose of correctly diagnosing chronic urinary symptoms including interstitial cystitis. Assessing ICD-10 codes demonstrated a change in diagnostic practices with an increase in the diagnosis of interstitial cystitis four months after implementation of the template. Conclusions from this study provide a starting point for the development of a usable template algorithm to help determine who may have interstitial cystitis instead of another chronic urinary tract issue.

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Chapter 1

Introduction

Interstitial cystitis (IC) is characterized by chronic pelvic pain that is poorly understood with some medical professionals being completely unaware of IC. There are some providers that question the existence of the disorder (Warren, Wesselmann, Greenberg, & Clauw 2014). The average length of time patients suffer from chronic urinary symptoms prior to IC diagnosis is seven years (Anderson & Zinkgraf, 2013). Patients with IC may wait two to four years and consult two to five doctors before they are correctly diagnosed (Bosch & Bosch, 2014). This study evaluated the usefulness of an EHR algorithm to assist providers in differentiating between interstitial cystitis and other common urologic and gynecological problems. The algorithm was made available to providers through a template in the Centricity electronic health records in a Federally Qualified Health Center in Pennsylvania.

Background of the Problem

Interstitial cystitis is a chronic illness with no known cause or cure. Women are primarily affected with an average incidence of 3-6% in the United States (McKernam, Nash, & Carr, 2016). Much like irritable bowel syndrome, chronic fatigue syndrome, and fibromyalgia, IC is a functional somatic syndrome with persistent bodily complaints in the absence of structural pathology that may profoundly affect a person's life (McKernam et al., 2016).

Interstitial cystitis is typically diagnosed in midlife, with age ranging from 16 to 88 years-old (McLennan, 2014), but symptoms often present themselves in early childhood and teens (Parsons, 2014; Hammett, Kruski, & Corbett, 2013). Twenty-five percent of adults can report

persistence of symptoms since they were children (Davis, Gnanappiragasam, & Thornhill, 2015).

Females are affected 90% of the time (Whitmore & Theoharides, 2011).

The bladder has a protective barrier called the glycosaminoglycan (GAG) layer

(McLennan, 2014). This layer appears to provide a mechanical and electrostatic defense against

any penetration by toxins, acid, or infectious agents (McLennan, 2014). When the lining of the

bladder, the GAG layer, begins to breakdown, the once impermeable layer becomes irritated

when acidic solutes leak from the urine into the tissue (Butrick, Howard, & Sand, 2010). This

leaking of urinary potassium leakage generates the IC symptoms of frequency, urgency, and

bladder pain (Jiang, Jhang, & Kuo, 2016).

Patients come to their provider in search of validation of their symptoms, confirmation of

a diagnosis, and for a treatment that works (McKernam et al., 2016). The diagnosis of IC is one

of exclusion of other urinary tract diseases (Jiang et al., 2016). There are no definitive tests

(Butrick et al., 2010). IC needs to be considered for any patient complaining of urinary

symptoms for greater than 6 weeks with a negative urine culture (Anderson & Zinkgraf, 2013) or

complaining of pain, pressure or discomfort over the suprapubic area of the bladder for the past 3

to 6 months (Whitmore & Theoharides, 2011).

The theoretical model Knowledge-To-Action, which takes knowledge learned from

research and transforms it into usable tools for clinical practice, will provide the basis for this

DNP Project (Kastner & Straus, 2012). A computer-based clinical decision algorithm was

developed to improve the providers' ability to correctly differentiate interstitial cystitis from

other chronic urinary problems. An algorithm (n.d.) is defined as a step-by-step process of

making a decision or a diagnosis with each step depending on the outcome of the previous one.

Purpose

The purpose of this before and after study was to evaluate the usability of an EHR algorithm to diagnose interstitial cystitis in women with chronic urinary symptoms.

PICO Question

The PICO question for this DNP Project is: Will clinicians report competence in the ability to diagnose IC and consider it more often in their differential diagnosis using an EHR algorithm template for chronic urinary tract symptoms?

Definition of Terms

Interstitial cystitis (IC)-There is no accepted name for this disorder (McLennan, 2014). The variety of names for IC causes confusion in practice and in research. For this study, the American Urological Association name and definition was used. "An unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder associated with lower urinary tract symptoms of more than six weeks duration, in the absence of infection or other identifiable causes" (Hanno, Erickson, Moldwin & Faraday, 2015, pp. 1547). Other names include:

Bladder Pain Syndrome (BPS) - from the European Society for the Study of Interstitial Cystitis "Chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder, accompanied by at least one other urinary symptom such as a persistent urge to void or urinary frequency. Confusable diseases as a cause of symptoms must be excluded by history, physical examination, urinalysis, urine culture, uroflowmetry, post-void residual, cystoscopy, and biopsy if indicated." (McLennan, 2014, pp. 386).

Painful Bladder Syndrome (PBS)- From the International Continence Society "Suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology" (Homma, 2014, pp. 43).

Hypersensitive Bladder (HSB) - "Increased bladder sensation, usually associated with urinary frequency and nocturia, with or without bladder pain" (Homma, 2014, pp. 45).

Algorithm (n.d.) - is defined as a step-by-step process of making a decision or a diagnosis with each step depending on the outcome of the previous one.

Need for the Study

Patients with bladder issues often seek help from their primary care provider first. With no gold standard criteria for IC, it is difficult to diagnose, and there are many other disorders that have overlapping symptoms (Butrick et al., 2010). The lack of provider knowledge of IC symptoms affects the time it takes for accurate diagnosis and implementation of appropriate treatment, ultimately negatively affecting the quality of life (Butrick et. al., 2010; Whitmore & Theoharides, 2011). An incomplete list of differential diagnoses may occur due to the misinterpretation of the symptoms. IC is often incorrectly diagnosed as overactive bladder (OAB), urinary tract infection, vulvodynia, endometriosis or gastrointestinal issues (Butrick et al., 2010; Warren et al., 2014; Whitmore & Theoharides, 2011). This study aimed to give primary care clinicians an EHR diagnostic algorithm tool to make an appropriate diagnosis of interstitial cystitis.

Significance of the Problem

Recent literature suggests that IC often is underdiagnosed or misdiagnosed. For every patient diagnosed with IC, at least five remain undiagnosed (Bosch & Bosch, 2014). It is estimated that in the United States 3.5-8 million women 18 years or older have IC symptoms but only 9.7% of those patients have been given the diagnosis of IC (McLennan, 2014). Living with a chronic illness such as IC creates feelings such as loss of control, anger, low self-esteem, and helplessness (McKernam et al., 2016). Rates of depression, anxiety, and suicidal ideation are higher in the IC population than in the general population (McKernam et al., 2016). Research has shown that medical cost for females with chronic health problems such as interstitial cystitis is twice the amount than for women not diagnosed with IC (Beckett, Elliott, Clemens, Ewing, & Berry, 2014). A report from a large managed care health system found that costs of IC with provider visits, medications, and any procedures were over $7,100 per year (Anderson & Zinkgraf, 2013). The Agency for Healthcare Research and Quality (AHRQ) stated in 20ll the average annual expenditure for treatment of pain conditions for women was $1,478. Over $900 was attributed to office visits and the remaining was spent on prescription medications. Beckett et al. (2014) also found that women with IC experience higher economic costs because of lost work related to pain. They report working in pain for at least 8 days out of the month and miss an average of a one-half day of work a month. Women who have anxiety and depression because of IC report decreased functioning and were less likely to work (McKernam et al., 2016).

Living with IC affects not only the individual but also may significantly affect people around them. For example, interstitial cystitis has the potential to adversely affect finances, mental health, quality of life, and relationships. Bosch and Bosch (2014) report that stress is a significant trigger for IC symptoms, therefore, women with IC may be less likely to take a

promotion or a higher paying job due to the stress it may cause. IC sufferers report their quality

of life is so disabling that it has been compared with those of end-stage renal failure (McKernam

et al., 2016). Living with IC may also affect sexual interest and satisfaction, which can lead to

feelings of guilt and depression (McKernam et al., 2016). The impairment of sexual function,

increased sexual distress and fear of pain during intercourse causes women with IC to avoid

intimacy and thus causes difficulties in relationships (McKernam et al., 2016). If providers are

given a tool that would aid in timely, accurate diagnosis, and recommend appropriate

interventions, the impact that IC has on a person may be far less than what is now seen.

Assumptions

Assumptions of this study include:

1. ICD-10 coding offers several options for a provider to use for a diagnosis other than
   interstitial cystitis.
2. Diagnosing IC will lead to treatment or referral for treatment of IC.

Summary of the Problem

   With research showing that primary care providers have a poor understanding of interstitial

cystitis, there is a need for an easy EHR algorithm to differentiate IC from other overlapping

urinary tract problems. IC is an underdiagnosed condition that has no gold standard for

diagnosis. Establishing a diagnostic tool, grounded in research, to identify women with IC will

assist providers in this challenging undertaking.

Chapter 2

Review of Related Literature

In the review of the literature, two main areas of previous research are addressed. First, in an overview of interstitial cystitis, the symptoms of interstitial cystitis, differential diagnosis, physical exam and other tests typically ordered to aid in diagnosis are presented. Second, a review of the process for developing an algorithm based on the theoretical model Knowledge-To-Action is presented.

Interstitial Cystitis: An Overview

The American Urological Association (AUA) has developed a guideline for diagnosis and treatment of interstitial cystitis (IC). Some of the guideline is derived from research and consensus-based processes but, the diagnosis of IC is primarily based on clinical principles and expert opinions (Hanno, et al., 2015). To develop the decision-making algorithm the basic assessment of urinary tract symptoms in the AUA's IC/BPS algorithm was expanded and defined. Increasing awareness of IC and education on diagnostic processes should decrease the significant misdiagnosis, under diagnosis and delayed diagnosis associated with this syndrome (Hanno et al., 2015). The AUA uses the definition of IC agreed upon by the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, "An unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder associated with lower urinary tract symptoms of more than six weeks duration, in the absence of infection or other identifiable causes" (Hanno et al., 2015, pp. 1547). Diagnosis of exclusion is complex when differentiating IC from other disorders such as cancer, infections, OAB and other sources of bladder pain and urinary symptoms (Whitmore & Theoharides, 2011).

Symptoms

Symptoms of IC include pain, urinary frequency and urgency, nocturia, and dyspareunia. Not all symptoms happen at the same time. Many times patients will only initially report a single symptom with eventual progression to multiple symptoms (Hanna et al., 2015).

Pain is the hallmark symptom of IC (Hanno et al., 2015). When the pain originates from the layers of the urinary bladder, the pain can be felt anywhere from the umbilicus to the perineum, inguinal or perirectal areas and it may also radiate down the legs (Parsons, 2014). Areas of the perineum include urethra, vulva, vagina, and rectum (Hanna et al., 2015). Women with IC often find it difficult to pinpoint the exact location of their pain (Taneja, 2010). Killinger, Boura, and Kenneth (2013) asked 749 women, over the age of 18 years, about pain characteristics, pelvic pain triggers, voiding symptoms, and IC symptoms. When the surveys were returned, the participants (214) were grouped with having either ulcerative IC (Hunner's ulcer) or non-ulcerative IC from their cystoscopy results. The researchers found that there was no significant difference in how the groups reported lower abdominal/pelvic pain location, severity, or description of their pain (Killinger et al., 2013). Furthermore, both groups reported similar triggers of IC symptoms including specific foods, exercise and/or stress (Killinger et al., 2013). Shorter, Ackerman, Varvara, and Moldwin (2014) questioned 52 subjects, and 90.4% reported that certain foods and beverages worsened their bladder symptoms. Barr (2014) described that 97% of IC sufferers associated pain with certain foods or drink and/or reported that pain worsened with bladder filling. Foods and drinks commonly associated with IC include citrus fruits and juices, tomato products, Vitamin C, artificial sweeteners, coffee, tea, soda, alcoholic beverages, and spicy foods (McLennan, 2014; Shorter et al., 2014). Drinking alcohol may also increase pain, with 94% of patients reporting increased pain with alcoholic beverages

(McLennan, 2014). Even though Hanna et al. (2015) noted that pain was a key descriptor in

100% of the IC population, it was not always the word that is used to describe the unpleasant

sensation. Many times patients describe the pain as a sensation of pressure or discomfort in the

pelvic area that increases when the bladder is filling and relieved with urination (Hanna et al.,

2015). The descriptive words used in the study by Killinger et al. (2013) varied slightly whether

the subject had ulcerative or non-ulcerative IC. Although not statistically significant, ulcerative

IC sufferers described the pain as sharp, stabbing, and hot burning while the non-ulcerative

group described the pain as aching, cramping, and tenderness. Dyspareunia was noted by 60% of

young patients (McLennan, 2014). Killinger et al. (2013) noted that those with non-ulcerative IC

were significantly more likely to have pain with vaginal penetration, including intercourse,

tampon use or vaginal exam ($p < 0.0006$). Interstitial cystitis should be part of the differential

diagnosis for anyone who presents with dyspareunia (Barr, 2014). Failure to consider the bladder

as the cause when someone is complaining of pelvic/abdominal pain can result in misdiagnosis,

ineffective treatments, and sometimes unnecessary surgical procedures or referral to pain clinics

(Taneja, 2010).

Urinary frequency is often the first symptom of IC but may not be perceived as a problem

until years later (Parsons, 2014). Warren et al. (2014) conducted a longitudinal study assessing

urinary symptoms prior to diagnosis of IC. Logistic regression revealed three prodromal

symptoms associated with IC. Of the 312 women studied, 57% ($p < 0.001$) reported one or more

prodromal symptoms, which included urinary frequency, urgency, and pelvic pain with urinary

symptoms. Of the 178 women who reported at least one prodromal symptom, the urinary

frequency was reported first 82% of the time, either alone or in the combination of the other

prodromal symptoms (Warren et al., 2014). Eighty-six percent of patients with IC report

urinating greater than 11 times during a 24-hour period and 71% report nocturia three or more

times a night (McLennan, 2014). Even though 92% of IC patients complain of urinary frequency,

it cannot be the sole diagnostic feature to distinguish from other lower urinary tract disorders

(Hanna et al., 2015). Combining urinary urgency with frequency increases the likelihood of

correct diagnosis. In Warren et al.'s (2014) study the prodromal symptom of urinary urgency was

reported as occurring at the same time or second to frequency 77% of the time. There are

qualitative differences in the urgency that is experienced by IC patients compared to overactive

bladder (OAB) suffers (Hanna et al., 2015). For a young person under the age of 30, the daytime

frequency is the most common presenting symptom (McLennan, 2014). In this age group, a

suspicion of IC needs to be considered if they present with frequency and pelvic pain. Rates

range from 50 to70% for correct diagnosis (McLennan, 2014).

Differential Diagnosis

Females are misdiagnosed 95% of the time as having gynecologic chronic pelvic pain,

vulvodynia, vaginitis, endometriosis, OAB, or urinary tract infections (UTI) (Parsons, 2014).

Pain with a full bladder can be a result of endometriosis, colitis, or diverticulitis (Taneja, 2010).

It becomes more difficult to diagnose IC when a patient has more than one condition (Barr,

2014). A history of a confirmed UTI by culture can be noted 18 to 36% of the time but

subsequent cultures are negative in IC patients (Hanna et al., 2015). With a history of recurrent

UTI symptoms such as frequency, urgency, nocturia and pelvic pain and negative urine cultures,

IC needs to be considered (Butrick et al., 2010). A person has a high risk of having IC if they are

under the age of 55, presenting with bladder symptoms with a negative urine urinalysis (Parsons,

2014).

There are a lot of similarities between overactive bladder (OAB) and IC that can make it challenging to differentiate. Two studies were reviewed comparing IC and OAB in regard to voiding characteristics and symptomology. Lai, Vetter, Jain, Gereau, and Andriole (2014) surveyed 26 subjects with IC, 53 with OAB, and 30 healthy controls about their symptoms. Kim, Oh, and Oh (2014) performed a retrospective study with 553 OAB and 192 IC patients completing a three-day voiding diary. When comparing symptoms of the two conditions, there is no significant difference in the severity of urinary frequency and urgency (Lai et al., 2014). When assessing the characteristics of the voiding, there was a difference in the volume of urinary frequency and the sensation of urgency (Kim et al., 2014). Kim et al. (2014) were able to show people with IC have smaller bladder function capacity, the bladder is more sensitive, and there are a shorter time intervals between voiding with a consistency regardless day or night ($p< 0.001$). Patients with IC void frequently, but with smaller volume ($p< 0.001$), their urgency is related to the sensation of the bladder expanding (Kim et al., 2014). IC sufferers void often due to the fear of pain (Homma, 2014). The urgency sensation is sufficient enough to awaken the person to void to relieve the bladder pain during the night (Kim et al., 2014). The urgency in OAB patients is not related to the increased bladder volume and pain. A person with OAB tends to void often because of the fear of leaking (Whitmore & Theoharides, 2011). Persons with OAB are able to continue to sleep until the bladder is fully distended and do not get the urgency feeling (Kim et al., 2014). Sufferers with OAB do not have nocturia, but they do experience incontinence. Even if an IC patient complains of incontinence, symptoms are not exactly the same as OAB. Some patients with IC will voluntarily pass urine to avoid a full expansion of their bladder which causes pain (Lai et al., 2014). The key differential symptom is the pain if it is present OAB can be ruled out (Barr, 2014).

Endometriosis can be differentiated by using the presence of dysmenorrhea (Barr, 2014). It is important for clinicians to remember endometriosis and IC frequently coexist (Butrick et al., 2010). A case-control study showing an association between a previous diagnosis of dysmenorrhea and IC was done in Taiwan (Chung, Liu, Lin, & Kang, 2014). Dysmenorrhea is defined as menstrual pain that interferes with daily activities. Chung et al. (2014) found subjects were significantly more likely to have a prior case of dysmenorrhea before their IC diagnosis. There seems to be a relationship between endometriosis and IC. Chung, Chung, Gordon, and Jennings (2002) found women with chronic pelvic pain and bladder tenderness on exam have a greater than 70% chance to have both endometriosis and IC. Symptoms of IC are usually worse a few days prior to menses, whereas for endometriosis the pain is usually worse during the cycle (Cox et al., 2016). If the clinician treats the dysmenorrhea that is associated with endometriosis, but the pain is not entirely resolved, he/she needs to consider an IC diagnosis.

Distinguishing between vulvodynia and IC needs to be accomplished with anyone with vulvar pain (Barr, 2014). Vulvodynia is often reported as a burning pain but lacks the urinary frequency and nocturia associated with IC (Butrick et al., 2010). This characteristic helps the clinician make the distinction.

Physical Exam

The physical exam should target the bladder but also focus on ruling out other causes of the patient's symptoms (Barr, 2014). A pelvic exam targeting the anterior vaginal wall with an empty bladder is one part of the physical exam that is necessary for the differential diagnosis of IC. There is 95% sensitivity in correctly identifying a person with IC when they have anterior vaginal wall tenderness (AVWT) on physical exam (Paulson & Paulson, 2011). To determine

AVWT the examiner places a finger into the vagina, stroking upwards underlying the bladder. Paulson and Paulson (2011) performed a cohort study to see if anterior vaginal wall tenderness (AVWT) could narrow down the diagnosis of interstitial cystitis. A sample of 284 patients with chronic pelvic pain of gynecologic and lower urinary tract origin was assessed by the Pelvic Pain and Urgency/Frequency symptom scale (PUF), patient's symptoms, physical exam, and cystoscopy. Patients with IC or a combination of IC and endometriosis had higher PUF scores and were significantly more likely to have AVWT then patients with endometriosis alone (Paulson & Paulson, 2011). The sensitivity of predicting endometriosis by AVWT was only 17% as compared to the 95% found in IC patients (Paulson & Paulson, 2011).

If a patient has recurrent UTI symptoms, the standard of care includes a urinalysis and urine culture. For patients with urinary symptoms and negative cultures, other conditions such as IC should be considered in the diagnostic processes. (Butrick et al., 2010).

Other tests

A questionnaire that can be helpful in screening for IC is called Pelvic Pain and Urgency/Frequency symptom scale (PUF). Parsons et al. (2002) designed and validated this symptom scale by using the intravesical potassium sensitivity test (PST), which is known to be associated with epithelial dysfunction in the bladder in a person with IC. During a PST, a catheter is placed in the bladder and potassium chloride is instilled. The potassium chloride infiltrates the abnormal bladder layer, which then mirrors the pain that IC suffers experience when urine fills the bladder (Taneja, 2010). Potassium sensitivity testing (PST) is no longer routinely done, even though it showed good sensitivity and specificity in clinical trials, it was shown to be too painful for a patient that was already miserable (Taneja, 2010).

The PUF questionnaire combines both urologic and gynecologic symptoms and has three

questions each on urinary frequency, urgency, and pelvic pain and two questions on symptoms

associated with intercourse (Parsons, 2014). The PUF is scored from zero (no symptoms) to 35

(severe symptoms), measuring pain, urinary urgency, frequency, nocturia, and dyspareunia in the

person's daily life (Butrick et al., 2010). (See Appendix A) During the questionnaire

development and testing, it was noted that an increasing PUF score was associated with an

increasing likelihood of a positive PST (Parsons et al., 2002). The researchers concluded that any

PUF score >10 warrant investigation for interstitial cystitis because a high PUF score indicated a

74% chance of having a positive PST (Parsons et al., 2002). No individual that scored less than

four on the PUF had a positive PST so this low score was considered normal (Parson et al.,

2002). As indicated above, PST testing is no longer part of the differential diagnosis of IC.

Cystoscopy is no longer routinely recommended for the diagnosis of IC (Boudry et al.,

2013; Jiang et al., 2016), however a referral to a urologist to have a cystoscopy should be done to

rule out malignancies if the patient is older than 40 years old, is a smoker and has hematuria

(Butrick et al., 2010). It is important to exclude carcinoma *in situ* that can occur in 1% of cases

(Boudry et al., 2013).

Recently, Jiang et al. (2016) reevaluated the PST as well as cystoscopy in their role in

regards to diagnoses of IC. Neither test was able to diagnose IC with 100% accuracy, but they

may be valuable in providing guidance for different treatment options (Jiang et al., 2016).

A test that is becoming more popular to determine if the bladder is the source of the pain

is to instill an anesthetic combination of lidocaine and heparin into the bladder (Parsons, 2014).

Pain from IC originates from the persistent breakdown of the glycosaminoglycan (GAG) layer

which allows urine to penetrate the interstitial layer of the bladder and cause an inflammatory

response (Nomiya et al., 2013). A study by Taneja (2010) wanted to see if it was possible to

differentiate between pain originating from the bladder and that from other pelvic organs using

intravesical instillations into the bladder. Lidocaine is known to give immediate relief of IC

symptoms when placed into the bladder (Nomiya et al., 2013). Taneja (2010) placed 20ml of 2%

lignocaine solution into the bladder of 22 women with pelvic pain. Sample inclusion criteria

were patients with lower abdominal pain of more than three months duration (Taneja, 2010).

Pelvic organs that were investigated included gastrointestinal, urological, and nephrological

organs (Taneja, 2010). A nurse recorded the pain using the Visual Analogue Scale (VAS) at set

increments of time. There were 15 participants (68.1%) who had a significant reduction of pain,

and of those who had a reduction of pain, 73% had near total alleviation of pain as a result of

bladder instillation. The 7 (38%) who had no or insignificant reduction of pain were referred to

other specialist and their pain was diagnosed as a non-bladder issue such as endometriosis (n=2),

PID (n=4), and diverticulitis (n=1) (Taneja, 2010). When the 15 responders had their

cystoscopy, all had visual evidence of IC. Cystoscopic evidence of IC is the presence of

glomerulations, or inflammation in the bladder wall (Jiang et al., 2016). Jiang et al. (2016)

discussed that the presence of glomerulations on cystoscopy has a sensitivity of 61.7% and a

specificity of 84% with grades two or more. With that in mind, a limitation of this study would

be that they do not discuss that a patient may have IC without any visual evidence on cystoscopy.

The study did have a small sample, but if the pain originated from the bladder only, and not from

other pelvic organs, the pain is expected to be numbed by intravesical lignocaine.

Development of an algorithm: Knowledge-to-Action framework

Theoretical Framework

The purpose of the knowledge-to-action (KTA) framework is to explain the process of gathering the best available knowledge from research on a subject and applying that knowledge to practice with the intention of improving health outcomes (Graham et al., 2006). The framework supports the process of transforming information from research to form operational tools for clinical practice. One such tool is an electronic decision-making algorithm. KTA is divided into two concepts: knowledge creation and action (Graham et al., 2006). The knowledge creation is portrayed as a funnel and a cycle represents the action of moving knowledge to implementation. (See Figure 1). There are three sections of the funnel, knowledge-inquiry, knowledge synthesis, and the resulting tools or products (Graham et al., 2006). As the decision maker moves through these sections broad knowledge is gradually reduced until only the most valid and useful knowledge/ information is left. Knowledge tools/products such as clinical practice guidelines, decision aids, and algorithms are developed after the systemic review of the research knowledge inquiry pertinent to the research question and synthesis of the applicable findings (Kastner & Straus, 2012). As the accumulation of IC research is screened and critiqued, the ability to establish explicit recommendations for a diagnostic tool becomes clear.
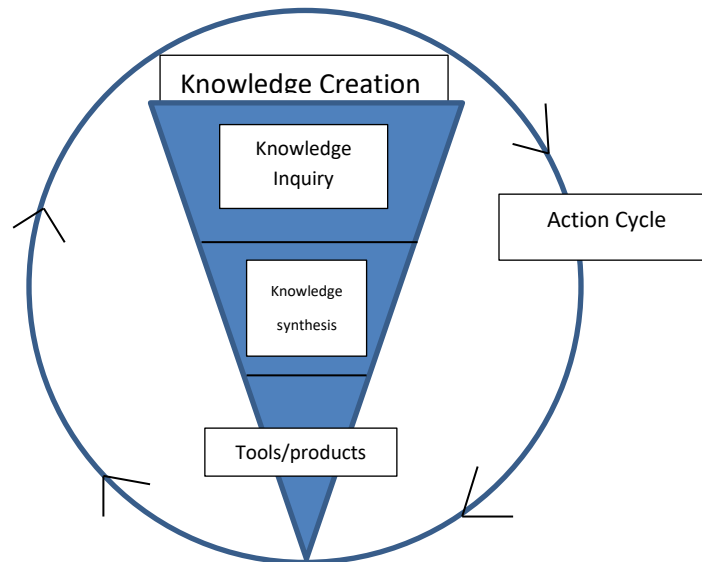
Knowledge to Action Framework (KTA)

Figure 1. The theoretical model developed by Ian Graham et al., (2006). Used with permission by the author (personal communication, October 23, 2016).

Kastner and Straus (2012) applied the knowledge-to-action framework as well as the Medical Research Council framework to develop a clinical decision tool for osteoporosis. The tool was developed using a seven-phase process that included gathering the data by a systemic review of research literature and developing a tool from that information, then tailoring the tool by assessing usability, acceptability, and feasibility in three family practice offices (Kastner & Straus, 2012). The study was successful in not only designing an osteoporosis tool but also establishing an outline that can be applied in developing other tools (Kastner & Straus, 2012). The knowledge-to-action framework was used in this project to develop an algorithm for IC.

Summary of Review of Related Literature

The review of the literature has shown evidence that a provider can differentiate IC from other common issues with a few simple steps. Combining basic urinary symptoms, a negative

urine culture, with an elevated PUF score is sufficient evidence to diagnose IC. Adding a

physical exam and assessing for anterior vaginal wall tenderness, which has 95% sensitivity to

interstitial cystitis, can give providers confidence that they have a correct diagnosis.

Chapter 3

Methodology

The purpose of this study was to develop an EHR-based algorithm that will help clinicians in diagnosing interstitial cystitis when a patient complains of chronic bladder symptoms. The algorithm was developed from the concept knowledge-to-action model, taking the best knowledge available on IC research and applying that information to differentiate IC from other possible pelvic problems. The PICO question that was answered: Will clinicians report competence in the ability to diagnose IC using an algorithm that is embedded in an EHR template for chronic urinary tract symptoms?

Research Design

The study represents an evaluation of an evidenced based algorithm. Data were collected using a modified Post-Study Usability Questionnaire (PSSUQ) to assess the independent variable, which is the new algorithm in an electronic health record. A Perceived Competence Scale questionnaire was utilized to assess the provider's perceived competence in diagnosing IC. An inquiry was conducted on ICD-10 codes for 21 common diagnoses for urinary complaints similar to IC as well as interstitial cystitis with and without hematuria. The inquiry was done before and after clinicians was educated and was introduced to an algorithm (see Appendices B and C) and the EHR template (see Appendix D) that assisted clinicians to distinguish IC over other problems such as endometriosis, OAB, and urinary tract infections.

Setting

The setting for this study took place in multi-specialty offices in over 12 counties in northwestern Pennsylvania. The multi-specialty Federally Qualified Health Centers (FQHC)

included OB/GYN, internal medicine, and family practice specialties. The Joint Commission

(JC) accredited these offices settings.

Sample

      A convenience sample of 19 providers was used. Providers included MD, DO, PA, and

NPs. Inclusion criteria were providers who see women older than 16 as a primary care provider

or for their women's health needs. Exclusion criteria were providers who do not see women for

their primary care needs and do not use the Centricity electronic health record.

Ethical Considerations

      Approval from the Institutional Review Board from Edinboro University and the Clinical

Issues Committee of the FQHC were obtained. Approval was also obtained to run an inquiry on

diagnostic habits of the providers in the study. A unique identifier designating each participant

was given by the Clinical Program Analyst. The analyst assessed the ICD-10 diagnostic habits

for each provider. An email was sent to each provider that stated that consent to participate in the

study was completely voluntary. Confidentiality was maintained with the post-test questionnaire

by the researcher emailing the questionnaire to the provider and then the provider sent their

responses to the researcher by inner office mail. There was no identifier on the questionnaires.

There were no risks or discomforts in participating in this study. A drawing with one winner

receiving a twenty-five dollar Amazon gift card was given as compensation.

Instrumentation

General demographics collected were participants' sex, occupation, specialty area they work in, and years in practice, years working with EMR, and their overall comfort level working with EMR.

The Post-Study Usability Questionnaire (PSSUQ) assessed the independent variable, the template algorithm. The PSSUQ (see Appendix E) is a 16-item survey that calculates the satisfaction of a product by the user (Garcia, 2013). In this study, the product is the Chronic Urinary Symptom template on the electronic health record. The participant is asked to respond to each item on a seven-point Likert-type scale. They were able to choose 1=" Strongly agree" to 7=" Strongly disagree". Averaging the subscales of System Quality, Information Quality, and Interface Quality will give an overall satisfaction score that is highly reliable (a=.94) (Garcia, 2013). Using the scale is free when used for research purposes. A "comments" section and an opportunity for the provider to make suggestions to improve the template were added to the questionnaire.

A query of ICD-10 codes (see figure 2) representing common urological and gynecological complaints similar to the IC diagnoses as well as interstitial cystitis with and without hematuria was evaluated. This query was completed before and after clinicians were educated to an EHR template that assisted clinicians to distinguish IC over other problems. The study compared the total number of IC diagnosis in the Centricity EHR system four months before and four months after the template was introduced. Since the template is intended to help differentiate IC from other common pelvic disorders, an evaluation of the ICD-10 codes used from the participating providers was assessed.

Figure 2. ICD-10 Diagnostic Codes

Disease	ICD-10	Disease	ICD-10	Disease	ICD-10
Urinary Tract Infection	N39.0	Over Active Bladder	N32.81	Urinary incontinence, unspecified	R32
Stress Incontinence	N39.3	Urge incontinence	N39.41	Mixed incontinence	N39.46
Dyspareunia	N94.1	Vaginismus	N94.2	Vulvodynia, unspecified	N94.819
Acute cystitis w/ hematuria	N30.01	Acute cystitis w/o hematuria	N30.00	Chronic cystitis w/o hematuria	N30.20
Chronic cystitis w/hematuria	N30.21	Unspecified cystitis w/o hematuria	N30.90	Unspecified cystitis w/hematuria	N30.91
Interstitial cystitis w/o hematuria	N30.10	Interstitial cystitis w/hematuria	N30.11	Endometriosis	N80.0
Dysuria	R30.0	Painful micturition, unspecified	R30.9	Frequency of micturition	R35.0
Nocturia	R35.1	Urgency of urination	R39.15		

The Perceived Competence Scale (see Appendix F) is a 4-item questionnaire developed

to assess the persons' perceived competence in a particular subject (Deci & Ryan, 2016). The

scale was used to measure the overall perception of competence for diagnosing IC. The

participant was asked to respond to each item on a seven-point Likert-type scale. They could

choose 1=" Strongly Disagree", 4=" Neutral", to 7=" Strongly Agree". The alpha measure of

internal consistency of the questionnaire was reported as above 0.80. The questionnaire is

copyrighted and is free to use for academic research projects (Deci & Ryan, 2016). A follow-up

question to "If the provider considered IC as a differential diagnosis on any patient in the past

four months" was added to the questionnaire. The question was," If you have considered IC

more often, did you use the ICD-10 code for interstitial cystitis?"

Data Collection

Approval from the Institutional Review Board at Edinboro University and the

Compliance Committee of the clinical site was obtained.

The providers who met the inclusion criteria and agreed to participate in the study

received a cover letter, a copy of the consent to participate in the study with general

demographics questions (see Appendix G) and a printout of the algorithm. The cover letter

described the purpose and explained the study. Respondents signed the consent to participate in

the study, completed the demographics form, and provided a preferred email address for the

researcher to send the post-test questionnaires. To capture all eligible providers, a general email

was sent to their work address explaining the purpose of the study and asked them to participate

in the study. All providers who responded with interest to participate met with the researcher to

be educated on IC and how to utilize the Chronic Urinary Symptoms template on the Centricity

electronic health record. All interested participants were educated on IC as well as the diagnostic

algorithm developed for the Centricity electronic health record. The developed template was

used for documentation and diagnosis of chronic urinary symptoms including IC. All participants

were entered into a drawing to win a twenty-five dollar Amazon gift card. Every provider

followed an itemized checklist to assure training consistency (see Appendix H).

An inquiry of 23 possible ICD-10 codes was run four months before and after education

on IC for all providers that agreed to participate in the study. The inquiry was used to

demonstrate the diagnosis codes used by each provider in the study for chronic urinary and

gynecological complaints. At the completion of the study, the providers received a post-test

email (see Appendix I) consisting of Perceived Competence scale, and the Post Study Usability

Questionnaire (PSSUQ). A reminder email to complete the questionnaires was sent one week

following the initial email.

After all the providers have responded, the researcher scored the questionnaires according

to the guidelines suggested. The questionnaires were placed in a sealed envelope and placed in a

locked file cabinet where they will be kept for three years. The results of the study will be shared

with the participants and the Chief Medical Officer of the FQHC.

Summary of Methodology

This study represents an evaluation of an evidence based algorithm. Data were collected

via the PSSUQ, Perceived Competence Scale, and ICD-10 codes used before and after

implementation of diagnostic template algorithm. The independent variable chronic urinary

symptoms algorithm was neither controlled nor manipulated as the investigator determined if the

algorithm would impact the provider's decision-making on diagnosing IC over other possible

ICD-10 codes for urinary symptoms, the dependent variable.

Chapter 4

Results and Discussion

This chapter will discuss the results and have an interpretation of the findings based on statistical analysis.

Descriptive Results

Fifty-three providers met inclusion criteria for the study. Nineteen providers agreed to participate in the study to appraise a Centricity template that was designed to help evaluate chronic urinary symptoms and differentiate interstitial cystitis (IC) over other urinary issues. The sample included 6(31.5%) Doctor of Osteopaths (DO), 6(31.5%) Medical Doctors (MD), 4(21%) Nurse Practitioners (NP), and 3(16%) Physician Assistants (PA). Out of the 19 that agreed to take part in the study, 14 returned the questionnaires providing a response rate of 73.7%. One was excluded because he left the practice and $n=4$ failed to return their questionnaires. The specialty distribution was as follows: 13(68%) family practice, 4(21%) OB/GYN, and 2 (11%) internal medicine. The mean years of practice were 12.9 (range, 1-38 years) and the mean years using electronic health records (EHR) was 4.7 (range, 1-10). All but one felt they were good to extremely comfortable with the use of the EHR (see table 1).

Table 1

Demographic Information on Providers Evaluating the "Chronic Urinary Symptoms Template"

Participants	Total Number	
	(n=19)	%
Degree		
MD	6	31.5%

DO	6	31.5
Nurse practitioner	4	21%
Physician Assistant	3	16%
Specialty		
Family	13	68%
OB/GYN	4	21%
Internal Medicine	2	11%
Year of practice		
1-5 years	5	26%
6-10	6	32%
11-20	3	16%
21+	5	26%
Years using EHR		
1-5	12	63%
6-10	7	37%
11-20	0	0%
21+	0	0%

Comfort level of using EHR

Poor/ With help	1	5%
Good/Moderate	5	26%
Very Good	12	63%
Extremely	1	5%

The Post-Study Usability Questionnaire (PSSUQ) was a 16-item survey and was used in the current study to examine the satisfaction and the usefulness of the template/algorithm in diagnosing and differentiating IC over other common bladder problems. Participants were able to choose from seven alternative responses ranging from 1-"Strongly Agree", 2-"Moderately Agree, 3-"Slightly Agree", 4-"Neutral", 5-"Slightly Disagree", 6-"Moderately Disagree, 7-"Strongly Disagree". Averaging the subscales of System Quality, Information Quality, and Interface Quality provided an overall satisfaction score for the PSSUQ. The mean scores for each question of the subscales are presented in Table 1. For the first sub-scale System Quality, the mean provider item response was low, suggesting providers felt the template was "easy to learn to use" (M=1.67, SD=.99) however," Whenever I made a mistake using the template, I could recover easily and quickly" was not as straightforward (M=2.36, SD=1.36). In Information Quality, the providers felt "The organization of information on the system screens was clear" (M=1.69, SD=.86) surpassed the "The information was effective in helping me complete the tasks and scenarios" (M=2.15, SD=1.52). Finally, the sub-scale Interface Quality, the providers agreed that "Overall, I am satisfied with this template quality" (M=2.23, SD=1.24) with the best score of the sub-category being "The interface of this template was pleasant" (M=1.84,

SD=1.21). The interface comprises those items that are used to interact with the template. For

example, some components of the interface are the keyboard, the mouse, and the screens,

including their graphics and language. Scores reflected the need for improvement in the

functions and capabilities of the "template quality", and productivity and recovering from

mistakes in the "system quality".

Table 2

Satisfaction Scores of the PSSUQ for Chronic Urinary Symptoms Template

Section	Min/Max (Range)	M (SD)
System Quality		2.04(1.11)
Overall, I am satisfied with how easy it is to use the template.	1/3(3)	1.77(.83)
It was simple to use this template.	1/4(4)	1.77(1.01)
I was able to complete the task and scenarios quickly using this template.	1/6(6)	2.08(1.51)
I felt comfortable using this template.	1/6(6)	2.14(1.56)
It was easy to learn to use this template.	1/4(4)	1.67(.99)
I believe I could become productive quickly using this template.	1/6(6)	2.57(1.60)
Whenever I made a mistake using the template, I could recover easily and quickly.	1/5(5)	2.36(1.36)
Information Quality		1.92(.97)
The information (such as on-screen messages and other documentation) was clear.	1/5(5)	1.92(1.38)

It was easy to find the information I needed.	1/4(4)	1.92(1.04)
The information was effective in helping me complete the tasks and scenarios.	1/6(6)	2.15(1.52)
The organization of information on the template screen was clear.	1/3(3)	1.69 (.86)
Template quality		2.077(1.17)
The interface of the template was pleasant.	1/4(4)	1.85(1.21)
I liked using the interface of the template.	1/6(6)	2.15(1.63)
This template has all the functions and capabilities I expect it to have.	1/4(4)	2.08(1.04)
Overall, I am satisfied with this template	1/5(5)	2.23(1.24)

Note. The 7-point Likert scale was 1-strongly agree, 2-moderately agree, 3-slightly agree, 4-neutral, 5-slightly disagree, 6-moderately disagree, and 7-strongly disagree.

The average scores and standard deviations for each sub-scale group are found in Table 3. Providers rated the Information Quality the best (M=1.92) and Template Quality the worst (M=2.07). When averaging the subscales of System Quality, Information Quality, and Interface Quality the overall satisfaction score was 2.036.

Table 3

Summary PSSUQ Subscale Scores Results with Overall Score

Sections	Average Score	Standard Deviation
System Quality	2.04	1.11
Information Quality	1.92	.97
Template Quality	2.07	1.17
Overall Average	2.036	1.081

Note. The 7-point Likert scale was 1-strongly agree, 2-moderately agree, 3-slightly agree, 4-neutral, 5-slightly disagree, 6-moderately disagree, and 7-strongly disagree.

There were "comment" sections in the survey that encouraged the participants to add input about the template functions, overall satisfaction of the template, and any suggestions on improving the Chronic Urinary Symptom template. Very few providers made comments. The comments that were received included that the template should include options for male clients and that the template should be part of the original progress note to save time on having to "load another form". One participant did comment that he did not have the chance to use the template at all in the four months it was available.

The Perceived Competence Scale was a four-item questionnaire that assessed providers' self-reports of feelings of competence in recognizing and diagnosing IC. The participant was asked to respond to each item on a 7-point Likert-type scale. They could choose 1=" Strongly Disagree", 2= "Moderately Disagree", 3= "Slightly Disagree", 4=" Neutral", 5= "Slightly Agree", 6=Moderately Agree", or 7=" Strongly Agree". It appeared that the providers perceived that they were competent in diagnosing IC given the relatively high average scores. The providers also felt they could consider IC more often as a differential diagnosis using the

template with a mean score of 6.29 (*SD*=.91). A follow-up question to considering IC diagnosis

as a differential diagnosis was if they had actually used the ICD-10 code for IC, (*n*=6) did use

the diagnosis, (*n*=5) did not, and (*n*=3) did not answer this question.

Table 4

Summary of the Perceived Competence Scale Descriptive Statistics

Statement	Min/Max (Range)	*M*(SD)
I feel confident in my ability in diagnosing interstitial cystitis	3/7(5)	5.79(.98)
I feel capable of diagnosing interstitial cystitis.	3/7(5)	5.93(1.07)
I am able to diagnose interstitial cystitis.	4/7(4)	6.07(.92)
I feel I consider interstitial cystitis more often as a differential diagnosis	4/7(4)	6.29(.91)

Note. The 7-point Likert scale was 1-strongly disagree, 2-moderately disagree, 3-slightly disagree, 4-neutral, 5-slightly agree, 6-moderately agree, 7-strongly agree.

The 21 ICD-10 codes that are commonly used for chronic urinary symptoms and IC with

and without hematuria are summarized in Table 5. The ICD-10 codes that were evaluated were

used a total of 235 times the four months prior to the template and 290 times four months after.

In evaluating the ICD-10 codes for this study the researcher combined related diagnosis codes to

make it easier to read. Urinary incontinence 26(11%) pre-test and 22(7.5%) post-test, is a

combination of mixed incontinence (N39.46) 2 pre-test/0 post-test; urge incontinence (N39.41) 4

pre-test/5 post-test; stress incontinence (N39.3) 5 pre-test/2 post-test; and unspecified

incontinence (R32) 15 pre-test/15 post-test. Dyspareunia (N94.1) 6(2.5%) pre-test and 7(2%)

post-test includes vaginismus (N94.2) and vulvodynia (N94.819) there was zero diagnosis in

either the pre-test or post-test evaluation. Cystitis 10(4%) pre-test and 5(1.7%) post-test includes

acute cystitis with hematuria (N30.01) 6 pre-test/5 post-test; acute cystitis without hematuria

(N30.00) 2 pre-test/0 post-test; chronic cystitis with hematuria (N30.21) 0 pre-test/0 post-test;

chronic cystitis without hematuria (N30.20) 2 pre-test/0 post-test; and unspecified cystitis with

hematuria (N30.91) 0 pre-test/0 post-test; unspecified cystitis without hematuria (N30.90) 0 pre-

test/0 post-test. Interstitial cystitis 0(0%) pre-test and 5(1.7%) post-test includes IC with

hematuria (N30.11) 0 pre-test/1 post-test and IC without hematuria (N30.10) 0 pre-test/4 post-

test. Dysuria (R30.0) 68(29%) pre-test and 96(33%) post-test includes painful micturition

(R30.9) with 0 pre and post-test.

Table 5

ICD-10 Codes Used Before and After Initiation of Template

ICD-10 code	Before	After
	(n=235)(%)	(n=290)(%)
Urinary Tract Infection (N39.0)	85(36%)	108((37%)
Overactive Bladder (N32.81)	18(8%)	11(4%)
Urinary Incontinence (R32, N39.3, N39.41, N39.46)	26(11%	22(7.5%)
Dyspareunia (N94.1, N94.2, N94.819)	6(2.5%)	7(2%)
Cystitis (N30.01, N30.00, N30.20, N30.21, N30.90, N30.91)	10(4%)	5(1.7%)
Interstitial cystitis (N30.10, N30.11)	0(0%)	5(1.7%)
Endometriosis (N80.0)	0(0%)	0(0%)

Dysuria (R30.0, R30.9)	68(29%)	96(33%)
Frequency (R35.0)	17(7%)	25(9%)
Nocturia (R35.1)	1(.4%)	5(1.7%)
Urgency (R39.15)	4(1.7%)	6(2%)

Discussion of the Descriptive Results

The PICO question that guided this study was the following: Will clinicians report competence in the ability to diagnose IC and consider it more often in their differential diagnosis using an EHR algorithm template for chronic urinary tract symptoms? The success of the project was determined by comparing the pre and post ICD-10 codes used and the providers' assessment of the usability of the algorithm. The established level of significance was $p<.05$. The statistical package used was IBM SPSS Statistics Version 23.0

Providers' Diagnosis of IC Before and After the Implementation of EMR

A Wilcoxon signed-rank test determined that there was a statistically significant median increase in the number of total interstitial cystitis diagnosis from before ($n=0$) to after (n=5) implementation of the EMR template, $z=2.236$, $p=.025$. Of the 19 participants recruited to the study, the introduction of the template was associated with an increase in IC diagnosis by 5 providers, which in this case meant that there were no IC diagnoses at either time point for the other 14 providers.

The Wilcoxon signed-rank test tested the hypothesis that the median difference between two related total post-IC diagnoses and total pre-IC diagnoses equals zero is rejected. There was

a significant change observed between the number of IC diagnosis given four months prior to using the template and the number of IC diagnosis given after the template was used.

<u>Providers' Experience with the EMR Template</u>

The providers expressed that the algorithm provided the necessary information to manage patients with chronic urinary symptoms by expressing the template as a whole was usable. The Post-Study Usability Questionnaire (PSSUQ) was summarized and averaged following the procedures suggested by the author. The providers moderately agreed ($M=2.036$, $SD=1.081$ minimum=1, maximum=6, range=5) that the template was usable, based on the average of all of the questions on the usability scale.

In evaluating the template with the PSSUQ, the participants scored Information Quality of the template better than the Template Quality or the System Quality. The Information Quality entailed the clarity and organization of the material and the ease of finding items of information on the template. The Template Quality measured the functions, capabilities, graphics and the language of the program. System Quality evaluated the ease in learning and using the template if the provider felt they could easily operate and be productive in utilizing the template. Even though the participants felt the Information Quality subscale exceeded the other subscales, Table 6 reveals a one-way repeated measure ANOVA, found no difference in the scores for the subscales of the PSSUQ.

Table 6

One-Way Repeated Measure ANOVA for the Average Scores of the Three Subscales of the

PSSUQ

Source		Type III Sum of Squares	Df	Mean Square	F	Sig.
Scales	Sphericity Assumed	.172	2	.086	.876	.429
	Greenhouse-Geisser	.172	1.648	.104	.876	.413
	Huynh-Feldt	.172	1.877	.092	.876	.424
	Lower-bound	.172	1.000	.172	.876	.368
Error(Scales)	Sphericity Assumed	2.356	24	.098		
	Greenhouse-Geisser	2.356	19.781	.119		
	Huynh-Feldt	2.356	22.523	.105		
	Lower-bound	2.356	12.000	.196		

The mean satisfaction scores for each question of the PSSUQ, in Table 3, reveals where

improvements can be made to the template. The poorest scores were in the functions and

capabilities ($M=2.08$, $SD=1.04$) of the "template quality", and the potential to quickly be

productive ($M=2.57$, $SD=1.60$) and recovering from mistakes easily and quickly ($M=2.36$,

$SD=1.36$) in the "system quality" subscales. The providers offered only a few comments. The

comments yielded improvements of the Template Quality subscale. One criticized the function

of the "template quality" by lacking the desire "to load another form" and two mentioned that the

template needed to" include male patients" as an improvement of the capability of the Chronic

Urinary Symptoms template.

An independent sample t-test was conducted to examine the differences between those

who answered "yes" ($n=6$) to the statement "I feel I consider interstitial cystitis more often as a

differential diagnosis" and those who answered "no" ($n=5$) on the PSSUQ subscales average and

Perceived Competence score mean. Those who did not answer *(n=3)* were not included in the t-test. Tables 7 and 8 show that there was no statistical difference for the "yes" and "no" group in either the Perceived Competence Scale mean nor the PSSUQ subscale average. The providers that denied using the ICD-10 code interstitial cystitis with or without hematuria *(n=5)* did have a lower average competence score *(M=5.86, SD=.29)* than those that did use the ICD-10 code for IC *(n=6)* *(M=6.37, SD=.56)*, but it was not significant.

Table 7

The Consideration of use of the IC Diagnosis and Perceived Competence Scale and PSSUQ

Group Statistics

	considered	N	Mean	Std. Deviation
Perceived Competence Mean[1]	No	5	5.8500	.28504
	Yes	6	6.3750	.56458
System Quality average score[2]	No	5	2.9286	1.41060
	Yes	6	1.6667	.55451
Information Quality average[2]	No	5	2.6000	1.08397
	Yes	5	1.5000	.77055
Template Quality average score[2]	No	5	2.8500	1.38744
	Yes	5	1.8000	.87321

Note. 1. For the Perceived Competence the 7-point Likert scale was 1-strongly disagree, 2-moderately disagree, 3-slightly disagree, 4-neutral, 5-slightly agree, 6-moderately agree, 7-strongly agree. 2. The PUSSQ subscale the 7-point Likert scale was 1-strongly agree, 2-moderately agree, 3-slightly agree, 4-neutral, 5-slightly disagree, 6-moderately disagree, 7-strongly disagree.

Table 8

The Consideration of use of the IC diagnosis and Perceived Competence Scale and PSSUQ

Independent Samples Test

	t	df	Sig. (2-tailed)
Perceived Competence mean	-1.878	9	.093
System Quality average score	2.029	9	.073
Information Quality average	1.849	8	.102
Template Quality average score	1.432	8	.190

The "no" group rated each PSSUQ subscales higher than the "yes" group with the System

Quality subscale average rating the highest of all the subscales. The System Quality assessed

how easy the template was to use; if the provider felt they could complete the tasks and scenarios

quickly using the template; if they felt comfortable using the template; if the provider felt they

could be productive quickly using the template; and if the provider made a mistake using the

template, could they recover easily and quickly. The providers who answered "no" scored this

subscale as not as usable as the providers who answered "yes". Possibly, the providers did not

use the IC diagnoses because they were not as confident in using the template system as other

practitioners. Although they did not use the diagnosis of IC, all but one provider did utilize the

template at least once for chronic urinary symptoms during the time frame and at least

considered IC in their differential diagnosis. This is known because the participant who did not

complete the questionnaire and stated that he/she "Had not diagnosed IC since using the

template". One provider that responded "no" did mention that the interstitial cystitis ICD-10

code was used "in my differential diagnoses but did not use as final diagnoses". The aspect that

there was no significant difference between the two groups is not surprising because the sample is very small and the interpretation must be explained with caution.

Limitations

Limitations of this study include:

1. The template made for this study is specific to the EHR system called Centricity which is currently in use by providers in the same Federally Qualified Health Center and may not be widely generalizable to other EHR systems.

2. The evaluation time is short. We would have had a larger pre and post measurements of the 23 ICD-10 codes.

3. Small sample size and the sample did not give a lot of suggestions on improvements of the template in the "comments" section.

4. Design with no control opens the door for many alternative explanations of both the significant and non-significant results.

5. Lack of connection between participants in the survey portion and the diagnosis portion makes it impossible to know if anything about the usability would actually affect a change in diagnosis.

6. A 2016 consensus guideline for diagnosis and treatment was published by Cox et al. These guidelines were based on MEDLINE, PUBMED and consensus office proceedings. Considering these guidelines, there are several adjustments to the information and quality of the template that could be made. The guideline categorized what is mandatory as well as recommended to be completed for adequate diagnosis. Changes to the algorithm include 1. Documenting what recommendations are mandatory

or recommended with a key to identify. 2. Modifying the "urine culture" to reflect the need of urinalysis and perform urine culture if there are signs of urinary tract infection present. 3. Changing the PUF score from 10 to 13, as the guideline suggests that "13 or greater distinguished IC more efficiently" (Cox et al., 2016 pp. 138). 4. Including cystoscopy as an option for high-risk patients. 5. Added frequency volume chart (FVC) test as a recommendation (see Appendix K). The FVC investigates the average volume the person is voiding. A person with IC will void an average of less than 100ml 17 to 25 times a day, compared to the normal 289 ml six times a day for an asymptomatic person (Cox et al., 2016).

Summary

Participants in different degrees and specialties with many years of experience evaluated the Chronic Urinary Symptoms Template. It was determined that the providers felt they were competent in diagnosing interstitial cystitis and that the template was usable in determining which patients had IC over other chronic urinary issues. The repeated measures pre-post change in median number IC diagnosis, as predicted, had a significant result (Wilcoxon sign test).

Chapter 5

Summary, Conclusions, and Recommendations

Summary of the findings

Interstitial cystitis has no gold standard for diagnosis. This study was conducted to test the usability of an algorithm developed to determine if women with chronic urinary symptoms had IC. This was important because without a criterion of diagnosis, primary care providers have a hard time adequately diagnosing IC. A before and after study design was used. Data were collected using a modified Post-Study Usability Questionnaire (PSSUQ), a Perceived Competence Scale Questionnaire and an inquiry on 23 ICD-10 codes used four months before and after a diagnostic algorithm was introduced. Evaluation of the findings suggests that the research question should be accepted. There was a significant difference found between the number of IC diagnosis given four months prior to using the template and the number of IC diagnosis given after the template. The providers moderately agreed that the template was usable. The providers felt they were competent in diagnosing IC, and they considered IC more often as a differential diagnosis using the template

Implications for Advanced Practice Nursing

Interstitial cystitis is a condition that is poorly understood. Diagnosis is often delayed and difficult because there are no objective signs or tests to confirm the diagnosis of IC (Berry et al., 2011). Patients that suffer from chronic urinary symptoms with no true diagnosis experience serious physical and psychological deficits without a timely diagnosis. Giving providers an accepted evidenced based algorithm template for chronic urinary symptoms would create confidence in the practitioner to correctly diagnose and then treat IC. The project was successful

in providing a foundation for developing an easy to follow algorithm to guide clinicians in correctly diagnosing chronic urinary issues. Although the sample size was small and adjustments to the algorithm were recommended, it is a good starting place to develop other templates in other EMR systems.

Recommendations for Further Research

Improvements can be made to the templates functions, capabilities, and graphics. Considering the new consensus guidelines published by Cox et al. (2016), there are several adjustments to the information and quality that also can be made. Another study would be recommended with these changes to the template. If this study would be duplicated, I would want to evaluate the competence score before and after the introduction of the template. The Perceived Competence Scale would be given before and after the introduction of the template. Further research would include a chart review for the ICD-10 codes urinary frequency, urgency, and nocturia. The review would evaluate if the symptoms were acute or chronic. If they were chronic, did the provider use the Chronic Urinary Symptoms template? Finally, further research needs to be done to assess reliability and validity of the algorithm. Reliability is established when the algorithm produces consistent results. Validity is established when the algorithm accurately indicates the diagnosis of IC.

During the process of introducing the template to the participants of the study, I was surprised to learn how many providers do not routinely perform a pelvic exam on their patients. More education needs to be done to stress the importance of performing a pelvic exam for the diagnosis of chronic pelvic pain.

This research demonstrated that a well formulated diagnostic algorithm template will help clinicians in diagnosing IC from a number of other urological and gynecological conditions. Developing an application for a smartphone or personal computer would make the algorithm available to many providers.

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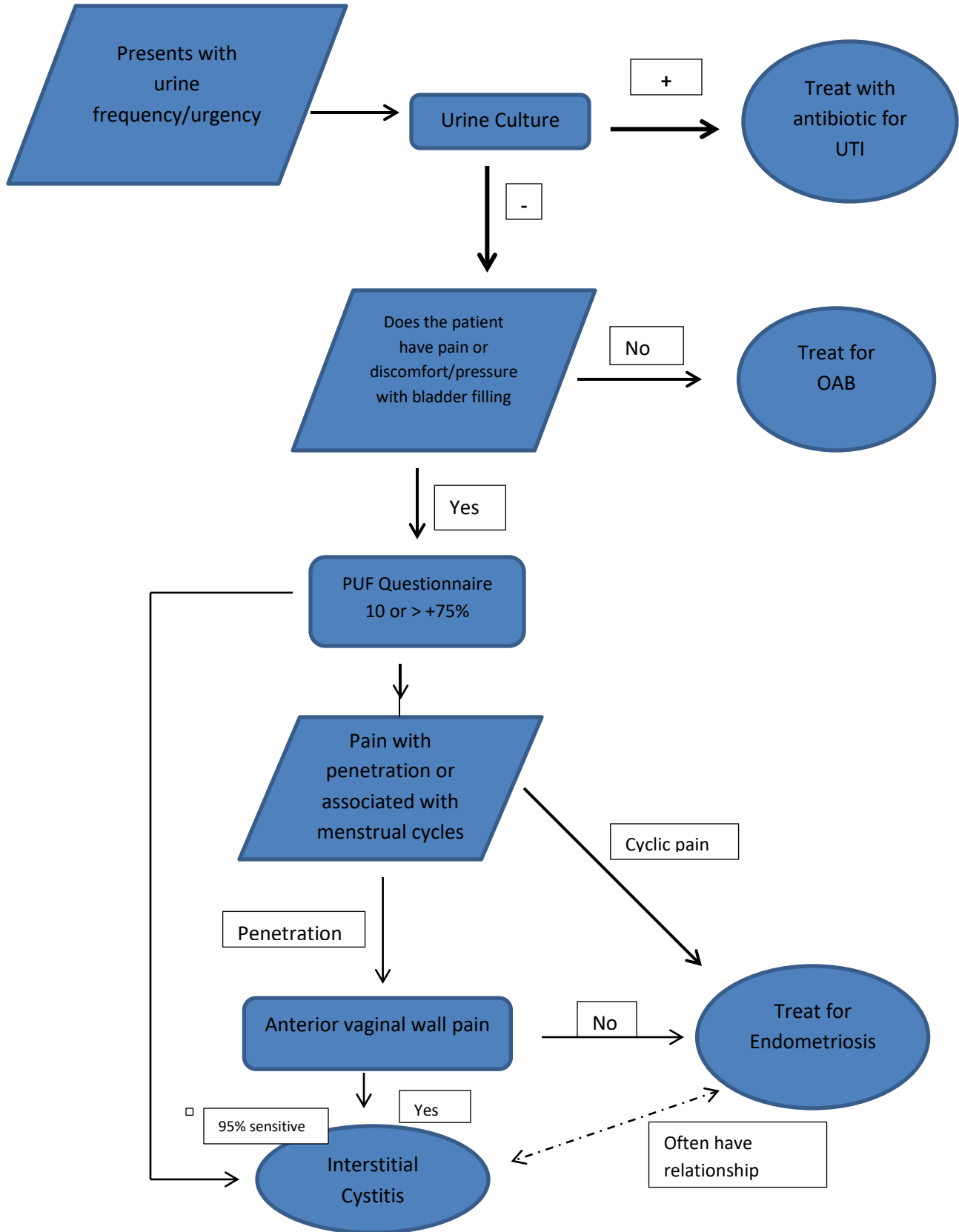*The Journal of Family Practice, 60*(6), 340-347.

Appendix A

PELVIC PAIN and URGENCY/FREQUENCY PATIENT SYMPTOM SCALE

Please circle the answer that best describes how you feel for each question.

		0	1	2	3	4	Symptom Score	Bother Score
1	How many times do you go to the bathroom during the day?	3-6	7-10	11-14	15-19	20+		
2	a. How many times do you go to the bathroom at night?	0	1	2	3	4+		
	b. If you get up at night to go to the bathroom, does it bother you?	Never Bothers	Occasionally	Usually	Always			
3	a. Do you now or have you ever had pain or symptoms during or after sexual intercourse?	Never	Occasionally	Usually	Always			
	b. Has pain or urgency ever made you avoid sexual intercourse?	Never	Occasionally	Usually	Always			
4	Do you have pain associated with your bladder or in your pelvis (vagina, labia, lower abdomen, urethra, perineum)	Never	Occasionally	Usually	Always			
5	a. If you have pain, is it usually		Mild	Mod	Severe			
	b. Does your pain bother you?	Never	Occasionally	Usually	Always			
6	Do you still have urgency after going to the bathroom?	Never	Occasionally	Usually	Always			
7	a. If you have urgency, is it usually		Mild	Mod	Severe			
	b. Does your urgency bother you?	Never	Occasionally	Usually	Always			
8	Are you sexually active? Yes____ No____							
	Symptom Score							
	Bother Score							
	Total Score		Symptom score	+	Bother	Score		

Appendix B

Chronic Urinary Symptoms Algorithm

```
┌──────────────────────┐
│  Presents with       │
│  urine               │──────▶  ┌──────────────┐    ┌───┐    ╭──────────────╮
│  frequency/urgency   │         │ Urine Culture│────│ + │───▶│  Treat with  │
└──────────────────────┘         └──────────────┘    └───┘    │  antibiotic for │
                                        │                       │  UTI          │
                                      ┌─┴─┐                     ╰──────────────╯
                                      │ - │
                                      └─┬─┘
                                        ▼
                        ┌──────────────────────────┐
                        │  Does the patient         │   ┌────┐    ╭──────────────╮
                        │  have pain or             │───│ No │───▶│  Treat for   │
                        │  discomfort/pressure      │   └────┘    │  OAB         │
                        │  with bladder filling     │             ╰──────────────╯
                        └──────────────────────────┘
                                        │
                                     ┌──────┐
                                     │ Yes  │
                                     └──────┘
                                        ▼
                           ┌────────────────────────┐
                           │  PUF Questionnaire      │
                           │  10 or > +75%           │
                           └────────────────────────┘
                                        │
                                        ▼
                        ┌──────────────────────────┐
                        │  Pain with                │   ┌────────────┐
                        │  penetration or           │──▶│ Cyclic pain│
                        │  associated with          │   └────────────┘
                        │  menstrual cycles         │
                        └──────────────────────────┘
                             │
                      ┌──────────────┐
                      │ Penetration  │
                      └──────────────┘
                             ▼
                ┌──────────────────────────┐    ┌────┐    ╭──────────────╮
                │  Anterior vaginal wall    │────│ No │───▶│  Treat for   │
                │  pain                     │    └────┘    │  Endometriosis│
                └──────────────────────────┘             ╰──────────────╯
                             │
                      ┌──────┐
                      │ Yes  │
                      └──────┘
   □ 95% sensitive        ▼
                     ╭──────────────╮
                     │  Interstitial │
                     │  Cystitis     │
                     ╰──────────────╯

                     Often have
                     relationship
```
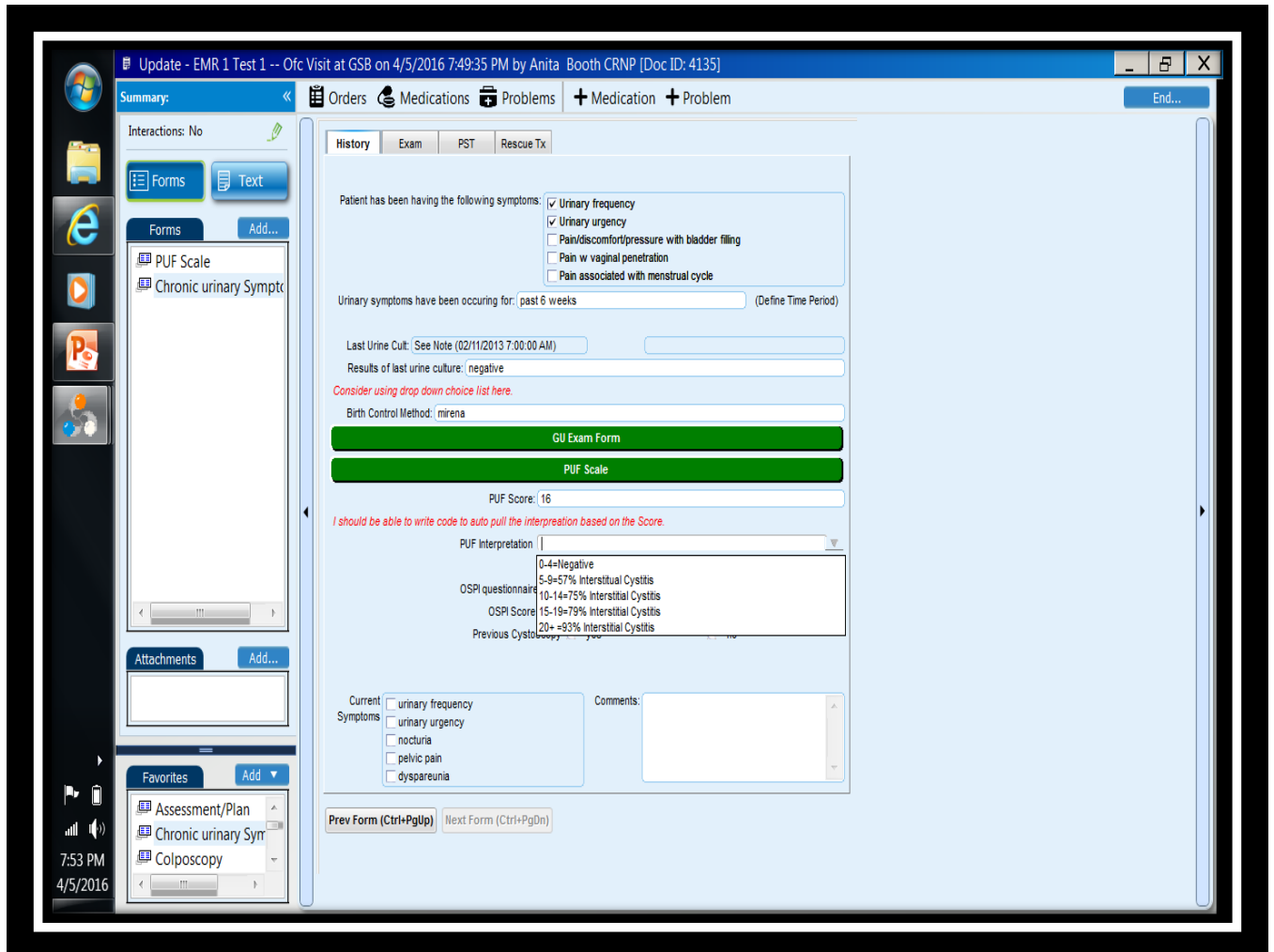
95% sensitive

Cyclic pain

Often have relationship

Appendix C

Chronic Urinary Symptoms Action Plan

Problem	Urine Culture	Pain	PUF (>then 10)	AVWT	Action
UTI	+	+/-	-	-	Antibiotic
OAB	-	-	+/-	-	Anticholinergic
Endometriosis	-	+	+/-	+/-	OCP (often interwoven
Interstitial Cystitis	-	+	+	+	Diet changes Refer

Appendix D

Centricity Template

Appendix E

The PSSUQ Survey

Post-Study Usability Questionnaire for Chronic Urinary Symptoms Template

	Strongly Agree					Strongly Disagree		
	1	2	3	4	5	6	7	n/a
1. Overall, I am satisfied with how easy it is to use the template.								
2. It was simple to use this template								
3. I was able to complete the tasks and scenarios quickly using this template.								
4. I felt comfortable using this template.								
5. It was easy to learn to use this template.								
6. I believe I could become productive quickly using this template.								
7. Whenever I made a mistake using the template, I could recover easily and quickly.								
8. The information (such as on-screen messages and other documentation) was clear.								
9. It was easy to find the information I needed								
10. The information was effective in helping me complete the tasks and scenarios.								
11. The organization of information on the template screens was clear.								
12. The interface* of this template was pleasant.								
13. I liked using the interface of this template.								
14. This template has all the functions and capabilities I expect it to have.								
Comments:								
15. Overall, I am satisfied with this template.								
Comments:								
Are there any suggestions on improving the Chronic Urinary Symptom Template?								

*The "interface" includes those items that you use to interact with the template. For example, some components of the interface are the keyboard, the mouse, and the screens (including their graphics and language).

Appendix F

Perceived Competence Scale for Diagnosing Interstitial Cystitis

Please read each item and give the number that indicates your level of agreement with the statement.

1	2	3	4	5	6	7
Strongly Disagree	Moderately Disagree	Slightly Disagree	Neutral	Slightly Agree	Moderately Agree	Strongly Agree

1. I feel confident in my ability in diagnosing interstitial cystitis._____

2. I feel capable in diagnosing interstitial cystitis._____

3. I am able to diagnose interstitial cystitis._____

4. I feel I consider interstitial cystitis more often as a differential diagnosis._____

5. If you have considered interstitial cystitis more often, did you use the ICD-10 code for

   IC?_____

Appendix G

EDINBORO UNIVERSITY OF PENNSYLVANIA

Edinboro, Pennsylvania

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Interstitial Cystitis: Algorithm to Simplify Diagnosis of Chronic Urinary Symptoms

Principal Investigator: Jill Rodgers

Co-Investigator: Anita Booth

Introduction

You are being asked by Anita Booth CRNP to be in a research study. You should understand that this study involves research. This consent describes your role as a participant in the study.

I am conducting this research as part of my Doctorate in Nursing Practice program. You are being asked to participate because my inclusion criteria include your office specialty and that you work in the Centricity electronic health system.

Purpose of The Study

The purpose of the study is to assess the usability of an algorithm for providers to aid in the diagnosis of interstitial cystitis in women with chronic urinary symptoms. This algorithm is based on evidenced based practice guidelines and will be an on an Electronic Health Record template.

What Will Happen During the Study?

If you would consent to the study I, Anita Booth, will schedule a time to come to your office to discuss interstitial cystitis and instruct you on a template that I have developed. After the discussion, you can consider using the Chronic Urinary Symptom template with your female patients that are ages 16 and older. In 4 months, I will email you a Post-Study Usability Questionnaire (PSSUQ) and a

Competence Questionnaire that will take approximately 10 minutes for you to complete and return. This email needs to be returned within 2 weeks from the time of it being sent. When the questionnaires have been completed and returned you will be entered to win a twenty-five dollar Amazon gift card that one provider will win.

With consent, you also agree to allow a designated clinical program analyst to look at 23 ICD-10 codes that are commonly used for urinary symptoms. An assessment of diagnostic habits 4 months prior and post template use will be analyzed.

What Are the Possible Risks or Discomforts?

There are no risks or discomforts in participating in this study. The researcher will know who participated in the study but there will be no identifier in the research. A unique identifier for each provider will be given, established by the clinical program analyst, who will gather the number of ICD-10 codes used pre and post use of the template. The identifier will be used in consideration that the researcher is a colleague with the participant.

What Are the Possible Benefits of Being in This Study?

The benefit will be developing an algorithm to assist providers in diagnosing interstitial cystitis. There are no direct benefits to the participants.

How Will the Data Collected Be Kept Confidential?

You should know that your name will be kept as confidential as possible, within local, state and federal laws. Records that identify you and this signed consent form may be looked at by the Edinboro University Institutional Review Board (IRB). The results of this study may be shared in aggregate form at a meeting or in a journal, but your name or individual results/score(s) will not be revealed.

What Happens If I Have More Questions?

Your questions about the research study and the use of the template will be answered by Anita Booth at (724) 854-3963. If you have a question about your rights as a research participant that you need to discuss with someone, you can call the Edinboro University Institutional Review Board at (814) 732-2856.

What Will Happen If You Decide Not To Be in the Study?

Your participation in the focus group activity is strictly voluntary. You may decide to quit at any time without any penalty, retribution, or repercussion.

PARTICIPANT'S STATEMENT

I had a chance to ask questions about the study. These questions were answered to my satisfaction.

I realize that being part of this study is my choice. I am at least 18 years of age. I have read the consent form. I was given a copy of this consent form for my own records.

_____   _____

         PARTICIPANT'S SIGNATURE   DATE

Appendix H

Provider Education Checklist

1. Review powerpoint of what is interstitial cystitis and where the information came

   from for the algorithm that was developed.

2. Review the ideal patients that the template is for.

3. Place "Chronic Urinary Symptoms Template" into the favorites section of the EHR.

4. Work through a test patient in the EHR Centricity template.

5. Fill out the demographic form with signature to give permission to evaluate

   diagnostic codes used 4 months before and after the education of template.

Appendix I

Post Study Email

Dear _____

I would like to take this opportunity to thank you for completing the study on Interstitial Cystitis: Algorithm to Simplify Diagnosis of Chronic Urinary Symptoms. When you agreed to participate in the study 4 months ago, you also agreed to complete 2 very simple questionnaires that will take you less than 10 minutes to complete. Attached to this email are the Post-Study Usability Questionnaire and the Competence Scale Questionnaire.

After the questionnaires are complete and returned to me, you will be entered to win a $25 dollar gift card from Amazon. Please return the questionnaires within 2 weeks of receiving this email.

Appendix J

Permission to Use Framework

Hi Anita, happy for you to use the framework for your paper. If you publish you will also need to get permission from the journal. ian

From: Todd Booth [mailto:tabooth11@verizon.net]
Sent: October 22, 2016 19:06
To: Graham, Dr. Ian (OHRI-CEP)
Subject: seeking permission to use framework

Seeking permission to use Knowledge to Action framework in my doctoral research paper. I am a doctoral student for nursing practice and I am doing a study titled: Interstitial cystitis: algorithm to simplify diagnosis of chronic urinary symptoms.

I am using your framework to explain the process of gathering the evidenced based information on different ways researchers have diagnosed IC to combine it to develop an algorithm to diagnose. IC has no gold standard to diagnose and I am hoping to develop one. I am not changing your framework in any way.

For my paper, I need written permission from you. Thank you in advance.

Anita Booth

Appendix K

Changes to Algorithm

History: (M) Presents with chronic urine frequency/urgency

Low risk for bladder cancer

Frequency = >10

U/A (M) Culture (R) FVC (R))

Refer to cystoscopy if high risk/smoker

+

Treat with antibiotic for UTI

-culture/FVC <100ml

History (M) Does the patient have pain or discomfort/pressure with bladder filling

Pain worse a few days prior to menses

Treat for OAB

No

Pain worse during menses

Yes

PUF Questionnaire (R) 13 or > +75%

History: (M) Pain with penetration or associated with menstrual cycles

Cyclic pain

Penetration

Physical (M) Abdominal and pelvic exam-Anterior vaginal wall pain

No

Treat for Endometriosis

Often Interwoven

Key:
M-mandatory
R-Recommended
U/A-urinalysis
FVC-Frequency volume chart

95% sensitive

Yes

Interstitial Cystitis