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Sexually Transmitted Infection or Urinary Tract Infection? Misdiagnosis of Chlamydia Trachomatis and Neisseria Gonorrhoeae Infections in Primary Care Practice

Bethany Mee Yeong Summers
University of Northern Colorado

UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

SEXUALLY TRANSMITTED INFECTION OR URINARY TRACT INFECTION? MISDIAGNOSIS OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE INFECTIONS IN PRIMARY CARE PRACTICE

A Capstone Research Project Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

Bethany Mee Yeong Summers

College of Natural and Health Sciences
School of Nursing
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has been approved as meeting the requirement for the Degree of Doctor of Nursing Practice in College of Natural and Health Sciences in the School of Nursing, Program of Nursing Practice.

Accepted by the Capstone Research Committee

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Kathleen N. Dunemn, Ph.D., APRN, CNM, Research Advisor

_____

Vicki Wilson, Ph.D., MS, RN, Co-Research Advisor

_____

Jill A. Quigley, M.D., Committee Member

Accepted by the Graduate School

_____

Linda L. Black, Ed.D.
Associate Provost and Dean
Graduate School and International Admissions

EXECUTIVE SUMMARY

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Sexually transmitted infections (STIs), formerly referred to as sexually transmitted diseases (STDs), remain a significant health concern in the United States. According to the Centers for Disease Control and Prevention (CDC; 2015), an estimated 20 million newly diagnosed STIs are made each year and nearly half of the cases were attributed to individuals between the ages of 15-24 with an astounding $16 billion in associated healthcare costs.

Urinary tract infections (UTIs) account for nearly five million primary care office visits each year (Johnson, 1996). A urinary tract infection is the presence of bacterial infection within the urinary tract; it is generally classified by the site of microbial infection such as urine (bacteriuria), bladder (cystitis), or kidney (pyelonephritis; Foxman, 2002). Diagnosis of either an STI or UTI can be difficult as presenting and associated symptoms such as complaints of urgency, frequency, and/or dysuria are similar in nature (Tomas, Getman, Donskey, & Hecker, 2015). In addition, the results of a urinalysis (UA) might present overlapping abnormalities--most commonly pyuria and positive leukocyte esterase (Tomas et al., 2015).

Less than 30% of reported chlamydial infections in women were symptomatic at time of diagnosis; most were detected through referral following required notification

that a prior sexual contact or partner was found to be infected or upon routine physical examination (Marrazzo et al., 1997). Consequently, the number of patients with asymptomatic chlamydial infection results in delay in initiation of antibiotic therapy, prolonged course of infection, and increases the likelihood of disease transmission and probability of negative sequelae (Marrazzo et al., 1997). Negative sequelae and health impact of untreated chlamydial infection include ectopic pregnancy, tubal infertility, chronic pelvic pain, and pelvic inflammatory disease (PID; Marrazzo et al., 1997).

To enhance quality and consistency of primary care practice, the purpose of this Doctor of Nursing Practice capstone project was to develop an evidence-based guideline for improving diagnostic screening methods for diagnosis of chlamydial and gonorrheal infections in females who present with symptomatic complaints otherwise suggestive of a urinary tract infection. Through utilization of two rounds of the Delphi method, healthcare providers in round one (six participants) and round two (four participants) provided their expert opinions regarding the necessity of a clinical practice guideline and factors that should be included within said guideline. Recommendations included age parameters (all female patients between 15-25 years of age and/or female patients older than 25 years with an identified risk factor), screening questions in assessment of risk factors (past and recent sexual history), and symptom presentation indicative of either a UTI or STI (i.e., dysuria, urinary frequency, urinary urgency, suprapubic pain, and hematuria). Implications of the Delphi method indicated the majority of participants felt routine STI testing was lacking at their respective organization, female patients were not being adequately screened for STIs when presenting with UTI complaints, and

availability of a clinical guideline would be effective in increasing STI testing rates for this patient population.

Background information was collected not only through use of Delphi questionnaires but a retrospective study was conducted evaluating frequency of ICD-9 and ICD-10 codes (CDC, 2017) for UTI from January 2013 through December 2016. In addition, an in-depth chart review was performed investigating female patient visits for UTI complaints (i.e., urinary urgency, frequency, and/or dysuria) from October 2016 through December 2016. The Stetler (2001) model was used to translate the acquired research into a tangible method of practice.

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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CINAHL	Cumulative Index to Nursing and Allied Health Literature
EBP	Evidence-Based Practice
ED	Emergency Department
EMR	Electronic Medical Record
HPV	Human Papillomavirus
LCR	Ligase Chain Reaction
MD	Medical Doctor
NAAT	Nucleic Acid Amplification Test
NP	Nurse Practitioner
PA	Physician Assistant
PAP	Papanicolaou Test
PID	Pelvic Inflammatory Disease
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
UA	Urinalysis
USPSTF	U.S. Preventive Services Task Force
UTI	Urinary Tract Infection
WHO	World Health Organization

CHAPTER I

STATEMENT OF THE PROBLEM

Background and Significance

Sexually transmitted infections (STIs), formerly referred to as sexually transmitted diseases (STDs), remain a significant health concern in the United States. According to the Centers for Disease Control and Prevention (CDC; 2015), an estimated 20 million newly diagnosed STIs are made each year; nearly half of the cases are attributed to individuals between the ages of 15-24 with an astounding $16 billion in associated healthcare costs. Undiagnosed and unreported cases of STIs remain a substantial health concern; therefore, the magnitude of the problem might be greater than what published reports allude to (CDC, 2015). In 2014, there was a considerable increase in nationally reported cases of chlamydia and gonorrhea from the prior year; 1,441,789 new cases of chlamydia (2.8% increase) and 350,062 new cases of gonorrhea (5.1% increase) were diagnosed (CDC, 2015).

Neisseria gonorrhoeae, a sexually transmitted bacterial infection, has been described dating back to the time of ancient Greeks. Before the advent and knowledge of antibiotics, recommended treatment included cold baths, vinegar, almond milk, and violet oil. During World War I, metallic compounds such as mercury, arsenic, bismuth, and radium were trialed as a cure. Until the 1930s, antibiotics, specifically penicillin and sulfonamide antibiotics, were investigated as treatment and cure for gonorrheal infections

(Planned Parenthood, 2014). *Chlamydia trachomatis* was first discovered in 1907 by Halberstaedter and von Prowazek (cited in Budai, 2007); it is a highly contagious gram-negative bacterium most commonly passed through sexual intercourse. Originally believed to be associated with gonorrhea, Halberstaedter and von Prowazek proved the existence of a new disease through examination of scrapings taken from an experimentally infected orangutan (Budai, 2007). Current antibiotic treatment recommendations include use of azithromycin or doxycycline; both treatment regimens presently continue to have high cure rates (CDC, 2016).

Although antibiotic regimens have effectively cured gonorrheal and chlamydial infections in the past, the emergence of antibiotic-resistant bacterium has prompted the New England Journal of Medicine to announce, "It is time to sound the alarm. During the past 3 years, the wily gonococcus has become less susceptible to our last line of antimicrobial defense, threatening our ability to cure gonorrhea and prevent severe sequelae" (Bolan, Sparling, & Wasserheit, 2012, p. 485). Various antibiotic classes previously successful in treatment of gonorrhea are no longer applicable; the rise of antibiotic-resistant gonorrhea has left only one class of antibiotics available--cephalosporin antibiotics. The World Health Organization (WHO; 2016) published new guidelines specifically for treatment of chlamydia and gonorrhea in response to the growing rate of antibiotic resistance partly attributed to overuse and misuse of antibiotics by physicians and other medical providers. To combat this alarming trend, it is necessary for individuals with gonorrheal or chlamydial infections to be diagnosed early and medicated appropriately to prevent spread to others, avert reinfection with untreated partners, and reduce the propagation of antibiotic resistance.

Urinary tract infections (UTIs) account for nearly 5 million primary care office visits each year (Johnson, 1996). Urinary tract infection is the presence of bacterial infection within the urinary tract and is generally classified by the site of microbial infection such as urine (bacteriuria), bladder (cystitis), or kidney (pyelonephritis; Foxman, 2002). Although considered to be one of the most widespread and common bacterial infections, an accurate diagnosis can be challenging as patients might be asymptomatic at initial presentation. Diagnosis is predicated upon symptoms identified by the patient and a positive urine culture. However, diagnosis is often made in outpatient settings without a positive urine culture, leading to misdiagnoses and probable error estimates in true disease incidence (Foxman, 2002).

Comparable to antibiotic resistance seen presently with chlamydia and gonorrhea treatment modalities, treatment regimens for UTIs are experiencing similar setbacks. Sanchez et al. (2016) performed a retrospective analysis investigating prevalence of antibiotic resistance from female patient data documented in 2003 compared with data collected in 2012. *Escherichia coli*, the most common causative agent or pathogen identified in both 2003 and 2012 data analyses, has shown considerable differences in treatment susceptibility. Urine samples taken from female patients in 2012 exhibited increased *E. coli* resistance to ciprofloxacin and trimethoprim-sulfamethoxazole, both therapy regimens highly effective in combating UTI in women in 2003 (Sanchez et al., 2016).

E. coli resistant antibiotics in treatment of UTI have also been found to significantly increase the workload of primary care practices as patients with resistant infections return for care for unrelieved or recurring symptoms. Setting aside the

increased workload of healthcare providers, unsuccessful treatment of resistant UTI negatively affects an individual's quality of life; patients unresponsive to treatment might experience symptoms twice as long as their counterparts with *E. coli* susceptible UTI (Butler et al., 2006). Due to the trending nature and devastating consequences of ineffective antibiotic therapies, it is essential healthcare providers have the tools and resources necessary in appropriately diagnosing and treating disease processes that might otherwise be incurable in the future.

Problem Statement

Diagnosis of either an STI or UTI can be difficult as presenting and associated symptoms such as complaints of urgency, frequency, and/or dysuria are similar in nature (Tomas, Getman, Donskey, & Hecker, 2015). In addition, the results of a urinalysis (UA) might present overlapping abnormalities--most commonly, pyuria and positive leukocyte esterase (Tomas et al., 2015). Less than 30% of reported chlamydial infections in women were symptomatic at time of diagnosis; most were detected through referral following required notification that a prior sexual contact or partner was found to be infected or upon routine physical examination (Marrazzo et al., 1997). Consequentially, the number of patients with asymptomatic chlamydial infection resulted in delay in starting antibiotic therapy, prolonged course of infection, and increased probability of disease transmission and development of negative sequelae (Marrazzo et al., 1997). The negative sequelae and health impact of untreated chlamydial infection included ectopic pregnancy, tubal infertility, chronic pelvic pain, and pelvic inflammatory disease (PID; Marrazzo et al., 1997).

Theoretical Framework

Continued incidence of chlamydia and gonorrhea infections in the United States highlights the pervasiveness of misconceptions and lack of general knowledge regarding the need for effective and accurate STI testing and diagnosis; there is a need to aptly apply current evidence and knowledge into practice. The Stetler (2001) model, originally developed in 1976, is an evidence-based utilization model to facilitate and simplify the transition of research into practice (see Figure 1). The model provides a stepwise approach in facilitation of research in application of evidence-based practice (EBP) in five phases: preparation, validation, evaluation/decision making, translation/application, and evaluation (Stetler, 2001).

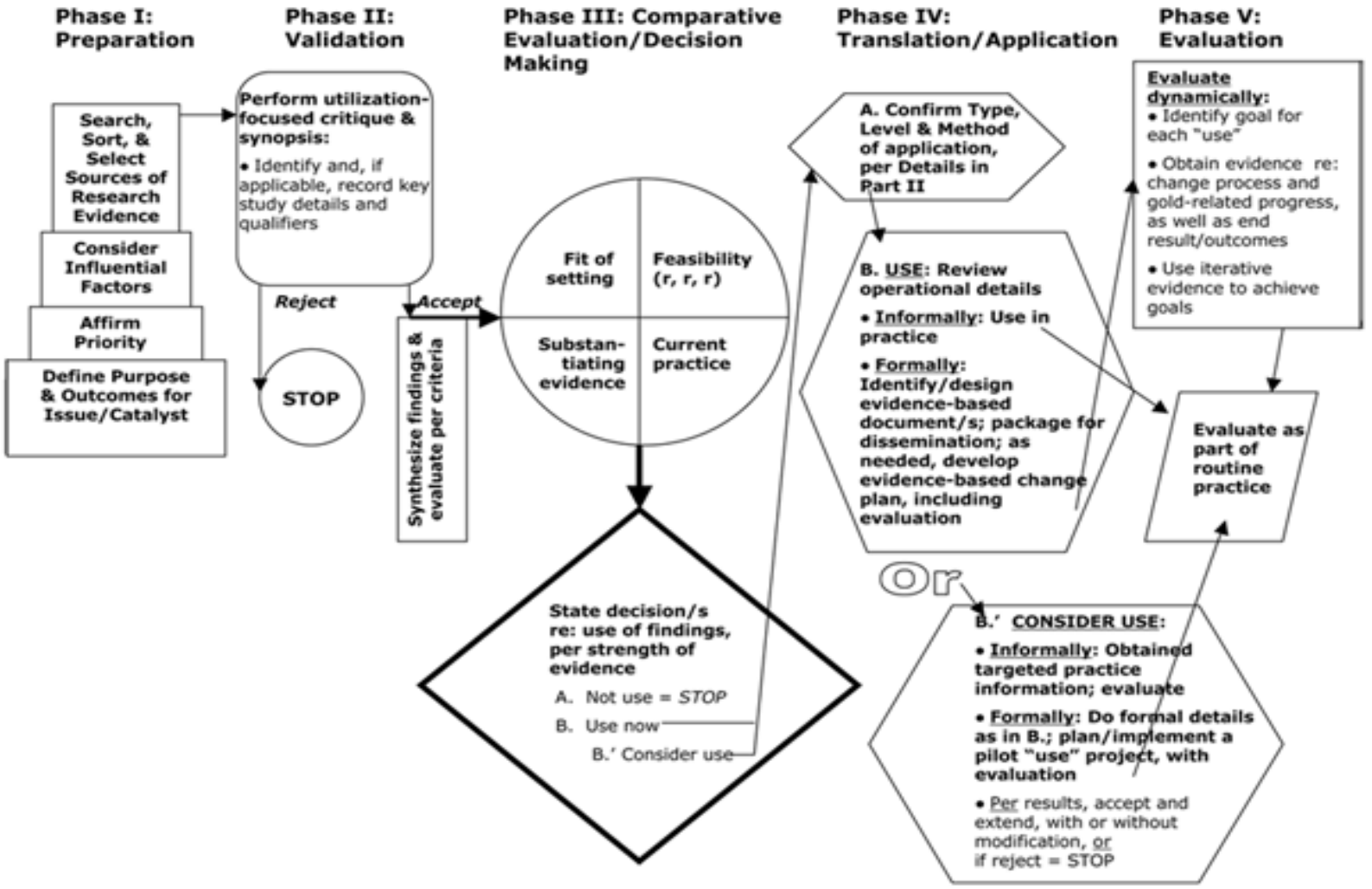

Figure 1. The Stetler model: Phases of research utilization for evidence-based practice.

- Phase I: Preparation. Phase I or the preparatory phase identified the purpose of the capstone project based upon evidence suggesting a need to revise a current practice problem. Additionally, this phase entailed development of the project foundation, project design, and Institutional Review Board (IRB) approval from both the practice organization and the University of Northern Colorado for project implementation.
- Phase II: Validation. Phase II encompassed the completion of a literature review. A comprehensive literature review required assessment of all included evidence for applicability to the capstone's purpose, credibility, and relevant value of implications for improved practice.
- Phase III: Comparative Evaluation/Decision-Making. Phase III included evaluation and feasibility of implementing a STI/UTI guideline within the designated primary care practice. This phase was achieved through utilization of the Delphi method; a panel of experts comprised of medical doctors, nurse practitioners, and physician assistants was provided questionnaires regarding appropriate clinical parameters for successful development and critical information necessary to include within the clinical practice guideline.
- Phase IV: Translation/Application. Phase IV encompassed the development of the guideline (based upon information gathered from the Delphi questionnaire and literature review), advisement for implementation into practice, and physical implementation of the guideline at the intended

healthcare organization. Due to time constraints for completion, this capstone project did not implement the guideline into practice.

- Phase V: Evaluation. The final phase appraises the outcomes attained after guideline implementation. Evaluation of the guideline entails a review of outcome measures in relation to the guideline's purpose. In addition, it is during this phase that other parameters such as cost-benefit analysis and appraisal of any negative or unexpected outcomes should be addressed. This capstone project did not include a post-implementation evaluation of the guideline as the capstone project did not implement the guideline into practice.

Literature Review

As part of the foundational basis of this capstone project, a literature review was conducted investigating current UTI and STI evaluation, diagnostic and/or testing methods for differentiation, and consequences of misdiagnosis. Electronic databases utilized were the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews, PubMed, and Google Scholar™. Keywords employed were sexually transmitted infections, urinary tract infections, complications of sexually transmitted infections, misdiagnosis of sexually transmitted infections, and prevalence of urinary tract infections and sexually transmitted infections in primary care. An inclusion criterion was articles originally written in the English language and published between 1995 and 2016. Study designs within this literature review included cross-sectional studies, retrospective cohort studies, observational cohort studies, systematic reviews, and meta-analyses.

Chlamydia and Gonorrhea Screening, Evaluation, and Diagnosis

In the United States, *Chlamydia trachomatis* is the most prevalent STI with approximately 1,000,000 new cases reported each year (Wilbanks, Galbraith, & Geisler, 2014). Due to the frequent asymptomatic presentation of chlamydial infections in women, universal screening has been suggested as the most effective means of disease detection; however, the cost of such practice is unrealistic. Therefore, it has been recommended that infection screening be selectively completed based upon organizational parameters or women be treated empirically using defined criteria addressing factors such as an individual's age, sexual behavior, and/or symptomatic complaint(s) at time of visit (Marrazzo et al., 1997). Cost-effectiveness analysis of no screening, selective screening, and universal screening of two separate cohorts--family planning clients and STD clients--for *C. trachomatis* found an approximate cost savings of $1,000 for each case prevented when using selective screening for individuals in both groups. Additionally, results of the analysis indicated universal screening for family planning clients was more beneficial with an added $667 cost savings for every case prevented (Marrazzo et al., 1997).

U.S. Preventive Services Task Force (USPSTF; 2016) has published eight recommendations for STI screening since 2000; each recommendation statement was founded upon a comprehensive systematic review. With regard to chlamydia and gonorrhea screening, key clinical recommendation statements included

> (1) Screen sexually active, nonpregnant women at increased risk of chlamydia, gonorrhea, HIV, and syphilis infection.
> (2) Screen all pregnant women for hepatitis B, HIV, and syphilis; additionally, screen all pregnant women at increased risk of chlamydia and gonorrhea infection.

> (3) Do not routinely screen women and men who are not at increased risk of sexually transmitted infections. (USPSTF, 2016, table 1)

Increased risk is delineated by the individual's age and sexual behavior. Categorization of high-risk sexual behavior is defined as having a new sexual partner, multiple concurrent sexual partners, inconsistent use of protective barrier methods, engaging in sexual activity under the influence of drugs or alcohol, and/or exchanging sex acts for drugs or money. Additional recommendations include universal screening for gonorrhea and chlamydia for all sexually active adolescents and women 25 years of age or younger (USPSTF, 2016).

Centers for Disease Control and Prevention (2016) screening recommendations for chlamydia and gonorrhea in women are similar to those made by the USPSTF (2016). Screening recommendations advise all sexually active women 25 years and younger or sexually active women older than 25 years regarded as higher-risk be tested for both chlamydia and gonorrhea annually. Testing for *C. trachomatis* should be performed using swab specimens from the vagina or endocervix or use of first-catch urine. Analysis of specimens from any of the accepted collection methods should be accomplished using nucleic acid amplification test (NAAT). If an individual is found to be positive for either chlamydia or gonorrhea, it is recommended that testing be repeated in three months upon completion of antibiotic treatment. Test-of-cure, generally performed three to four weeks after completing therapy, is only recommended if noncompliance with medication therapy is suspected, symptoms are persistent, or there are any concerns for reinfection (CDC, 2016).

In 2012, the USPSTF released updated recommendations for primary care practice screening of cervical cancer in women. Prior to 2012, women were

recommended to initiate cervical cancer screening "within 3 years of the onset of sexual activity, followed by annual screening" (Bogler et al., 2015, p. e461). Most recent recommendations stated screening should not be started until the age of 21 years with a papanicolaou (PAP) test completed every three years or every five years in combination with human papillomavirus (HPV) testing (USPSTF, 2012). As many women choose not to have yearly STI testing completed unless done with their routine PAP examination, there was some concern regarding the negative relationship new recommendations might have on STI screening. Bogler et al. (2015) conducted a retrospective study of five family practices and found screening for gonorrhea and chlamydia decreased by 50% since publication of the new guidelines in 2012. Therefore, primary care practices and providers need to maximize other opportunities and patient care visits to ensure sexual health and STI screening are completed, especially for high-risk, young, female populations.

As already stated, consequences of untreated chlamydia and gonorrhea infection include infertility, ectopic pregnancy, and pelvic inflammatory disease. To prevent these unwanted effects, it is essential timely and effective diagnosis be made. Part of the difficulty in screening is lack of consensus regarding the most useful diagnostic tool and screening methods. A systematic review by Watson et al. (2002) evaluated current lab tests available for their effectiveness and overall accuracy in diagnosing chlamydial infections in asymptomatic and sexually active individuals. Nucleic acid amplification tests more accurately detected asymptomatic chlamydial infections when compared to non-culture tests. Results of the meta-analysis also demonstrated NAATs could be

effectively performed using urine samples, which are simple, cost-effective, non-invasive, and non-discriminatory (Watson et al., 2002).

Urine-based testing for diagnosis of chlamydia and gonorrhea using ligase chain reaction (LCR), a method of DNA amplification, has been found to be both sensitive and specific; ease and availability of urine-based testing allows for greater access for individuals seeking STD testing and effectively screens disease presence in asymptomatic individuals otherwise not pursuing healthcare services (Jones, Knaup, Hayes, & Stoner, 2000). Operation of this knowledge was applied in a community-based urine testing program in St. Louis, Missouri. Of the 277 individuals in this study, greater than 90% of participants denied any genitourinary symptoms at time of screening and testing. Nearly 9% of urine tested returned positive for chlamydial or gonococcal infection. In addition, approximately 75% of participants positive for gonorrhea were co-infected with chlamydia. Surprisingly, infection did not correlate with number of sex partners, use of barrier methods at last sexual encounter, race or ethnicity, gender, or previous STD history (Jones et al., 2000); this information exemplifies the need for proactive screening, especially in individuals experiencing symptoms indicative of a UTI or STI.

Co-Infection and Consequences of Chlamydia and Gonorrhea

Numerous studies have shown individuals with one STI were more likely and more susceptible to additional infections with other venereal diseases. Of particular concern was co-infection with chlamydia and gonorrhea. Conclusions drawn from the study by Sonkar et al. (2014) found a significant percentage of women presenting with complaint of vaginal discharge who subsequently had STI testing performed and lab results indicating co-infection(s) with *C. trachomatis*, *N. gonorrhea*, and/or *T. vaginalis*.

Similarly, results of a cross-sectional analysis performed by Kahn et al. (2005) observed a high co-infection rate of chlamydia and gonorrhea. Adolescent males and females positive for gonorrhea had greater than a 50% co-infection rate with chlamydia.

According to Haggerty et al. (2010), approximately 8% of women in the United States during their lifetime have been given a diagnosis of PID. Pelvic inflammatory disease is "thought to occur as microorganisms ascend from the lower genital tract, infecting and causing inflammation of the uterus, fallopian tubes, and ovaries" (Haggerty et al., 2010, p. S134). One of the most common pathogens associated with development of PID is *C. trachomatis*. Gynecologic and reproductive consequences of untreated PID include but are not limited to chronic pelvic pain, ectopic pregnancy, and infertility. The timeframe between infection with a microorganism and development of PID is unclear. However, it was found up to 5% of women within a two-week period developed PID between diagnosis with chlamydia infection and onset of treatment (Haggerty et al., 2010; Hook, Spitters, Reichart, Neumann, & Quinn, 1994).

Screening and Diagnosis of Urinary Tract Infections

The urinary tract is composed of the kidneys, the ureters, the bladder, and the urethra. An individual develops a UTI when bacteria ascend from the urethra and into the bladder. A bladder infection, otherwise known as cystitis, is one of the most common bacterial infections; women typically report symptoms of burning or pain with urination (dysuria) and increased urinary frequency. Similar to gonorrhea and chlamydia infections, women are disproportionately affected due to the female anatomic structure.

According to UpToDate® (2016), a UTI should be suspected in non-pregnant women who present with one or more of the following symptoms: frequency, urgency,

dysuria, hematuria, and/or suprapubic pain. For diagnosis, UpToDate recommends a UA for evaluation of pyuria or the presence of pus in the urine. Many primary care offices do not have in-house technology to perform a UA; therefore, use of dipstick urine strips are typically employed to detect the presence of nitrite and leukocyte esterase, indicative of a UTI. UpToDate does not recommend routine urine cultures for women suspected of an uncomplicated UTI. Urine cultures are suggested if the patient presents with symptoms not typical for a UTI, recurrent urine infection complaints within three months, or if symptoms persist after completion of antibiotic therapy.

Overreliance on UA and dipstick results and lack of confirmatory urine cultures in diagnosis might lend to over-diagnosis of UTIs. As stated earlier, Tomas et al. (2015) found an abnormal UA result in patients with both UTIs and STIs after a two-month observational cohort study. Of the 264 women included in the study, 92% of study participants had an abnormal UA, which was defined as "greater-than-trace leukocyte esterase level, a positive nitrite test result, or pyuria" (Tomas et al., 2015, p. 2689). Nearly 60% of women were diagnosed with a UTI and were prescribed treatment without a urine culture. When study urine cultures were performed on each patient sample, culture results indicated over-diagnosis of UTI to be 52%.

Sexually Transmitted Infection/Urinary Tract Infection Misdiagnosis

Effective management of any disease requires accurate diagnosis; however, many challenges can arise when attempting to differentiate between diseases with similar symptomology. In a study conducted by Huppert et al. (2007), the authors found discordant relationships between urinary symptoms and presence or absence of an STI; symptomology could not be used as a predictor for disease distinction. Similarly, other

studies have shown only half of women given a singular diagnosis of a UTI at time of discharge had a subsequent confirmed urine culture; instead, up to 50% of those cultures indicated the presence of an STI (Berg, Benson, Haraszkiewicz, Grieb, & McDonald, 1996; Tomas et al., 2015; Wilbanks et al., 2014).

In a study conducted by Wilbanks et al. (2014), the authors retrospectively evaluated medical charts of female patients who presented to an emergency department (ED) with a primary complaint of dysuria and were later diagnosed with a UTI. Of the 280 women ultimately included in the study, results of the study revealed only a fraction (17%) of the females were asked questions regarding recent sexual history even when secondary complaints included vaginal bleeding, vaginal discharge, and pelvic pain. Sexually transmitted infection or chlamydia testing had been ordered or performed in merely 20% of this patient population; unexpectedly, only 30% of female patients with a prior history of chlamydial infection were tested again. Although 67% of UAs performed were negative for presence of urinary nitrate, fewer than 7% of these samples were then sent for chlamydia testing. Results of the study also showed less than half of the women appropriately diagnosed with chlamydia were prescribed the recommended treatment; most were prescribed medication used in UTI treatment and ineffective against chlamydia infection (Wilbanks et al., 2014).

Additional studies illustrated 10% to 50% of women would test positive for an STI when presenting with typical UTI symptoms or might not have any symptoms at all (Mehta, Rothman, Kelen, Quinn, & Zenilman, 2001; Shapiro et al., 2005; Todd, Haase, & Stoner, 2001). A prospective, observational cohort study completed by Shapiro et al. (2001) sought to determine and differentiate the incidence of UTIs and STIs when

considering associated positive and negative urine culture results, initial symptom presentation, and patient history. Conclusions of the study found approximately 17% of female participants who presented with symptoms of a UTI had an STI instead; no statistically significant difference was found between positive or negative urine cultures. Results of analysis found the only variable predictive of a positive STI result was sexual history of greater than one sexual partner within the last 12 months; no other variables within the history or physical examination (including pelvic examination) could successfully differentiate between women who tested positive or negative for an STI (Shapiro et al., 2005).

CHAPTER II

PROJECT DESCRIPTION

Research Question

Q1 Within the outpatient setting, will the development of a STI/UTI urinalysis guideline reduce the incidence of misdiagnoses of urinary tract infections in patients with a sexually transmitted infection, more specifically infection with chlamydia or gonorrhea?

Project Objectives

Primary care practice settings are an essential component of healthcare practice; they provide an opportunity for both the medical provider and patient to improve upon an individual's overall health and well-being. Acute visits for complaints of urinary frequency, dysuria, and other symptoms suggestive of a UTI comprise a substantial portion of office visits each year. However, as depicted by the literature review, screening for other microbial etiologies such as STIs are variable and inconsistent. This lack of STI evaluation might lead to misdiagnosis and prescription of inadequate pharmaceutical therapy, predisposing the individual to gynecological and reproductive complications in the future. In addition, due to the silent nature of chlamydia and gonorrhea, failure to eradicate these STIs potentiates the spread of these diseases to other individuals.

Objectives for this capstone project entailed creation of a STI/UTI urinalysis clinical practice guideline to aide and support healthcare providers at Peak Health Family

Medicine in distinguishing between patients requiring more in-depth screening when presenting to the office with UTI complaints. Objectives for this capstone project were as follows:

1. Gathered information regarding current screening and testing practices for female adolescents and women who presented to Peak Health Family Medicine with UTI complaints.
    - Performed a retrospective study evaluating frequency of International Classification of Diseases (ICD)-9 and ICD-10 diagnosis codes for UTI from January 2013 through December 2016 (CDC, 2017).
    - Performed an in-depth retrospective review of female patient charts with a chief complaint of UTI symptoms (i.e., urgency, frequency, and/or dysuria).
    - A panel of medical personnel was questioned regarding their expert opinion and knowledge regarding creation of said guideline.
    - Increased awareness of current prevalence of chlamydia and gonorrhea infection in primary/outpatient care.
    - Increased knowledge regarding benefits of STI testing with patients presenting with UTI complaints.
2. Developed a STI/UTI urinalysis guideline for medical providers in provision of evaluation, screening, testing, and treatment of female patients who presented with UTI complaints.
    - Early diagnosis of STI infection.

- Decreased or prevented transmission rates of chlamydia and gonorrhea.
- Reduced probability of negative sequelae from untreated chlamydia and gonorrhea infections.

3. Planned for implementation of the clinical practice guideline. However, as previously stated, this capstone author did not physically implement the clinical practice guideline due to time constraints.

Project Plan

Setting and Resources

The setting for this capstone project took place at Peak Health Family Medicine. Peak Health Family Medicine, which opened in 2012, is a private primary care practice located in Littleton, Colorado. The office is composed of one medical doctor (MD), two physician assistants (PA), and one nurse practitioner (NP). Care provided at this facility includes proactive preventative care, comprehensive women's and men's health, pediatric and adolescent care, and medical weight loss. Retrospective evaluation of frequency of ICD-9 and ICD-10 diagnoses (CDC, 2017) for UTI was gathered from Peak Health Family Medicine's electronic medical record (EMR) from January 2013 through December 2016. In addition, an in-depth chart review was performed investigating female patient visits for UTI complaints (i.e., urinary urgency, frequency, and/or dysuria) from October 2016 through December 2016.

Based upon information gathered from the literature review, it was evident family practice offices have played a role in the continued incidence and prevalence of chlamydia and gonorrheal infections in the United States. Due to similar presentations of

urinary complaints for both UTI and STIs, a STI/UTI urinalysis clinical practice guideline was necessary to improve patient care and decrease the trend of undiagnosed and ineffectively treated disease processes. The impact of STI is non-discriminatory; the effects can be seen in every gender, race, and socioeconomic category.

Financial resources necessary for successful completion of this capstone project were minimal as this capstone project was in fulfillment of the Doctor of Nursing Practice degree as outlined by the University of Northern Colorado Graduate School. The majority of labor required was performed by the student with one exception. Upon completion of both portions of the retrospective study, statistical analysis of the data was completed in conjunction with Kathleen Dunemn, Ph.D., APRN, CNM-BC, and Research Advisor for this capstone project. Miscellaneous budgetary demands included cost to print materials. Resource support was provided by Peak Health Family Medicine through use of their EMR--an integral part of the retrospective study.

Sample

The population under investigation for the retrospective portion of this capstone project was women between the ages of 15-65 who presented to Peak Health Family Medicine with a chief complaint indicative of a UTI such as complaint of dysuria, urinary frequency, and/or urinary urgency between October 2016 and December 2016. Frequency and/or prevalence of ICD-9 and ICD-10 diagnosis (CDC, 2017) of urinary tract infection were collected from January 2013 to December 2016.

Methods

Timeline of Project

- Fall 2016—Approval of phenomenon of interest
- January 2017 to February/March 2017
    - Institutional Review Board approval was obtained from the University of Northern Colorado's Institutional Review Board (see Appendix A). A statement of mutual agreement was also signed between Peak Health Family Medicine and the University of Northern Colorado (see Appendix B).
    - Defense of first three chapters of capstone project
- April 2017
    - Retrospective study completed from evaluation of patient charts (October 2016-December 2016) and ICD-9 and ICD-10 diagnoses analysis (2013-2016)
    - Initial Delphi questionnaire sent to providers (see Appendix C) along with informed consent to participate in human research (see Appendix D)
- May 2017
    - Development of clinical practice guideline
    - Second Delphi questionnaire sent to providers (see Appendix E)
    - Development of plan for implementation

- June 2017
    - Submission of capstone project to project committee
    - Final defense of capstone project

Design

Phase one. The first step in phase one of the EBP project entailed the completion of a thorough literature review. Upon completion of the literature review, it was evident there was a significant need for the development of a STI/UTI guideline to assist providers in identifying individuals who would be deemed high-risk or have increased susceptibility in contracting an STI such as chlamydia and/or gonorrhea. The second step in phase one was the conduction of a retrospective review of patient charts; each identified chart was evaluated for initial patient complaint(s), procedures conducted, results of procedures, diagnoses, and whether the patient returned to care after initial treatment of a UTI and later identified as having an STI.

Phase two. Phase two was the development of a clinical practice guideline; the Delphi method was utilized to build said practice guideline. The development of the practice guideline included collaboration with experts to identify necessary components that would need to be included within the guideline such as laboratory tests and questions to ask the patient when presenting with specific complaints associated with typical urinary tract infections. Experts included a physician, physician assistants, and nurse practitioners involved in the diagnosis, management, and prevention of sexually transmitted infections within the community. Administration of the initial Delphi questionnaire spanned beyond the medical providers at Peak Health Family Medicine to

include healthcare providers at other organizations such as Planned Parenthood and Kaiser Permanente.

Phase three. Phase three was the plan for implementation. The plan for implementation entailed distribution of the clinical guideline to stakeholders at Peak Health Family Medicine to review and modify. A second Delphi questionnaire was then administered to the medical providers at Peak Health Family Medicine for evaluation of the guideline as the clinical guideline was specifically tailored for their primary care private practice (see Appendix E). During this phase, the tools for measurement were evaluated such as the most effective means with which to identify or quantify the presence of proper utilization of the clinical guideline in addition to evaluating whether the clinical guideline achieved the stated objectives.

Phase four. Phase four would have included the physical implementation of the clinical guideline in practice. Phase four was not completed during this capstone project. However, the guideline was made available to Peak Health Family Medicine to implement when time and resources allowed.

CHAPTER III

EVALUATION OF PLAN

To enhance quality and consistency of primary care practice, the purpose of this DNP capstone project was to develop an evidence-based guideline for improved diagnostic screening methods for diagnosing chlamydial and gonorrheal infections in females who presented with symptomatic complaints otherwise suggestive of a urinary tract infection. Peak Health Family Medicine did not have a guideline in place to adequately differentiate between women who might have a common UTI versus an STI. As evidenced by the literature review, negative sequelae of undiagnosed and untreated STIs are severe and, unfortunately, fairly widespread. Three objectives were accomplished for this capstone project.

Objective One

Objective one was to gather past information regarding screening, testing, and diagnostic practices for female patients who presented to Peak Health Family Medicine with symptoms typical of a UTI between October 2016 and December 2016. The first objective was accomplished via two methods. A retrospective study was conducted investigating patient charts, specifically charts for female patient visits with a chief complaint of urgency, frequency, dysuria, and/or UTI. Analysis of the data revealed the number or percentage of visits concerning UTI complaints and the relative influence a guideline could have on daily practice at Peak Health Family Medicine. Secondly, the

Delphi method or survey was utilized to garner general knowledge, suggestions, and practice from a panel of medical experts in development of the clinical practice guideline.

Objective Two

Objective two was the development of the clinical practice guideline for evaluation, screening, testing, and treatment of female patients at Peak Health Family Medicine who present with complaints typical of a UTI. Using information gathered from the retrospective patient study and Delphi questionnaire, the foundational basis of the STI/UTI urinalysis guideline was founded upon recommendations from the USPSTF (2016) and medical provider suggestions regarding information that should be included within the guideline. During creation of the guideline, each provider who completed the Delphi survey was asked to provide expert opinion on the need for implementing such a guideline, feasibility of use of said guideline, and applicability of use in day-to-day practice. Once the guideline had been created, a second Delphi questionnaire was sent regarding evaluation of the guideline in relation to the aforementioned criteria.

Objective Three

The third objective of this capstone project was the plan for implementing the clinical guideline into practice. Implementation of this clinical guideline at Peak Health Family Medicine was not part of this completed capstone project. However, if Peak Health Family Medicine chooses to implement this guideline in the future, it would be highly recommended they evaluate the success of the guideline through one or more of the following measures. First, it would be prudent to conduct another retrospective chart study comparing results from pre- and post-guideline implementation for screening and testing of female patients with urinary complaints. Second, it would also be beneficial to

examine the percentage of STI diagnoses made prior to and after the implementation of the clinical practice guideline to analyze any statistical differences. Finally, after a trial period, any revisions should be made such as inclusion or expansion of criteria including age of the female patient, addition of symptoms, etc.

CHAPTER IV

RESULTS AND OUTCOME STATEMENTS

This DNP capstone project sought to address the current problem regarding misdiagnosis of STIs and UTIs in primary care practice--more specifically, misdiagnosis of chlamydia and gonorrheal infections in female patients with symptom complaints otherwise indicative of a UTI. The first objective of this capstone project was to collect information concerning screening, testing, and diagnostic practices for female patients 15 through 65 years of age who visited Peak Health Family Medicine with a chief complaint suggestive of a UTI. Objective two was development of a STI/UTI urinalysis clinical practice guideline to assist medical providers at Peak Health Family Medicine in evaluation, screening, testing, and treatment of female patients who presented with symptoms typical of a UTI who might otherwise have an undiagnosed STI. The third and final objective was a plan for implementing and evaluating the STI/UTI Urinalysis Clinical Practice Guideline in practice. Physical implementation of the guideline was not a component of the final capstone project; therefore, evaluation of said guideline post implementation was not discussed nor included. However, recommendations regarding beneficial evaluative elements and measures for future application are addressed.

Objective One

Objective one was achieved through completion of a two-part retrospective study that entailed a three-month patient chart review and a four-year ICD-9 and ICD-10 diagnoses analysis (CDC, 2017). Both portions of this study were conducted utilizing the EMR at Peak Health Family Medicine, which makes use of an eMDs platform or system. For the first portion of the study, female patient charts from October 1, 2016 through December 31, 2016 were assessed for specific parameters; patients were included in the study if they met the following criteria: (a) the patient was female, (b) between 15 and 65 years of age, and (c) chief complaint was suggestive of a UTI. The second step or part of the study was completion of a four-year retrospective analysis (January 1, 2013 through December 31, 2016) evaluating overall frequency of documented ICD-9 and ICD-10 diagnoses codes for UTI, UTI-specific symptomology, chlamydia, and/or gonorrhea. Due to time and additional processes required in evaluation of individual patient charts, it was not feasible to conduct a four-year patient chart review. To truly meet objective one, however, it was necessary for a chart review to be included. For this reason, a chart review with a condensed timeframe provided similar data and related insight in achieving original outlined goals.

Part One: Materials and Methods

For the retrospective chart review, the group under investigation was a convenience sample using Peak Health Family Medicine's EMR. Patients were included if all of the aforementioned criteria were met. If a patient's chart did not meet each of the specified criteria, the chart was automatically excluded from the study. As this portion of the study did not use human subjects and no identifying patient information was

collected, no informed consent was required. The following capstone project and all included studies were given Institutional Review Board approval by the University of Northern Colorado (see Appendix A).

The initial step in conducting the retrospective chart review was identifying all potential subjects: every female 15 to 65 years old between October 1, 2016 and December 31, 2016. The age parameter was established to incorporate the main screening recommendations from both the CDC (2016) and USPSTF (2016) for chlamydia and gonorrhea. Based upon knowledge that infection rates of chlamydia and gonorrhea are highest in females 15-25 years of age, additional data analysis was performed specifically investigating this patient demographic. After application of age and gender parameters, each of the chart's chief complaint(s) was examined and assessed for symptom complaints characteristic for a UTI or if the term *UTI Symptoms* was explicitly noted. Within this EMR platform, supplementary symptoms and added complaints were incorporated within the umbrella term of UTI symptoms; therefore, complaints of flank pain, abdominal pain, hematuria, nausea, urinary frequency, dysuria, urinary urgency, dyspareunia, and chills were all included.

After a chart had met all inclusionary criteria listed above, the second step included review of the chart for results of urinalysis (if one had been performed), positive or negative urine culture results (if one had been sent), diagnosis/diagnoses of visit, and associated treatment. The third and final aspect of the chart review was evaluation for testing of either chlamydia, gonorrhea and/or both chlamydia and gonorrhea principally in female patients 15 to 25 years of age.

Part One: Results

Results of the study revealed Peak Health Family Medicine provided care to 41 female patients (see Appendix F) between October 1, 2016 and December 31, 2016 whose documented chief complaint was indicative of a UTI and were between 15 and 65 years of age. Of the 41 patient visits, eight visits occurred in October, 15 in November, and 18 in December. The most frequently documented chief complaint was UTI symptoms in 73.2% (30/41) of patient charts. In addition to complaint of UTI symptoms, other specific complaints included flank pain, abdominal pain, hematuria, nausea, urinary frequency, urinary urgency, dysuria, chills, dyspareunia, and hesitancy. In conjunction with UTI complaints, four patient charts (9.8%; 4/41) listed other gynecological complaints such as vaginal irritation, vaginal discharge, vaginal itching, and/or vaginal odor.

A urinalysis was ordered and performed 95.1% (39/41) of the time; one patient was excluded from a UA due to having taken AZO while there was no notation for lack of UA being performed on the second patient. Of the 39 urinalyses performed, 30.8% (12/39) were interpreted as a negative UA result. A UA result was positive if any of the following findings were documented: blood in urine, leukocytes, protein urine, nitrite, ketones, and glucose. A urine culture was sent for 35 of the 41 patients (85.4%); subsequent culture findings were 48.6% (17/35) of cultures were positive for a UTI and 51.4% (18/35) were negative for a UTI. Relatedly, microorganisms grown in positive cultures included *Escherichia coli* (76.5%; 13/17), Group B *Streptococcus* (11.8%; 2/17), and *Klebsiella pneumoniae* (11.8%; 2/17).

One patient (2.4%; 1/41) was tested for chlamydia and gonorrhea within the three-month chart review. When exclusively looking at patients between 15 and 25 years of age, seven patients were seen between October 1, 2016 and December 31, 2016, thus increasing the testing percentage for chlamydia and gonorrhea to 14.3% (1/7). All seven patients had a UA performed with 85.7% (6/7) of the urine samples sent for culture. Results of urinalysis and urine culture were positive for 57.1% (4/7) and 33.3% (2/6) of the samples, respectively. Antibiotic therapy was prescribed for 71.4% (5/7) of this patient population.

Part One: Outcome Statements

Over the course of three months, Peak Health Family Medicine had 41 female patient visits for UTI related care; however, there appeared to be a discrepancy in number of patient visits for the month of October (8/41) when compared to November (15/41) and December (18/41). It was found the practice was closed for more days in the month of October than in November or December for a team-building vacation in Mexico. The additional closure time could account for the decreased number of patient visits during this month.

Although the EMR utilized at Peak Health Family Medicine enabled the umbrella term of UTI symptoms to be chosen as the patient's chief complaint, it offered the user the ability to add additional symptom complaints. As discussed by Tomas et al. (2015), the challenge in STI and UTI diagnosis is the overlapping symptomology such as complaint of urgency, frequency, and/or dysuria. Results of the chart review supported this finding; urinary frequency (48.8%; 20/41), urinary urgency (43.9%; 18/41), and dysuria (46.3%; 19/41) were complaints verbalized by nearly half of all patients.

Providers consistently ordered and performed a urinalysis for patients. If the patient who had taken AZO was included, the percentage of ordered UA for UTI complaints would increase to 97.8%. Urine cultures were also routinely sent. Standard practice at this organization was for most, if not all urine samples be sent for culture and sensitivity testing regardless of the UA result. Subsequent urine culture findings indicated more than half (51.4%; 18/35) of urine cultures sent were negative for growth. The high percentage of negative urine culture results aligned with other study findings that showed only about half of UTI diagnoses were confirmed with a positive urine culture (Berg et al., 1996; Tomas et al., 2015; Wilbanks et al., 2014).

The percentage of patients tested for chlamydia and gonorrhea was trivial regardless of whether the author categorized female patients into the 15- to 25-year-old age range (14.3%) or expanded the age range to 15 to 65 years of age (2.4%). Of particular concern was the small percentage of female patients 15 to 25 years of age who had chlamydia and gonorrhea testing completed. According to published screening recommendations made by the CDC (2016) and USPSTF (2016), females within this age group, if sexually active, should have yearly STI (chlamydia and gonorrhea) testing completed. For the seven females 15 to 25 years of age included in the study, 57.1% (4/6) of UA results were positive; however, only 33.3% (2/6) of urine culture results were positive and confirmed the presence of a UTI. Unfortunately, the corresponding percentage of negative urine cultures (66.7%; 4/6) might represent potential undiagnosed and untreated STI(s) in this group of female patients.

Part Two: Materials and Methods

Similar to the chart review, the second part of the retrospective study utilized the EMR in completion of a four-year ICD-9 and ICD-10 (CDC, 2017) diagnoses analysis. Frequency of every diagnosis/diagnoses made by each provider for all patient visits at Peak Health Family Medicine was documented from January 1, 2013 through December 31, 2016. Both ICD-9 and ICD-10 codes were included in this capstone project as Peak Health Family Medicine transitioned from ICD-9 to ICD-10 coding in 2015. Resultant data from 2015 included both ICD-9 and ICD-10 codes, whereas all other years only comprised either ICD-9 or ICD-10 diagnoses.

Diagnosis codes included in the study were as follows: acute cystitis; dysuria; urinary frequency; urinary tract infection; urgency of urination; acute pyelonephritis; hematuria, unspecified; gross hematuria; cystitis; acute cystitis without hematuria; acute cystitis with hematuria; cystitis unspecified without hematuria; cystitis unspecified with hematuria; and gonococcal infection of lower genitourinary tract, unspecified (see Table 1). Of note, not every ICD-9 code had an associated ICD-10 code and vice versa (CDC, 2017). All healthcare organizations were required to transition from use of ICD-9 to ICD-10 coding structure by October 1, 2015. The ICD-10 was developed to improve data quality for purposes of monitoring public health conditions, increasing access to data for epidemiological research, enhancing clinical decision making, establishing standardized measurement outcomes, and decreasing fraud and abuse (CDC, 2017).

Table 1

International Classification of Diseases Diagnosis Codes

Diagnosis	ICD-9 Code	ICD-10 Code
Acute cystitis	595	
Dysuria	788.1	R30.0
Urinary frequency	788.41	
Urinary tract infection	599	N39.0
Urgency of urination	788.63	R39.15
Acute pyelonephritis	590.1	N10
Hematuria, unspecified	599.7	R31.9
Gross hematuria	599.71	R31.0
Cystitis	595.9	
Acute cystitis without hematuria		N30.00
Acute cystitis with hematuria		N30.01
Cystitis, unspecified without hematuria		N30.90
Cystitis, unspecified with hematuria		N30.91
Gonococcal infection of lower genitourinary tract, unspecified		A54.0

Part Two: Results

Results of the retrospective analysis demonstrated an upward trend from January 1, 2013 to December 31, 2016 in number of UTI diagnoses documented and UTI associated symptoms (see Figure 2). Incidence of all applicable diagnoses as a whole

(excluding diagnosis code A54.0) revealed that 134 UTI related diagnoses were rendered in 2013, 142 in 2014, 217 in 2015, and 222 in 2016. Acute cystitis was the most frequent diagnosis made every year during this study; the diagnosis accounted for 48.5% in 2013, 47.9% in 2014, 44.7% in 2015, and 50.5% in 2016 of UTI-related diagnoses for each respective year. Due to increased specificity requirements in ICD-10 coding for diagnosis of acute cystitis, diagnosis codes N30.0 (acute cystitis without hematuria), N30.01 (acute cystitis with hematuria), N30.90 (cystitis, unspecified without hematuria), and N30.91 (cystitis, unspecified with hematuria) were all factored into the total number of acute cystitis diagnoses to correlate with the more indiscriminate ICD-9 code 595 (CDC, 2017). Zero chlamydia diagnoses were made during this four year review. Diagnosis of "Gonococcal infection of lower genitourinary tract, unspecified" was documented once in 2015. For detailed differentiation of ICD-9 and/or ICD-10 codes for each study year, see Figures 3 through 7.

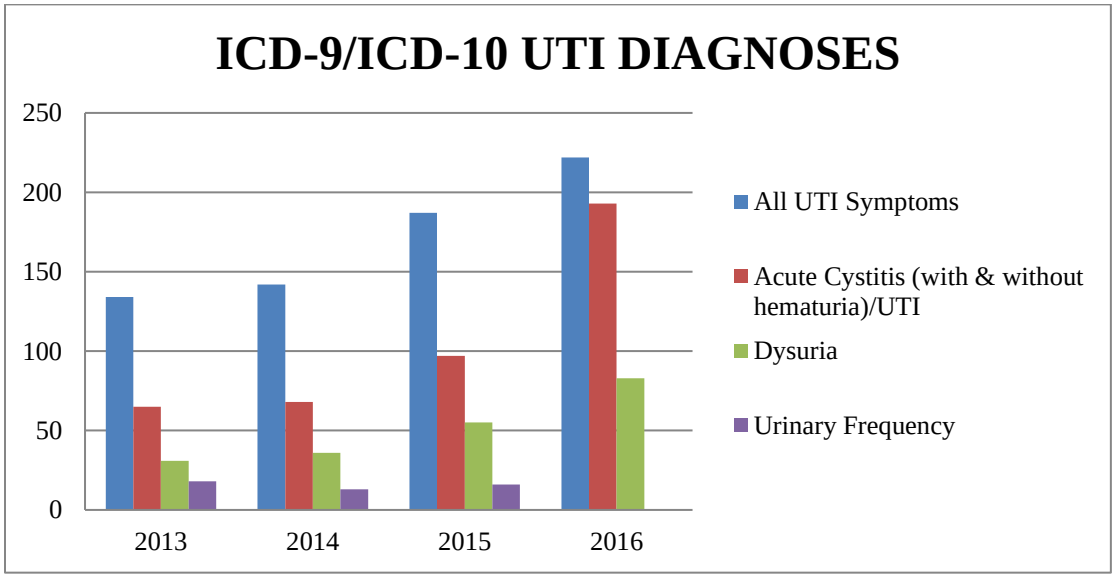

Figure 2. International classification of diseases diagnosis codes related to urinary tract infection symptoms, 2013-2016.

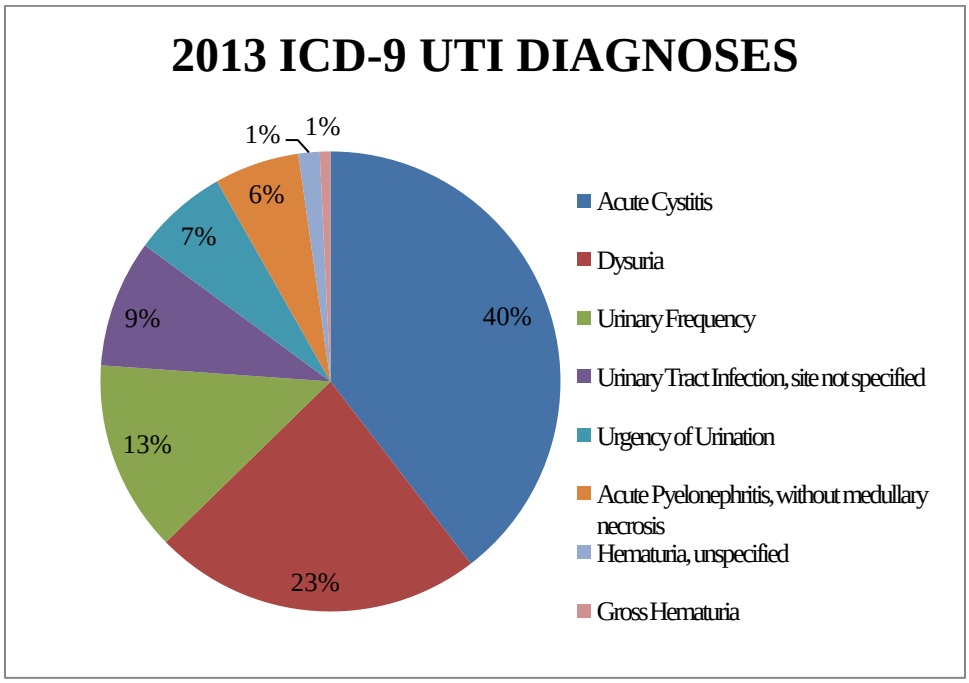

Figure 3. Differentiation of international classification of diseases-9 urinary tract infection diagnosis codes for 2013.

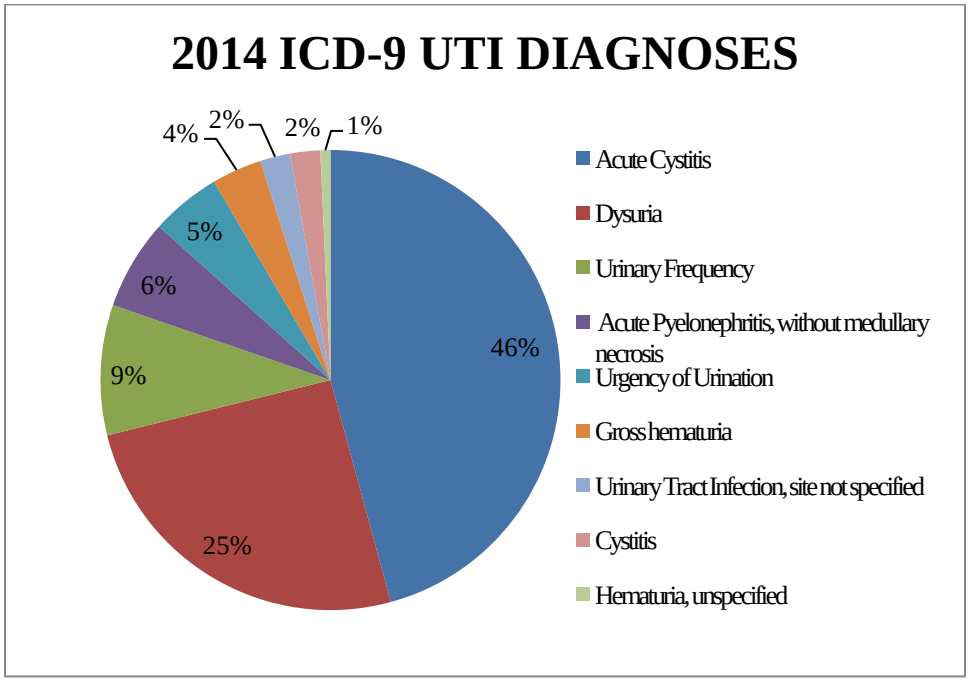

Figure 4. Differentiation of international classification of diseases-9 urinary tract infection diagnosis codes for 2014.

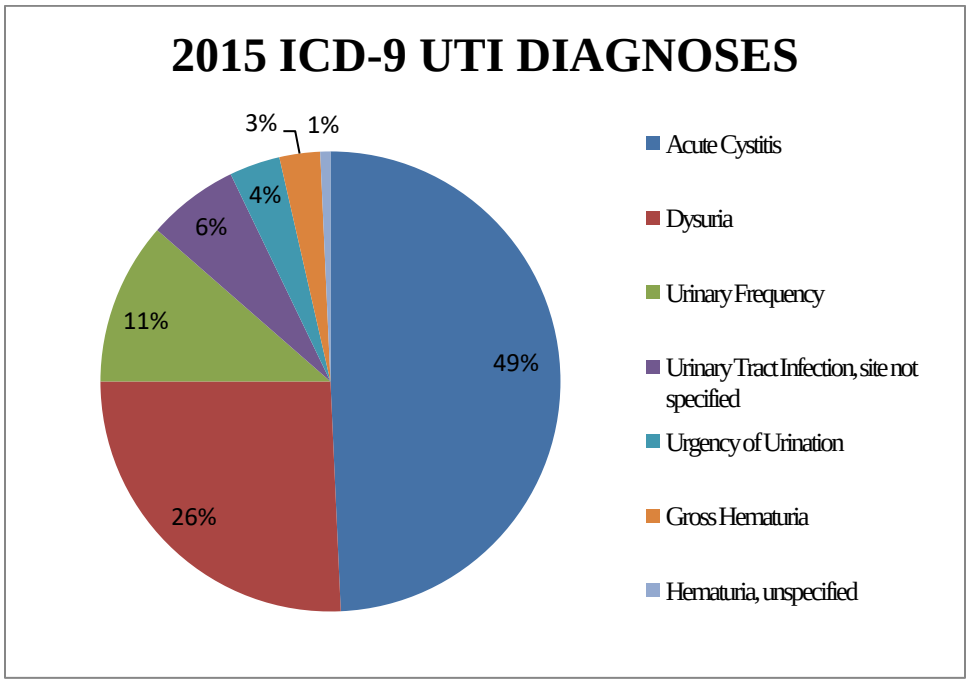

Figure 5. Differentiation of international classification of diseases-9 urinary tract infection diagnosis codes for 2015.

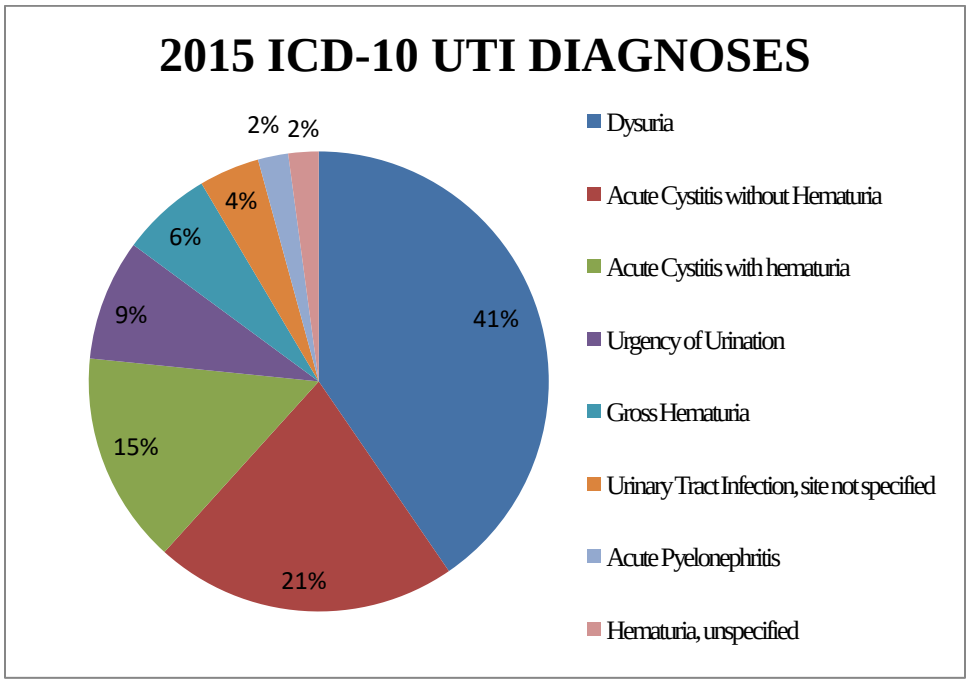

Figure 6. Differentiation of international classification of diseases-10 urinary tract infection diagnosis codes for 2015.

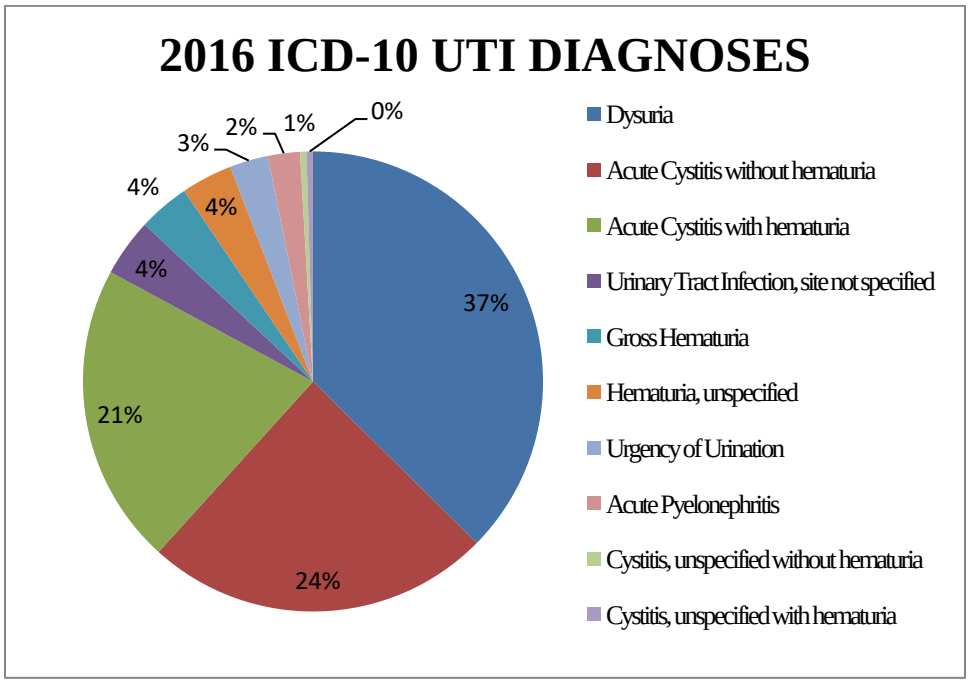

Figure 7. Differentiation of international classification of diseases-10 urinary tract infection diagnosis codes for 2016.

Part Two: Outcome Statements

Expectation for any growing practice is the number of patient visits or encounters would increase accordingly; thus, the upward trend in number of UTI diagnoses documented from January 1, 2013 to December 31, 2016 was anticipated. Although the author did not foresee chlamydia and gonorrhea to be a commonly made diagnosis at this practice, results of the study were unexpected. Over the course of four years, infection with chlamydia was documented zero times, whereas diagnosis of gonococcal infection was documented once.

Peak Health Family Medicine is located in Jefferson County. According to Colorado Youth Matter (2015), chlamydia rate (per 100,000) and gonorrhea rate (per 100,000) in Jefferson County was 917.95 and 79.69, respectively, for adolescents 15- to 19-years-old in 2012. The most recent 2017 population estimate for Jefferson County

was 534,543 with 50% of the population female and approximately 12.5% of this subset 15 to 24 years of age (Suburban Stats, 2015). Given the infection rate for both chlamydia and gonorrhea in Jefferson County, it is highly probable/highly likely that diagnosis of either of these STIs was missed.

Objective one (Part One and Part Two) required application of both Phase I (Preparation) and Phase II (Validation) of the Stetler (2001) model. Results from the retrospective study provided evidence indicating modifications were needed in current STI and UTI management and a practice problem did exist. Knowledge acquired from the completed literature review provided the author with an explanation and background information for study findings and reiterated the relevant value and credibility of a clinical guideline.

Objective Two

Objective two was creation of the STI/UTI Urinalysis Clinical Practice Guideline (see Appendix G). Objective two required incorporation and utilization of Phases I-IV within the theoretical framework of the Stetler (2001) model; Preparation (Phase I), Validation (Phase II), Comparative Evaluation/Decision-Making (Phase III), and Translation/Application (Phase IV) were all applied in achieving this objective. Round one of the Delphi questionnaire was employed in developing the guideline, whereas round two of the Delphi questionnaire was used to garner expert opinion regarding any identified weaknesses and/or suggested changes in the clinical guideline.

Rounds One and Two of the Delphi Questionnaire

Round one of the Delphi questionnaire was developed using evidence-based information collected from the literature review completed for this DNP capstone project

in addition to published screening and testing guidelines for chlamydia and gonorrhea from both the CDC (2016) and USPSTF (2016). The purpose of the initial Delphi questionnaire was to assemble expert opinions regarding the need to implement an STI/UTI urinalysis clinical practice guideline, potential utility of said guideline, feasibility of use, and applicability of use in routine practice. Additionally, round one incorporated questions regarding study participants' adherence to current practices in screening, testing, and diagnosis of UTIs in female patients as advised by UpToDate (2016). Informed consent (see Appendix D) was provided with each round of the questionnaire; consent for participation was implied with completion and return of the completed questionnaire to the author. Round one of the Delphi questionnaire was available to participants for completion for 10 days (see Appendix C) while round two was available for seven days (see Appendix E). Two rounds of the Delphi method were ultimately employed and required to obtain essential information in creating and completing the STI/UTI Urinalysis Clinical Practice Guideline (see Appendix G).

Participants

Experts or participants for this DNP project were composed of nurse practitioners, physician assistants, and physicians. Providers from a variety of disciplines and Denver Metro locations were requested to participate in round one. Round one of the Delphi questionnaire resulted in a 75% (6/8) response rate with six respondents composed of one physician, three nurse practitioners, and two physician assistants. Disciplines represented included urgent care, OB/GYN, and family medicine (see Table 2). Participation in round two was limited to medical providers employed at Peak Health Family Medicine as the guideline was created specifically for their organization. Round two generated a

100% (4/4) response rate with all four medical providers at the organization completing the second Delphi questionnaire. Peak Health Family Medicine is comprised of one physician, two physician assistants, and one nurse practitioner.

Table 2

Demographics of Participants in Round One of Delphi Questionnaire

Participant Number	Career Title/Role	Discipline	Denver Metro Area
Participant #1	NP	Urgent Care	North
Participant #2	NP	OB/GYN	South
Participant #3	PA	Family Medicine	South
Participant #4	MD	Family Medicine	South
Participant #5	NP	Family Medicine	South
Participant #6	PA	Family Medicine	South

Data Collection

Collection of data occurred between April 2017 and May 2017. Questions from round one were intended to gather expert opinions regarding agreement with and adherence to current STI recommendations from the CDC (2016) and USPSTF (2016). In addition, questions from round one were structured to garner attitudes toward need for a guideline in differentiation between STIs and UTIs and suggestions regarding inclusionary components of said guideline. Rounds one and two of the Delphi questionnaires were sent through e-mail. The general purpose of round two was to attain provider consensus surrounding each aspect of the proposed guideline in preparation of the final version of the guideline for implementation. Consensus, as defined by this DNP

project, was a statistical score of 0.70 or greater for each question, representing majority agreement among participants for each component of the clinical guideline.

Results and Outcome Statements:
Round One Delphi Questionnaire

Round one of the Delphi questionnaire was composed of 11 questions. In question six, 66.7% (4/6) of participants felt patients were not being adequately screened for STI(s) at their organization. Analogous to participant response to question six, 66.7% (4/6) of healthcare providers did not feel patients were routinely screened for STI(s) at their organization when presenting with a chief complaint indicative of a UTI (question seven). Although 33.3% (2/6) of study participants felt that patients were being adequately screened for STI(s) and routinely screened for STI(s) when a female presents with UTI symptoms at their organization, the same comment was made to both questions: "In OB/GYN, but not always in primary care or peds." Based upon responses from questions six and seven, it was apparent providers were aware that STI screening might be insufficient and opportunities were being missed or overlooked in addressing sexual health.

As a follow-up to question seven, question eight ("How often do you believe female patients are being tested at your organization for chlamydia and gonorrhea infections when presenting with a chief complaint otherwise indicative of a UTI?"), 16.7% (1/6) responded 90% to 100%, 16.7% (1/6) responded 70% to 79%, and 66.7% (4/6) responded less than 20%. When asked if screening for chlamydia and gonorrhea would occur more frequently if a clinical guideline was made available to each of the healthcare provider's respective organization, 100% (6/6) indicated a guideline would increase screening for these diseases.

Question 10 provided a list of potential criteria to be included within the STI/UTI Urinalysis Clinical Practice Guideline in assessment of known risk factors for infection with either chlamydia or gonorrhea. Participants were asked to check all criteria that should be covered within the guideline; criteria as well as percentages included:

- Age (66.7%; 4/6)
- Current form of contraception (33.3%; 2/6)
- Number of past sexual partners within the past year (66.7%;4/6)
- New sexual partner (83.3%; 5/6)
- History of prior sexually transmitted infection(s; 66.7%; 4/6)

  If yes, did you receive a test of cure?
- Substance use (alcohol, tobacco, recreational drugs; 33.3%; 2/6)
- Sex in exchange for money or drugs (66.7%; 4/6)
- Current symptoms (urinary urgency, urinary frequency, dysuria, hematuria, vaginal discharge, pelvic, pain; 100%; 6/6)
- Result of UA (66.7%; 4/6)
- Urine sent for culture (83.3%; 5/6)

  If yes, did the culture return back positive/negative for a UTI?
- Other, please indicate

Half of participants (3/6) believed the criteria should include the follow-up question--"If yes, did you receive a test of cure?"--for patients with a prior history of STI(s), whereas 66.7% (4/6) believed the follow-up question should be included--"If yes, did the culture return back positive/negative for a UTI?"--if a urine had been sent for culture analysis.

The final question in round one requested that participants make additional recommendations or comment about the proposed clinical guideline. A comment to this question was as follows:

> Given the similar presentation of both UTI and GC/Chlamydia (STD), I do not feel anything other than complaints of symptoms and history of sexual activity should be required to test for both. Given the prevalence of undiagnosed STD, ease of test, and ease of treatment, there isn't any reason to not test every sexually active female. Certainly all the rest of the history is important but should not prevent testing of both (who know what a patient will admit to!).

Numerous studies have shown that symptomology alone is a poor predictor of and does not adequately differentiate between the presence and/or absence of an STI or UTI. In fact, research indicated the only factor found to be predictive of a positive STI result was history of greater than one sexual partner within the last 12 months (Shapiro et al., 2005). Therefore, as expressed by the comment above, research supports testing for both chlamydia and gonorrhea in female patients with a history of sexual activity especially given the current and rising rate of undiagnosed STIs.

Conclusions drawn from round one of the Delphi questionnaire reiterated and supported benefits that could be garnered from creation and implementation of a clinical guideline. Incorporating participant responses from round one of the Delphi method and published screening recommendations, a draft of the guideline was completed. The STI/UTI Urinalysis Clinical Practice Guideline was divided into the following sections:

- Overview
- 2014 U.S. Preventive Services Task Force (USPSTF) Screening Recommendations for Chlamydia and Gonorrhea
- Assessment of Risk
- Clinical Manifestations and Testing

- Collection of Urine
- Results of Initial Urinalysis
- Urine Culture
- Suggested Algorithm

Results and Outcome Statements:
Round Two Delphi Questionnaire

Round two of the Delphi questionnaire included 10 questions that provided an overview of some of the responses collected from round one of the Delphi questionnaire in addition to statistical data collected from the retrospective chart reviews. As stated previously, consensus defined by this DNP project was a statistical score of 0.70 or greater for each question, representing majority agreement among participants for each component of the clinical guideline.

Each question in round two resulted in 100% (4/4) consensus. All agreed the current adherence to current STI screening recommendations was too low (question one); providers were surprised by results of the chart review, which revealed the percentage of negative urine cultures for female patients diagnosed and treated for a UTI (question three). Questions 6 through 10 required the participants to evaluate the draft of the clinical guideline. Question six reviewed risk factors to be included within the Assessment of Risk section; providers did not believe any additional risk factors should be contained in the guideline. Question seven had the participants review the outlined Clinical Manifestations and Testing portions of the guideline. Although all providers agreed with the Clinical Manifestations and Testing portion, the following comment was made:

> I understand need for two urine specimens however what do you do with the "same-day" patient which is the vast majority of UTI patients? How would you propose getting a "dirty" urine on a patient who awoke with s/s and then is on your schedule the same afternoon?

Organizational education regarding collection requirements for a "dirty urine" sample would be paramount in ensuring patients come prepared to their office visit ready to provide two urine samples. Outlined within the body of the guideline were steps and information necessary to properly collect dirty urine samples. Patients would need to be instructed to refrain from voiding for a minimum one hour period prior to their scheduled appointment (Elliot Hospital Laboratory, 2014). As long as patients are made aware of this requirement prior to their appointment, the one hour no-void requisite should not be a hindrance in completing STI testing.

Questions eight and nine asked participants to review the remaining sections outlining suggested parameters for a positive UA result and parameters for ordering additional testing such as urine cultures and STI testing. All providers approved of the outlined parameters and no additional comments were offered. Although the initial draft of the clinical guideline had received 100% provider consensus, some modifications were made by the author to make the final guideline more comprehensive. For example, an additional section was added to the guideline listing the most recent recommended pharmaceutical regimens and alternative regimens in treatment of chlamydia and gonorrhea infections. A full version of the STI/UTI Urinalysis Clinical Practice Guideline can be found in Appendix G.

Objective Three

Objective three and the final objective of this DNP capstone project was plan for implementation of the STI/UTI Urinalysis Clinical Practice Guideline into practice at

Peak Health Family Medicine. Although physical implementation of the guideline was not a component of this project, necessary resources were provided to the organization for implementation at a later date. Objective three was accomplished by developing the clinical guideline utilizing information gathered from the literature review, current published guidelines for both STIs and UTIs, and responses collected from the Delphi questionnaires. Participant responses from rounds one and two of the Delphi method provided needed consensus in successful creation of said guideline. As discussed and analyzed under the results section of objective two, questionnaire replies provided the structural foundation in achieving objective three.

Key Facilitators and Key Barriers to Project Objectives

Key Facilitators

Successful and effective completion of this DNP capstone project could be attributed to the following key factors: availability and use of the eMDs EMR platform and provider engagement and interest in capstone objectives at Peak Health Family Medicine. It would not have been possible for the author to complete the two-part retrospective study without use of the EMR as it aided in efficient gathering of information, particularly with regard to the four-year ICD-9 and ICD-10 (CDC, 2017) diagnoses analysis. As stated previously, individual chart reviews required a considerable amount of time; a four-year review of every patient chart for every provider would not have been feasible within the timeline specified in completion of this project. Inspiration for this DNP capstone project arose from an article displayed in the office of one of the providers at Peak Health Family Medicine. It was advantageous to the author to have chosen a topic already an area of interest to some of the providers within the

organization. Successful facilitation of this project was greatly aided by the involvement and desire of all providers at Peak Health Family Medicine in improving their current healthcare practice surrounding STI and UTI screening and diagnosis.

Key stakeholders of this DNP capstone project primarily included healthcare providers at Peak Health Family Medicine and female patients (established and new) who visit the organization seeking treatment for UTI symptoms. The STI/UTI Urinalysis Clinical Practice Guideline will facilitate and support providers in distinguishing between patients who might require additional testing when presenting to the office with UTI complaints. Early diagnosis of STIs such as chlamydia and gonorrhea can only occur if appropriate testing is performed. The negative impact and unintended consequences of untreated STIs are significant; therefore, it is imperative that providers aptly evaluate female patients who would benefit from STI testing.

Key Barriers

Barriers to project objectives included limitations of the EMR in completion of the retrospective study, organizational growth of Peak Health Family Medicine and associated incidence in UTI patient visits between 2013 and 2016, and a relatively small sample size for round one of the Delphi questionnaire. To assess the applicability of the STI/UTI Urinalysis Clinical Practice Guideline at Peak Health Family Medicine, an evaluation of UTI diagnostic frequency was performed. However, the EMR could not separate total yearly ICD code frequency between genders. Therefore, although it was beneficial to see the trending nature of UTI diagnoses year after year within this practice, it could not be quantified what diagnoses were linked with male patient visits and what diagnoses were linked with female office visits. Although women tend to be

disproportionately affected by UTIs, the author could not state with certainty that the majority of UTI diagnoses made were for Peak Health Family Medicine's female patient population.

The four-year ICD-9 and ICD-10 (CDC, 2017) diagnoses analysis indicated Peak Health Family Medicine saw an increasing number of patients each successive year for UTIs. However, the organization had two medical providers in 2013, whereas four medical providers were employed at the organization at the end of 2016. Therefore, it would have been beneficial to have had the capability to delineate between each individual provider each year to appreciate whether the increasing numbers of UTI associated diagnoses were correlated with patient demographics or due to the practice treating more patients each year with the addition of providers. As the purpose of this portion of the retrospective chart review was to provide Peak Health Family Medicine with an indication about general applicability and utility of a clinical guideline for future practice, the delineation between providers was not required but would have provided more comprehensive and detailed information.

Utilization and effectiveness of the Delphi method through a series of questionnaires was founded upon the knowledge that study subjects were experts within their field and their responses and participation contributed positively to the ascribed objectives. A barrier to implementation of round one of the Delphi questionnaire was the relatively small number of participants. The author had hoped to garner participation from healthcare providers at organizations exposed to STIs more frequently such as Planned Parenthood; however, round one questionnaires were not returned to the author from requested study panel members. Additionally, where large healthcare organizations

such as Kaiser Permanente have a multitude of providers who could be contacted easily through their intranet and shared e-mail groups, Peak Health Family Medicine is a private, primary care practice with a limited amount of staff. It was difficult to obtain a large listing of healthcare providers, contributing significantly to the small number of study subjects ultimately requested to participate in round one of the Delphi method.

The Delphi method and associated Delphi questionnaire(s) were determined by the author to be the most efficient and effective means to collect opinions and attitudes of multiple providers who practice in a variety of settings and healthcare disciplines. Structure of the Delphi method allows for collection of both quantitative and qualitative data and could be adapted to changing objectives. An added limitation or barrier was the relative ease of invited individuals to decline participation. Similarly, the potential for bias in panel providers' responses existed as opinions could differ between individuals who chose to participate versus individuals who declined participation.

Unintended Consequences

An unintended positive consequence of this DNP capstone project was the overwhelming support and provider interest in actually implementing the guideline in the future. Due to time constraints in completion of this capstone project, physical implementation and post-implementation evaluation would not have been a realistic component of this project. However, the author was not certain whether Peak Health Family Medicine would choose to trial the clinical guideline. Based upon discussions with medical providers at this organization, it appears there is a considerable amount of interest in trialing the guideline in day-to-day practice and future use of said guideline is likely.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

As depicted and supported by the literature review and responses gathered from the Delphi questionnaires, STI screening and evaluation have been variable and inconsistent. Lack of appropriate STI diagnosis might result in prescribing inadequate and incorrect pharmaceutical therapy, potential spread the disease(s) to other individuals, and predisposes the individual to reproductive and gynecological complications in the future. The following recommendations and implications for practice serve to address the problem statement of this DNP capstone project--that diagnosis of either an STI or UTI can be difficult as presenting and associated symptoms such as complaints of urgency, frequency, and/or dysuria are similar in nature (Tomas et al., 2015). It is essential for healthcare providers to have the necessary tools and resources available to appropriately diagnose, differentiate, and treat STIs and UTIs to prevent the negative health impact of untreated chlamydia and gonorrheal infections. Accordingly, development of the STI/UTI Urinalysis Clinical Practice Guideline was created to address this deficit in practice and aide providers at Peak Health Family Medicine in providing comprehensive, evidence-based care as outlined by the Stetler (2001) model.

Recommendations for Guideline Implementation within the Framework of the Organization's Strategic Plan

Phase four, the final phase of this DNP capstone project, would ultimately entail implementation of the guideline into daily practice at Peak Health Family Medicine and outcomes evaluation post-guideline implementation. Based upon results garnered from completion of the retrospective study and information assembled from the Delphi questionnaires, the author recommends the project move forward. The timeframe in which to physically implement the guideline has been left to the discretion of Peak Health Family Medicine's healthcare providers.

To increase the likelihood of successful guideline implementation, the author advises the following steps be taken prior to integrating said guideline into routine practice. First, it would be prudent to provide education surrounding the guideline to all applicable staff members. An educational seminar about the guideline and each individual's role could be provided during the weekly staff meeting. Staff members to include in the educational training would be the receptionists, medical assistants, and registered nurse. It would be the responsibility of the receptionists to be mindful of the fact that two urine samples could potentially be required for female patients who call to schedule an appointment for complaint of UTI symptoms. To collect a dirty urine sample, the patient cannot urinate for one hour (at minimum) prior to urine collection. This information would need to be communicated clearly to the patient. Each medical assistant would need to be aware of varying collection requirements of a dirty versus clean urine sample and be cognizant to keep each sample separate to prevent cross-contamination. The registered nurse would be expected to perform the same duties as the medical assistants when needed.

Once it has been ascertained that all staff members have access to and knowledge of the STI/UTI Urinalysis Clinical Practice Guideline, a specific implementation date and trial timeframe should be chosen. As with any other patient visit, it would be up to the provider to determine and order the necessary tests. However, providers should be encouraged to follow the algorithm provided by the guideline (for at least the trial timeframe). If adherence to the guideline is low or sporadic, evaluation of the guideline would not be of any benefit and objectives of performing a post-implementation evaluation would be lost.

Recommendations for Guideline Evaluation

Post-implementation evaluation should be conducted once the trial timeframe has ended. Based upon current job responsibilities of staff members at Peak Health Family Medicine, the registered nurse would be best suited to take responsibility in performing this component of phase four. As the author already conducted a three-month retrospective chart review during phase two of this DNP capstone project, it is suggested that three months be the minimum duration for the trial timeframe. Upon completion of the trial, another chart review should be completed mirroring the same parameters outlined in Chapter IV. A results comparison of the two studies would be simple and would provide the practice with a relatively clear picture about the utility of the guideline. Additional evaluation that would be beneficial would be a questionnaire concerning provider perception of the guideline, identification of any changes or updates needed to the guideline, and appraisal of any unexpected (positive or negative) outcomes.

Ongoing Activities or Evaluations Outside the Scope of the Doctor of Nursing Practice Project

This DNP capstone project lightly touched upon the unintended consequence in the rate of STI screening after the USPSTF updated their cervical cancer screening recommendations in women in 2012. Screening for chlamydia and gonorrhea was found to have decreased by 50% since release and publication of the new guidelines (Bogler et al., 2015). The discordant screening recommendation for cervical cancer and chlamydia/gonorrhea emphasizes the importance and need for primary care providers in routinely addressing sexual health during other patient care visits. Ease of urine-based testing in diagnosis of chlamydia and gonorrhea should increase the frequency of screening for these diseases, especially for young female patients 15 to 25 years of age. Discussions with patients regarding STIs can be uncomfortable; however, if discussions begin at an early age and become a normalized part of patient visit questions, it is more likely that yearly STI screening will be performed.

Personal Goals and Contribution to Advanced Practice Nursing

The role of an Advanced Practice Nurse continues to progress and develop with the dynamic nature of the current healthcare system. The field of advanced practice nursing has morphed to meet the demands of medicine by providing evidence-based practice, emphasizing nursing leadership, and facilitating quality improvement projects. Contributions to advanced practice nursing can vary greatly and come in many forms; simple changes can sometimes have a considerable impact. Dedication to this DNP capstone project was the author's hope of effecting positive change and cultivating not only the current health of young female patients but also maximizing their future health.

A personal goal of the author was to effectively culminate skills and knowledge learned through the DNP program and successfully harness the acquired tools and processes beyond the scope of assigned coursework. Attainment of personal goals and successful completion of this DNP capstone project mandated the author step firmly into a leadership role in demonstrating competency and readiness to advance into the position as a Doctor of Nursing Practice.

Five Criteria for Executing a Successful Doctor of Nursing Practice Final Project

With the emergence and recent proliferation of Doctor of Nursing Practice programs across the country, there arose discussion regarding potential variability and expectations amongst the assorted DNP programs. As stated by the American Association of Colleges of Nursing (AACN; 2006), the fundamental purpose of DNP programs "should be to produce nurses that are uniquely prepared to bridge the gap between the discovery of new knowledge and the scholarship of translation, application, and integration of this new knowledge in practice" (Waldrop, Caruso, Fuchs, & Hypes, 2014, p. 300). To achieve or ensure each program was meeting expectations, the AACN *Essentials of Doctoral Education in Advanced Nursing Practice* were provided as an instrument to comprehensively evaluate DNP capstone projects. Waldrop et al. (2014) summarized the AACN instrument and developed the acronym EC as PIE (E = Enhances; C = Culmination; P = Partnerships; I = Implements; E = Evaluates) that outlines five essential criteria required for all completed DNP capstone projects (see Figure 8). Each of the five criteria "must be present and come together to form one complete 'pie' representing evidence-based practice that is robust and innovative, culminating in a rigorous doctoral level DNP final project," (Waldrop et al., 2014, p. 300).

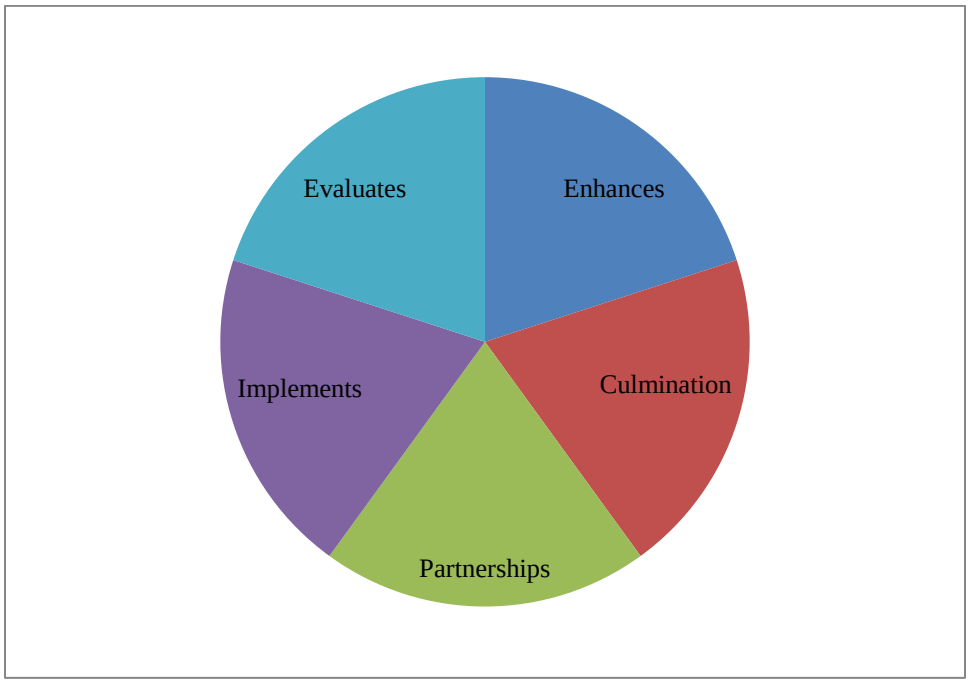

Figure 8. Five criteria for executing a successful Doctor of Nursing Practice final project (Waldrop et al., 2014).

The first of the five criteria or pieces of the pie stipulates the DNP capstone project must *enhance* health. Enhancement of health can be achieved through improvement in healthcare policy, health outcomes, or practice outcomes (Waldrop et al., 2014). The explicit purpose of this capstone project was to improve diagnostic differentiation between STIs and UTIs in female patients within a primary care practice setting. By decreasing the frequency of misdiagnosed chlamydial and gonorrheal infections, female patients should not only be more appropriately treated but treated sooner corresponding to both better health and practice outcomes.

Criteria two is evidence or demonstration of the *culmination* of practice inquiry. The culmination of practice investigation or inquiry is specified as the ability or the purposeful execution of the DNP student to attain expert knowledge about a specific topic or problem and aptly apply this knowledge to enact practical change within the

clinical care setting (Waldrop et al., 2014). This criterion was accomplished during phase one of this DNP capstone project by conducting a comprehensive literature review that evaluated past and current issues surrounding misdiagnosis of STIs and UTIs. In addition to the literature review, feasibility and necessity for practice change were assessed to gauge true applicability of such change within the identified family practice care setting.

Criteria three necessitates the formation of *partnerships*; through engagement in partnerships with members of an interdisciplinary team, the DNP student collaborates and more effectively achieves the stated goals and purpose of the capstone project (Waldrop et al., 2014). Peak Health Family Medicine is composed of medical assistants, a registered nurse, PAs, an NP, and an MD all working together as an interdisciplinary team to coordinate care for each and every patient. Successfully developing the clinical practice guideline required active involvement and participation from each of the medical providers at Peak Health Family Medicine including the DNP student. Implementation of the guideline (in the future) will require not only the medical providers but all members of the team working together to ensure the guideline is effectively and correctly instigated and utilized.

Implement/apply/translate evidence is the cornerstone of criteria four. Criteria four is demonstrated by thoughtful evaluation of evidence and translation or application of such evidence into meaningful use (Waldrop et al., 2014). Evaluation of evidence for this capstone project was completed during the literature review. Information gathered from the various studies indicated the need for a change in practice to aid medical providers in differentiating STI and UTI diagnoses. In addition, the development of the clinical practice guideline required valuation and application of a multitude of sources

including national screening guidelines published by the USPSTF (2016) and CDC (2016) in addition to responses collected from the Delphi questionnaires.

The fifth and final criterion for a successful DNP project is *evaluation* of healthcare or practice outcomes. Evaluation of outcome measures are not limited to but might include measures such as financial cost, accessibility of care, quality improvement, and/or consequences of a healthcare policy (Waldrop et al., 2014). Due to time constraints, this DNP capstone project did not implement the clinical guideline into practice. However, several outcome measures were discussed and advised for Peak Health Family Medicine in order to calculate and value the implications of said guideline in accordance with day-to-day practice within their organization.

Summary

Continued rise of chlamydia and gonorrhea infections in young females has been attributed to a variety of causes; however, a significant contributing factor is the misdiagnosis of these disease processes for urinary tract infections. Overlapping symptomology of urinary tract infections and sexually transmitted infections has perpetuated this problem. Considerable amount of evidence has demonstrated a substantial percentage of female patients will test positive for a sexually transmitted infection when presenting with symptoms commonly associated with a UTI (Mehta et al., 2001; Shapiro et al., 2005; Todd et al., 2001). The CDC (2016) and USPSTF (2016) recommend annual screening for chlamydia and gonorrhea in female patients 15 to 25 years of age and in females older than 25 years who have an identified risk factor. Development of the STI/UTI Urinalysis Clinical Practice Guideline was created to facilitate comprehensive preventative care through integration of evidence-based

literature. Proper guideline utilization will enhance STI screening and diagnosis in adolescent females and women with identified high-risk factors. Early diagnosis and treatment of STIs within this population will effectively decrease or prevent future reproductive and gynecological consequences due to untreated chlamydia and/or gonorrhea infections.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	April 5, 2017
TO:	Bethany Summers
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1036000-1] SEXUALLY TRANSMITTED INFECTION OR URINARY TRACT INFECTION? MISDIAGNOSIS OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE INFECTIONS IN PRIMARY CARE PRACTICE
SUBMISSION TYPE:	New Project
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	April 5, 2017
EXPIRATION DATE:	April 5, 2021

Thank you for your submission of New Project materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

Thank you for your patience with the UNC IRB process. Your application materials are very clear and thorough and have been verified/approved exempt.

Best wishes with your study and don't hesitate to contact me with any IRB-related questions or concerns.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX B

STATEMENT OF MUTUAL AGREEMENT

Statement of Mutual Agreement
University of Northern Colorado
Doctor of Nursing Practice Capstone Project

Bethany M. Summers, BSN, RN, BA, DNP-S
January 9, 2017

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between Peak Health Family Medicine and Bethany M. Summers, DNP Candidate from University of Northern Colorado, concerning her proposed Capstone Project.

Proposed Capstone Project Title: Sexually Transmitted Infection or Urinary Tract Infection? Misdiagnosis of Chlamydia Trachomatis and Neisseria Gonorrhoeae Infections in Primary Care Practice

Brief Description of Proposed Capstone Project:

In order to enhance quality and consistency of primary care practice, the purpose of this DNP capstone project is to develop an evidence-based guideline for improved diagnostic screening methods for diagnosis of chlamydial and gonorrheal infections in females who present with symptomatic complaints otherwise suggestive of a urinary tract infection. Through utilization of the Delphi Method, the clinical practice guideline will address factors such as age parameters, screening questions regarding past and recent sexual history, and symptom presentation which may be indicative of either a UTI or STI.

Background information will be collected not only through use of Delphi questionnaires, but a retrospective study will be conducted evaluating patient charts from 2012 through 2016 investigating patient visits for complaints of urinary urgency, frequency, and/or dysuria. The following capstone project will use the Stetler Model to translate acquired research into a tangible method of practice.

Goal of Capstone Project:

Objectives for this capstone project entails creation of a UTI/STI urinalyses clinical practice guideline to aide and support health care providers at Peak Health Family Medicine in distinguishing between patients requiring more in-depth screening when presenting to the office with UTI complaints.

Proposed On-site Activities:

Proposed on-site activities will include the conduction of a retrospective study evaluating patient charts with a chief complaint of urgency, frequency, and/or dysuria. Two or more rounds of

questionnaires employing the Delphi Method will be utilized in creation of a clinical practice guideline tailored specifically for medical providers at Peak Health Family Medicine. The clinical practice guideline will be available to Peak Health Family Medicine for future use if they so desire.

Confidentiality of Patient Records:

The retrospective portion of this Capstone Project will be performed by reviewing patient charts; however, no information regarding specific patient identification will be collected. Collected data will be limited to demographic characteristics such as age and sex. The purpose of the retrospective study is to gather information in order to garner a greater understanding regarding number of patients presenting to Peak Health Family Medicine each year with UTI complaints. Information collected from the study will provide an increased awareness of the potential benefit and implications of implementing an STI/UTI urinalyses guideline.

In addition, all responses from each round of Delphi questionnaires will be kept anonymous; only the DNP student and Capstone Chair/Research Advisor will have access to the completed surveys to protect the opinions and identity of respondents.

The designated Capstone Community/Agency Member will agree to participate in the review and approval of the proposal and presentation of the final version of the project. He/she will attend (on campus or remotely) the meetings for both.

The DNP Capstone Project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish finding and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

Signature of DNP Student — Date: 1/9/2017

Signature of Committee/Agency Member — Date: 3/10/17

Signature of DNP Capstone Chair/Research Advisor — Date: 3/18/17

APPENDIX C

DELPHI ROUND ONE QUESTIONNAIRE

Phase One: Delphi Study Round One Questionnaire

1. What is your current career title/role? (You may indicate more than one if applicable)

MD _____DO _____APN _____PA _____Other, please indicate _____

2. In which discipline do you primarily work?

Family Medicine _____

Internal Medicine _____

Pediatric Medicine _____

OB/GYN _____

Other, please indicate _____

3. In which Denver Metro Area region do you work?

North _____

Central _____

South _____

4. Do you feel providers at your organization follow current recommendations for Sexually Transmitted Infection (STI) screening & diagnosis? Specifically, screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in female patients?

Is always followed by providers in my discipline _____

Followed by some providers in my discipline _____

Followed by some providers in another discipline _____ (which one) _____

Rarely followed _____

Should not be followed _____

Should be followed more frequently than is currently _____

Other, please indicate _____

5. Do you feel providers at your organization follow current recommendations for Urinary Tract Infection (UTI) screening & diagnosis?

Is always followed by providers in my discipline _____

Followed by some providers in my discipline _____

Followed by some providers in another discipline _____ (which one) _____

Rarely followed _____

Should not be followed _____

Should be followed more frequently than is currently _____

Other, please indicate _____

6. Do you feel patients are being adequately screened for STI(s) at your organization?

Yes _____

No _____

7. Do you feel patients are being routinely screened for STI(s) at your organization when presenting with a chief complaint otherwise indicative of a UTI?

Yes _____

No_____

8. How often do you believe female patients are being tested at your organization for chlamydia and gonorrhea infections when presenting with a chief complaint otherwise indicative of a UTI?

90% - 100% _____ 50% - 59% _____ Less than 20% _____

80% - 89% _____ 40% - 49% _____

70% - 79% _____ 30% - 39% _____

60 % - 69% _____ 20% - 29% _____

9. If a clinical guideline were available to you and your organization for improved screening of female patients at higher risk for chlamydia and gonorrhea infections, do you believe it would increase screening for these diseases?

Yes _____

No _____

10. What do you believe should be covered in an STI/UTI Urinalyses Guideline? *The guideline will focus solely on the female patient population at this time. (check all that apply)

_____ Age

_____ Current form of contraception

_____ Number of past sexual partners within the past year

_____ New sexual partner

_____ History of prior sexually transmitted infection(s)

_____ If yes, did you receive a test of cure?

_____ Substance Use (alcohol, tobacco, recreational drugs)

_____ Sex in exchange for money or drugs

_____ Current symptoms (urinary urgency, urinary frequency, dysuria, hematuria, vaginal discharge, pelvic pain)

_____ Result of UA

_____ Urine sent for culture?

_____ If yes, did the culture return back positive/negative for a UTI?

Other, please indicate _____

11. Are there any comments about this recommendation you would like to make?

APPENDIX D

INFORMED CONSENT FORM FOR HUMAN PARTICIPATION IN RESEARCH

CONSENT FORM FOR HUMAN PARTICIPATION IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO
PEAK HEALTH FAMILY MEDICINE

INFORMED CONSENT – NO SIGNATURE DOCUMENT

Project Title: Sexually Transmitted Infection or Urinary Tract Infection? Misdiagnosis of Chlamydia Trachomatis and Neisseria Gonorrhoeae Infections in Primary Care Practice

Student Researcher: Bethany M. Summers, BSN, RN, BA, DNP-S
Research Advisor: Kathleen N. Dunemn, PhD, APRN, CNM, School of Nursing
Co-Research Advisor: Vicki Wilson, PhD, MS, RN, School of Nursing
Committee Member: Jill A. Quigley, M.D.

Expert Consensus: A Delphi Study

The purpose of the following Doctor of Nursing Practice Capstone Project is to develop an evidence-based clinical guideline for improved diagnostic screening methods for diagnosis of chlamydial and gonorrheal infections in females who present with symptomatic complaints otherwise suggestive of a urinary tract infection. Evaluation and assessment of current screening practices for Sexually Transmitted Infections (STIs) and Urinary Tract Infections (UTIs) by medical providers at Peak Health Family Medicine will be conducted. In addition to Peak Health Family Medicine, medical providers within other healthcare organizations inside the Denver Metro Area will also be requested to participate.

The Delphi Method is a structured communication tool or technique that utilizes a questionnaire format to survey a panel of experts (within the field of study under investigation), using two or more rounds of questioning. Information gathered from the Literature Review regarding misdiagnosis of STIs and UTIs was used in development of the first round of questions. The first round of questions will also relay general information regarding current recommendations from both the United States Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention (CDC) in diagnostic evaluation of both STIs and UTIs. Responses gathered from round one will be used in development of the clinical practice guideline. A second round of questions will then be conducted in evaluation of the proposed guideline in applicability to practice at Peak Health Family Medicine. Responses gathered from the first round of questioning will be anonymously shared with the participants during the second round.

The Delphi Method, originally developed in the 1950's, has been used in healthcare, as well as other industries and is of value when there is uncertainly or lack of empirical knowledge to achieve general consensus. It is an effective tool to assist in protocol changes as it requires integration of expert review and opinion even in the presence of disagreement. It is anticipated that two rounds will be necessary for completion of this capstone project. All Delphi surveys will be sent and returned electronically with a private e-mail account only accessible by the DNP student. It is estimated that each

participant will spend approximately 15-20 minutes in completion of survey questions within each round of the Delphi process.

Participation is voluntary and all responses collected from the surveys will be kept **anonymous**. The data collected will be kept on a password protected thumb drive that will have restricted accessibility; information collected will be available only to the DNP student and her Research Advisor. There are no anticipated risks to participants. This is a quality improvement project to improve the evaluation, differentiation, and diagnosis of STIs versus UTIs.

You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in a loss of benefits to which you are otherwise entitled. If you have any questions, please contact one of the undersigned.

Having read the above document and having had an opportunity to ask any questions, please complete the questionnaire "Phase One: Delphi Study Round One Questionnaire" if you would like to participate in this research. By completing and returning the Delphi questionnaire, it will be assumed that you have communicated consent in participation. Please print and keep this form for future reference. Please return the completed survey to BethanyMSummers@gmail.com.

If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado, Greeley, CO 80639; Phone 970-351-1910.

This informed consent will be e-mailed and accompany each round of the study.

Student Researcher: Bethany M. Summers, BSN, RN, DNP-S

Research Advisor: Kathleen N. Dunemn, PhD, APRN, CNM
E-mail: Kathleen.Dunemn@unco.edu
Phone: (970) 351-3081/ (303) 649-5581

Co-Research Advisor: Vicki Wilson, PhD, MS, RN
E-mail: Vicki.Wilson@unco.edu
Phone: (970) 351-1295

Committee Member: Jill A. Quigley, M.D.
Address: Peak Health Family Medicine
10901 West Toller Drive, Suite 100
Littleton, CO 80127
Phone: (303) 973-3529

APPENDIX E

DELPHI ROUND TWO QUESTIONNAIRE

Phase Two: Delphi Study Round Two Questionnaire

Thank you for your participation in the Delphi Study Round Two Questionnaire. The purpose of the Phase Two: Delphi Study Round Two Questionnaire is to build consensus around the proposed Clinical Practice Guideline for use by Peak Health Family Medicine. The objective of the proposed Clinical Practice Guideline is to assist in the differentiation between a Sexually Transmitted Infection (STI), specifically infection with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*, and a Urinary Tract Infection (UTI) in female patients who present with symptom complaints indicative of a UTI.

A retrospective chart review was conducted reviewing Peak Health Family Medicine's electronic medical record (EMR) of female patient charts from October 1, 2016 through December 31, 2016. Patient charts were included if (1) the patient was female, (2) between 15-65 years of age, and (3) chief complaint was suggestive of a UTI. Additionally, a four year retrospective study (January 1, 2013 – December 31, 2016) was completed evaluating the frequency of ICD 9 and ICD 10 diagnoses codes for UTI, chlamydia and gonorrhea. Information gathered from these two studies in addition to responses from the Phase One: Delphi Study Round One Questionnaire was used in development of the proposed Clinical Practice Guideline. Responses from the Delphi Study Round One Questionnaire included medical providers from NextCare Urgent Care, Kaiser Permanente, and Peak Health Family Medicine.

Please respond to the following questions:

1. 50% of participants responded that current recommendations for STI screening & diagnosis (specifically screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in female patients) *is always followed by providers in my discipline*. 33% of respondents felt that current recommendations *should be followed more frequently than is currently*. Would you agree that 50% adherence to current screening recommendations is too low?

Yes _____

No _____

Additional Comments

2. The majority of respondents felt that current recommendations for UTI screening & diagnosis is *always followed by providers in my discipline*. Would you agree that the current recommendation as published by UpToDate is a reasonable guideline in the screening and diagnosis for UTI in women?

Yes _____

No _____

Additional Comments

3. Of the 41 female patients who were seen at Peak Health Family Medicine between October 1, 2016 and December 31, 2016 for UTI complaints, 78.0% (32) of patients were diagnosed and prescribed antibiotic therapy in treatment of a UTI. Of the 32 patients treated for a UTI, results of the subsequent urine culture were negative for 46.8% (15) of those started on antibiotic therapy. Are you surprised by this finding?

Yes, I assumed the percentage of positive culture results would be higher _____

Yes, I assumed the percentage of positive culture results would be lower _____

No, the percentage of negative urine cultures is to be expected _____

Additional Comments

4. More than half of participants responded that they did not feel patients are being adequately screened for STIs at their organization. Additionally, only 33% of respondents believed that patients were being routinely screened for STI(s) when presenting with a chief complaint otherwise indicative of a UTI. Would you agree that a Clinical Practice Guideline would increase the frequency of such screening?

Yes _____

No _____

Additional Comments

5. When asked about the frequency or percentage of female patients being tested for chlamydia and gonorrhea infections when presenting with a chief complaint otherwise indicative of a UTI, the majority of participants responded with an estimated frequency of *less than 20%*. Results of the chart review revealed that patients were tested for chlamydia and/or gonorrhea 2.4% of the time. Based upon this statistic alone, would you agree that testing for chlamydia and gonorrhea needs to occur more often?

Yes _____

No _____

Additional Comments

6. Based upon the proposed Clinical Practice Guideline, are there any additional risk factors that should be included in the Assessment of Risk?

Yes _____

If yes, please specify _____

No _____

Additional Comments

7. Based upon the proposed Clinical Practice Guideline, do you agree with the outlined Clinical Manifestations and Testing guideline?

Yes _____

No _____

If no, please specify _____

Additional Comments

8. Based upon the proposed Clinical Practice Guideline, do you agree with the included parameters for a positive UA result?

Yes _____

No _____

If no, please specify _____

Additional Comments

9. Based upon the proposed Clinical Practice Guideline, do you agree with the included parameters for additional testing i.e. urine culture and STI testing?

Yes _____

No _____

If no, please specify _____

Additional Comments

10. Are there any other comments you would like to make about the proposed Clinical Practice Guideline?

Yes _____

If yes, please specify _____

No _____

Additional Comments

Thank you for your participation in completion of the above questionnaire. If you have any questions or comments that were not addressed, please contact me at BethanyMSummers@gmail.com.

APPENDIX F

RESULTS OF CHART REVIEW

DECEMBER							
Age	**Chief Complaint**	**Specific Complaints**	**Result of Urinalysis**	**Sent for Urine Culture?**	**Result of Urine Culture**	**Rx for UTI Prescribed**	**Test Sent for Chlamydia/ Gonorrhea?**
64	UTI Symptoms	Flank Pain	Negative	Yes	Negative	Yes	No
17	UTI Symptoms	Abdominal Pain, Hematuria, Nausea, Urinary Frequency, Dysuria	Blood in Urine: Positive	Yes	Negative	Yes	No
50	UTI Symptoms	Urgency, Urinary Frequency, Dysuria	Not Completed - AZO	Yes	Negative	Yes	No
34	UTI Symptoms	Abdominal Pain, Chills, Nausea, Urgency	Blood in Urine: Positive; Protein Urine: 2+; Leukocytes: 1+	Yes	Negative	Yes	No
54	UTI Symptoms	Nausea, Urgency, Urinary Frequency	Blood in Urine: Positive; Protein Urine: Trace	No	N/A	Yes	No
45	UTI Symptoms	Abdominal Pain, Hematuria, Nausea, Urgency, Urinary Frequency, Dysuria	Blood in Urine: Positive; Leukocytes: 2+	Yes	Positive	Yes	No
29	UTI Symptoms	Hematuria, Urgency, Urinary Frequency	Blood in Urine: Positive; Protein Urine: 2+; Leukocytes: 4+	Yes	Positive	Yes	No
45	Low Back Pain	N/A	Negative	No	N/A	No	No
29	UTI Symptoms	Abdominal Pain, Urgency, Urinary Frequency, Dysuria, Vaginal Irritation	Ketones: Trace; Protein Urine: 1+; Leukocytes: 1+	Yes	Negative	Yes	No
59	UTI Symptoms	Abdominal Pain, Chills, Nausea, Urgency, Urinary Frequency, Vaginal Discharge	Negative	Yes	Positive	Yes	No
48	Abdominal Pain	Dysuria	Leukocytes: Trace	Yes	Negative	No	No
51	UTI Symptoms	Dysuria	Negative	Yes	Negative	Yes	No
57	UTI Symptoms	Dyspareunia, Dysuria, Vaginal Discharge, Vaginal Itching	Leukocytes: Positive	Yes	Negative	No	No
19	Dysuria	Vaginal Odor, Vaginal Itching	Negative	Yes	Positive	No	No
61	UTI Symptoms	Flank Pain	Blood in Urine: Positive; Leukocytes: 1+	Yes	Negative	Yes	No
25	UTI Symptoms	Dysuria	Blood in Urine: Positive; Protein Urine: 2+; Leukocytes: 2+	Yes	Negative	Yes	No
36	UTI Symptoms	Urgency	Negative	Yes	Negative	Yes	No
48	Flank Pain	Nausea	Negative	No	N/A	No	No

NOVEMBER							
36	UTI Symptoms	Flank Pain, Nausea, Urgency, Urinary Frequency	Blood in Urine: Positive; Protein Urine: 2+; Leukocytes: 4+	Yes	Positive	Yes	No
52	UTI Symptoms	Abdominal Pain, Fever, Urinary Frequency	Blood in Urine: Positive; Leukocytes: 2+	Yes	Positive	Yes	No
17	UTI Symptoms	Dysuria	Negative	No	N/A	No	Yes
47	UTI Symptoms	Abdominal Pain, Fever, Hematuria	Blood in Urine: Positive	Yes	Negative	Yes	No
52	UTI Symptoms	Urinary Frequency, Dysuria	Leukocytes: 2+	Yes	Positive	Yes	No
55	UTI Symptoms	Abdominal Pain, Flank Pain, Odor	Blood in Urine: Positive; Protein Urine: 2+; Nitrite: Positive; Leuk	Yes	Positive	Yes	No
32	Dysuria	Flank Pain, Hesitancy, Urgency, Urinary Frequency	Blood in Urine: Positive	Yes	Negative	Yes	No
63	Low Back Pain	N/A	Negative	Yes	Negative	No	No
35	UTI Symptoms	Hematuria, Urgency, Urinary Frequency	Leukocytes: 1+	Yes	Positive	Yes	No
53	Dysuria	Dysuria	Protein Urine: Trace; Leukocytes: 2+	Yes	Positive	Yes	No
31	UTI Symptoms	Dysuria, Urgency	Blood in Urine: Positive; Leukocytes: 3+	Yes	Positive	Yes	No
35	UTI Symptoms	Flank Pain, Urgency, Urinary Frequency	Blood in Urine: Positive; Protein Urine: 2+	Yes	Positive	Yes	No
15	Dysuria	Abdominal Pain, Dysuria	Nitrite: Positive	Yes	Positive	Yes	No
17	UTI Symptoms	Abdominal Pain, Hematuria, Nausea, Urinary Frequency, Dysuria	Blood in Urine: Positive; Protein Urine: 1+	Yes	Negative	Yes	No
49	Dysuria	Abdominal Pain, Flank Pain, Hematuria, Urgency, Urinary Frequency, Dysuria	Blood in Urine: Positive; Nitrite: Positive; Leukocytes: 3+	No	N/A	Yes	No

OCTOBER							
45	UTI Symptoms	Cloudy Urine, Pelvic Pain, Hematuria	Negative	Yes	Positive	No	No
36	UTI Symptoms	Abdominal Pain, Urgency, Urinary Frequency, Dysuria	Ketones: 1+; Leukocytes: 2+	Yes	Negative	Yes	No
48	Urinary Urgency	Abdominal Pain, Chills, Urinary Frequency, Urgency	Glucose: 3+	No	N/A	No	No
59	UTI Symptoms	Cloudy Urine, Pelvic Pain, Hematuria	Nitrite: Positive; Leukocytes: 1+	Yes	Positive	Yes	No
29	Dysuria	Chills, Fever, Flank Pain, Hematuria, Nausea, Urinary Frequency	Blood in Urine: Positive	Yes	Negative	Yes	No
42	UTI Symptoms	Urgency, Urinary Frequency, Dysuria	Not Performed	Yes	Positive	Yes	No
46	UTI Symptoms	Discomfort	Negative	Yes	Positive	Yes	No
23	UTI Symptoms	Dysuria, Urgency, Urinary Frequency, Chills, Flank Pain, Hesitancy, Urinary Incontinence	Negative	Yes	Negative	Yes	No

APPENDIX G

URINALYSIS CLINICAL PRACTICE GUIDELINE

PEAK HEALTH FAMILY MEDICINE
CLINICAL PRACTICE GUIDELINE

TITLE: Sexually Transmitted Infection (*Chlamydia trachomatis/Neisseria gonorrhoeae*) or Urinary Tract Infection (Acute Cystitis) Urinalysis Clinical Practice Guideline

Reviewed: June, 2017

Target Population: All female patients between 15 to 25 years of age and female patients older than 25 years of age with at least one identified risk factor.

Rationale: The following guideline will assist in the differentiation between a Sexually Transmitted Infection (STI), specifically infection with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*, and a Urinary Tract Infection (UTI).

Author: Bethany Mee Yeong Summers, BSN, RN, DNP-S

1. **Overview**

Diagnosis of either an STI or UTI can be difficult as presenting and associated symptoms such as complaint of urgency, frequency, and/or dysuria are similar in nature (Tomas, Getman, Donskey, & Hecker, 2015). In addition, the results of a urinalysis (UA) may present overlapping abnormalities; most commonly pyuria and positive leukocyte esterase (Tomas et al., 2015).

A retrospective study of five family practices found that screening for gonorrhea and chlamydia decreased by 50% since publication of the new cervical cancer screening guidelines by the U.S. Preventive Services Task Force (USPSTF) in 2012 (Bogler et al., 2015). Therefore, primary care practices and providers need to maximize other opportunities and patient care visits to ensure that sexual health and STI screening are completed, especially within the high-risk, young, female patient population.

Due to the frequent asymptomatic presentation of chlamydial infections in women, universal screening has been suggested as the most effective means in disease detection; however, the cost of such practice is unrealistic. It has therefore been recommended that infection screening be selectively completed based upon organizational parameters or that women be treated empirically using defined criteria addressing factors such as an individual's age, sexual behavior, and/or symptomatic complaint(s) at time of visit (Marrazzo et al., 1997).

Urine-based testing for diagnosis of chlamydia and gonorrhea using nucleic acid amplification tests (NAATs) has been found to be both sensitive and specific; ease and availability of urine-based testing allows for increased STI testing and effectively screens disease presence in asymptomatic individuals otherwise not pursuing healthcare services (Jones, Knaup, Hayes, & Stoner, 2000).

2. **2014 U.S. Preventive Services Task Force (USPSTF) Screening Recommendations for Chlamydia and Gonorrhea**

Summary of Recommendations and Evidence

Population	Recommendation	Grade*
Sexually Active Women	The USPSTF recommends screening for chlamydia in sexually active women age 24 years and younger and in older women who are at increased risk for infection.	**B**
Sexually Active Women	The USPSTF recommends screening for gonorrhea in sexually active women age 24 years and younger and in older women who are at increased risk for infection.	**B**

United States Preventive Services Task Force (2014). *Chlamydia and gonorrhea: Screening*. Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening

***Grade B**
Definition: The USPSTF recommends this service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
Suggestions for Practice: Offer or provide this service.

3. **Assessment of Risk**

If any of the risk factors listed below apply to the patient in question, the patient is categorized as ***high risk*** (USPSTF, 2016).

(a) Age: *Infection rates for Chlamydia and Gonorrhea are highest in sexually active females 20 to 24 years of age, closely followed by females 15 to 19 years of age.*
(b) New sex partner
(c) More than one sex partner
(d) Sex partner with concurrent partners
(e) Sex partner who has an STI
(f) Exchanging sex for money or drugs

4. **Clinical Manifestations & Testing**

A. Order a “dirty urine” sample and a clean catch urinalysis (UA) for all female patients between 15 to 25 years of age.

B. Order a dirty urine sample and a clean catch UA for all female patients older than 25 years of age with one identified risk factor.

C. Order a clean catch urinalysis (UA) for all female patients with any of the following symptoms:

(a) Dysuria
(b) Urinary frequency
(c) Urinary urgency
(d) Suprapubic pain
(e) Hematuria

5. **Collection of Urine**

A. First-void or “Dirty” Urine Specimen (Elliot Hospital Laboratory, 2014),

For the most accurate results, instruct patient:

i. No urination for at minimum one hour (two hours or more is preferred) prior to urine collection.

ii. No cleansing of the urogenital/peri-urethral area prior to urine collection.

iii. Initial urine stream should be collected.

iv. 20-30 mL of urine should be collected.

*Instruct patient to not overfill the container as large volumes of urine may cause dilution and reduce sensitivity of testing.

For the most accurate results, instruct staff:

v. Specimen container must be clearly labeled as a dirty urine sample.

vi. Specimen container must be clearly labeled with patient name, DOB, collection date, and collection time.

B. Clean Catch Urine Specimen Elliot Hospital Laboratory, 2014)

For the most accurate results, instruct patient:

i. Wash hands with warm water and soap.

ii. Cleanse urogenital/peri-urethral area with fresh towelette.

iii. Begin to urinate in toilet.

iv. Place specimen container in urine midstream.

For the most accurate results, instruct staff:

v. Specimen container must be clearly labeled as a clean urine sample.

vi. Specimen container must be clearly labeled with patient name, DOB, collection date, and collection time.

6. **Results of Initial Urinalysis**

A. UA Positive
The UA is considered positive if any of the following are present:
(a) Leukocyte esterase
(b) Nitrite
(c) Hematuria

7. **Urine Culture**

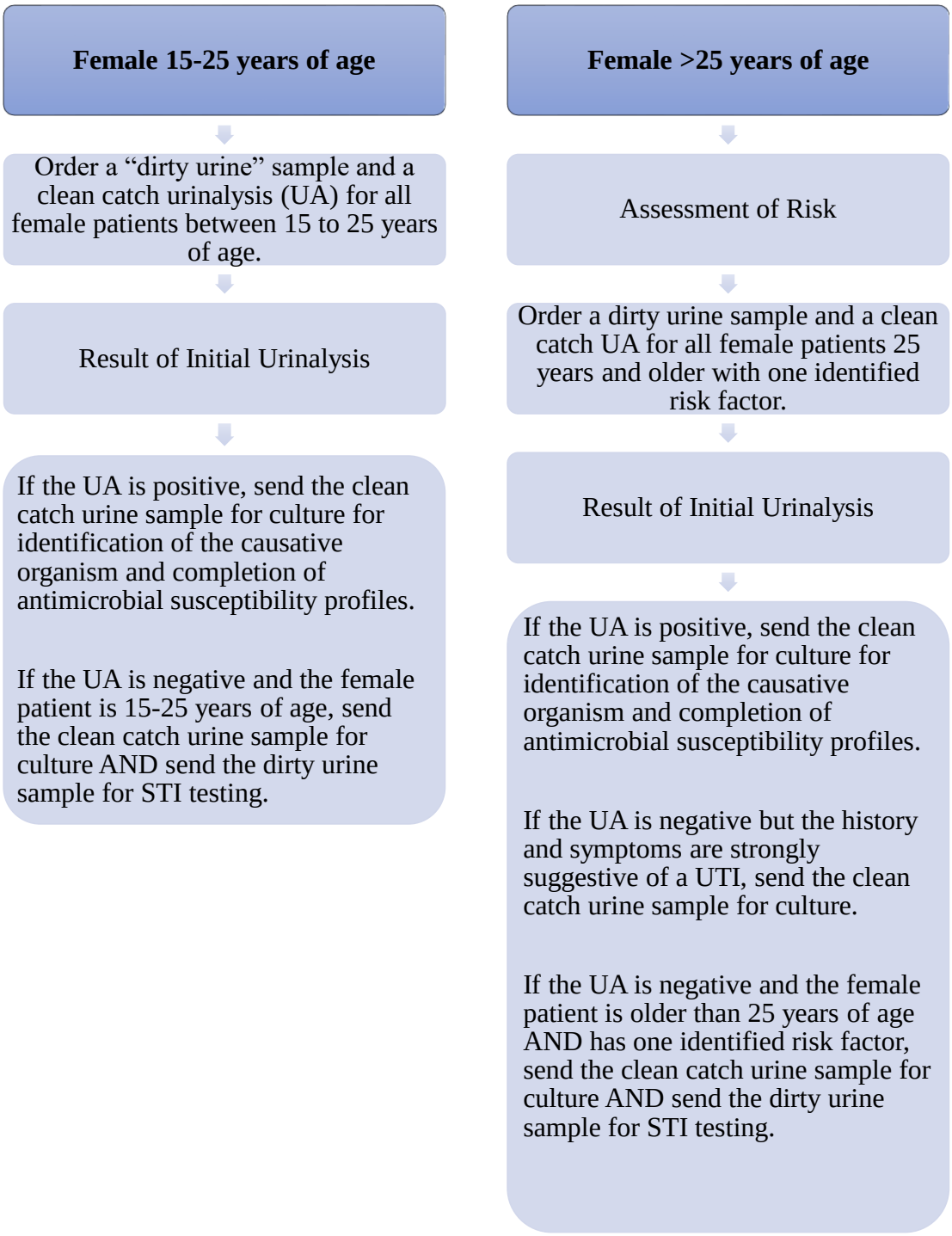
A. If the UA is positive, send the clean catch urine sample for culture for identification of the causative organism and completion of antimicrobial susceptibility profiles.

B. If the UA is negative but the history and symptoms are strongly suggestive of a UTI, send the clean catch urine sample for culture.

C. If the UA is negative and the female patient is 15-25 years of age, send the clean catch urine sample for culture AND send the dirty urine sample for STI (chlamydia and gonorrhea) testing.

D. If the UA is negative and the female patient is older than 25 years of age AND has one identified risk factor, send the clean catch urine sample for culture AND send the dirty urine sample for STI (chlamydia and gonorrhea) testing.

8. **Suggested Algorithm**



9. **Treatment**

A. Chlamydia
   a. *Recommended Regimens* (CDC, 2016)
      i. Azithromycin 1 g PO in a single dose OR
      ii. Doxycycline 100 mg PO BID X 7 days
   b. *Alternative Regimens* (CDC, 2016)
      i. Erythromycin base 500 mg PO QID X 7 days
      ii. Erythromycin ethylsuccinate 800 mg PO QID X 7 days
      iii. Levofloxacin 500 mg PO X 7 days
      iv. Ofloxacin 300 mg PO BID X 7 days

B. Gonorrhea
   a. *Recommended Regimen* (CDC, 2016)
      i. Ceftriaxone 250 mg IM in a single dose PLUS Azithromycin 1 g PO in a single dose
   b. *Alternative Regimens* (CDC, 2016)
      i. Cefixime 400 mg PO in a single dose PLUS Azithromycin 1 g PO in a single dose

References:

Centers for Disease Control and Prevention. (2016). *2015 sexually transmitted diseases treatment guidelines*. Retrieved from https://www.cdc.gov/std/tg2015/screening-recommendations.htm

Elliot Hospital Laboratory. (2014). *Urine collections*. Retrieved from https://www.testmenu.com/elliothospitallaboratory/TestDirectory/SiteFile?fileName=Urine_Collections_090113.pdf

U.S. Preventive Services Task Force. (2016). *USPSTF recommendations for STI screening*. Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-recommendations-for-sti-screening