

Regis University

## ePublications at Regis University

---

Regis University Student Publications  
(comprehensive collection)

Regis University Student Publications

---

Fall 2020

### Considerations of Antibiotic Treatment for Genital Ureaplasma

Shelbie Paul  
*Regis University*

Follow this and additional works at: <https://epublications.regis.edu/theses>

---

#### Recommended Citation

Paul, Shelbie, "Considerations of Antibiotic Treatment for Genital Ureaplasma" (2020). *Regis University Student Publications (comprehensive collection)*. 980.  
<https://epublications.regis.edu/theses/980>

This Thesis - Open Access is brought to you for free and open access by the Regis University Student Publications at ePublications at Regis University. It has been accepted for inclusion in Regis University Student Publications (comprehensive collection) by an authorized administrator of ePublications at Regis University. For more information, please contact [epublications@regis.edu](mailto:epublications@regis.edu).

Considerations of Antibiotic Treatment for Genital Ureaplasma

Shelbie Paul

Submitted as Partial Fulfillment for the Doctor of Nursing Practice Degree

Regis University

August 13, 2020

## CONSIDERATIONS OF ANTIBIOTIC TREATMENT

### **Abstract**

Genital Ureaplasma is a worldwide issue in obstetrics and gynecology. Morbidities can include pelvic inflammatory disease, infertility, miscarriage, preterm delivery, and chorioamnionitis, if left untreated. The quality improvement (QI) initiative used a retrospective chart review of 128 subjects, collecting data of antibiotic treatment differences and recurrence of genital Ureaplasma at a corporate owned obstetrical and gynecologic outpatient clinic in the metro-Denver area. The investigator used the percentage change mathematical formula to determine the percentage difference between patient antibiotic treatment only with symptomatic genital Ureaplasma versus antibiotic treatment of the patient and the partner. Overall, the project did not show statistical difference between the two variables (percentage change of 14.47%). However, unintentional findings were reported on the recurrence difference between patient and patient and partner treatment between the antibiotics doxycycline (20.7% and 16.57%), azithromycin (50.07% and 50.7%), and clindamycin (100% recurrence rate with and without partner treatment). The major limitation of this project was the small sample size. The most significant implication of this project was that the antibiotic findings were consistent with CDC and UpToDate guidelines. It appeared that doxycycline has a higher success rate for treatment of genital Ureaplasma. Further investigation is recommended.

*Keywords:* DNP project, antibiotic treatment, mycoplasmas

Copyright © 2020 Shelbie Paul. All rights reserved. No part of this work may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the author's prior written permission.

## Considerations of Antibiotic Treatment for Genital Ureaplasma Executive Summary

### **Problem**

Symptomatic genital Ureaplasma is an emerging concern in gynecology. With potential risks of untreated symptomatic genital Ureaplasma including pelvic inflammatory disease, infertility, miscarriage, preterm delivery, and chorioamnionitis, it is imperative that provider education with a review of CDC guidelines are explored starting at the clinical level. The PICO statement the project sought to address was whether women with symptomatic genital Ureaplasma have a decreased incidence of symptomatic recurrence when both the patient and the partner are treated with antibiotic therapy than treatment of the patient alone.

### **Purpose**

This capstone project which was a quality improvement (QI) initiative, investigated if there was a difference in the incidence of symptomatic recurrence of genital Ureaplasma in the female patient when treating the patient and partner as compared to treating the patient alone with antibiotic therapy.

### **Goals**

The primary goal of the project was to determine whether the relationship between antibiotic treatment differences and recurrence of symptomatic genital Ureaplasma was statistically significant. A secondary goal was to explore the recommendations of evidenced-based guidelines related to urethritis and cervicitis caused by Ureaplasma

### **Objective**

The objective of this quality improvement initiative was to conduct a retrospective chart review of the antibiotic treatment differences of patient and partner treatment versus patient only treatment for genital Ureaplasma within a corporate owned obstetrics and gynecology office in the metro-Denver area

### **Plan**

In planning the project, a data collection tool was created and approved by the QI project site administrator to identify the diagnosis for the visit using ICD-10 codes as identifiers, positive PCR testing for genital Ureaplasma, antibiotic treatment (doxycycline, azithromycin, or other), partner treatment, test of cure results, and recurrence of symptoms resulting in a return visit in a 3-month period of time. A priori sampling size of 128 was calculated using the G\*Power software (Department of Psychology, 2019) with the alpha of 0.05 and power of 0.80. The investigator used a percentage change mathematical formula to determine the percentage difference between the two scores. The inferential statistic used was Kendall's tau.

### **Outcomes and Results**

The project did not show statistical difference between the two variables (percentage change of 14.47%). However, unintentional findings were reported on the recurrence difference between patient and patient and partner treatment between the antibiotics doxycycline (20.7% and 16.57%), azithromycin (50.07% and 50.7%), and clindamycin (100% recurrence rate with and without partner treatment). The unintentional findings are consistent with CDC and UpToDate guidelines. It appeared that doxycycline has a higher success rate for treatment of genital Ureaplasma.

## Acknowledgments

Thank you to my husband, son, daughter, sister, and parents for understanding my educational priorities and providing the time for me to study and write countless hours, without distraction. Your ongoing support, encouragement, and love has made this journey possible.

Thanks to my mentors, Joan Girard, WHNP-BC and Shana Martin, MSN, CNM for being open to change and spending hours discussing the subject of genital Mycoplasmas and trends.

Thank you to my capstone chair, Kathleen Whalen, PhD, who guided me throughout my DNP journey. Dr. Whalen, you have provided encouragement and positive reinforcement throughout this journey. Thank you for believing in me and my project. I was very fortunate to have you as my capstone chair.

Thank you to Dr. Kruschke, EdD, MS, RN, CNE for the time, ongoing excitement, and encouragement while running the statistical data. This was the exciting part and it actually made sense!

Thank you to the DNP faculty at Regis University and fellow DNP cohort for providing me with unwavering leadership, guidance, and support during this educational journey.

Lastly, a special thank you to Gail Markowski, ANP-C, ACNP-C, CCRN, for your encouragement, friendship, humor, and support from NY. We made the journey together and we ate the frog!

## Table of Contents

I. Preliminary Pages .....	
A. Copyright Page.....	i
B. Executive Summary.....	ii
C. Acknowledgments.....	iii
D. Table of Contents.....	iv
E. List of Tables .....	vi
F. List of Figures.....	vii
G. List of Appendices.....	viii
II. Problem Recognition and Definition .....	1
A. Statement of Purpose .....	1
B. Problem Statement.....	2
C. PICO Statement and Practice Question .....	3
D. Project Significance, Scope and Rationale .....	3
E. Theoretical Foundation for Project and Change .....	4
F. Literature Selection/ Systematic Process.....	6
G. Scope of Evidence.....	7
H. Background of the Problem .....	7
III. Review of the Evidence .....	8
A. Systematic Review of the Literature Example.....	8
IV. Project Plan and Evaluation.....	12
A. Project Strengths, Weakness, Opportunities, and Threats.....	12
B. Driving, Restraining, and Sustaining Forces .....	13

D. Needs, Resources, and Sustainability .....	14
E. Feasibility Risk and Unintended Consequences.....	15
F. Stakeholders and Project Team.....	16
G. Cost- Benefit Analysis.....	16
H. Mission /Vision / and Goals.....	17
I. Process/ Outcome Objectives .....	18
J. Logic Model.....	18
K. Project Design.....	19
L. Data Collection.....	20
M. Population/ Sampling Parameters.....	21
N. Setting for EBP Project.....	21
N. Study Instrument.....	22
O. Protection of Human Rights.....	23
P. Data Collection and Treatment Protocol.....	24
V. Project Findings and Results.....	25
A. Objective I.....	25
B. Statistical Data.....	25
C. Results.....	26
D. Limitations/Recommendations/ Implications for Change .....	29
VI. Summary.....	30
VII. References.....	32



## **List of Tables**

A. Table 1: Partner Treatment and Recurrence Rate.....	27
B. Table 2: Kendall's Tau.....	27
C. Table 3: Evaluating Partner Treatment, Antibiotic, and Recurrence.....	29

**List of Figures**

A. Figure 1: Statistical Pie Chart.....	26
---	----

## **List of Appendices**

A. Appendix A: Neuman's Systems Model.....	38
B. Appendix B: Lewin's Theory of Change.....	39
C. Appendix C: Literature Review Example.....	40
D. Appendix D: SWOT Analysis.....	41
E. Appendix E: Budget and Resources.....	42
F. Appendix F: Letter of Intent.....	43
G. Appendix G: Timeline.....	45
H. Appendix H: Logic Model.....	46
I. Appendix I: Data Dictionary.....	47
J. Appendix J: Collection Instrument for Retrospective Chart Review.....	48
K. Appendix K: CITI Training Certificate.....	49
L. Appendix L: HCA Approval Email.....	52
M. Appendix M: Data Use Agreement.....	53
N. Appendix N: IRB Net Board Action Email.....	57

## Considerations of Antibiotic Treatment for Genital Ureaplasma

Symptomatic genital Ureaplasma is a world-wide issue in obstetrics and gynecology. A single study performed at a multicenter/multicultural laboratory concluded 47.3% (n=833) of the female participants sampled tested positive for genital Ureaplasma when the patient presented with clinical symptoms of vaginitis (Leli, et al., 2018). This exposure rate is consistent with other studies. With potential risks of untreated symptomatic genital Ureaplasma including pelvic inflammatory disease, infertility, miscarriage, preterm delivery, and chorioamnionitis, it is imperative that education starting at the clinical level is explored. This quality improvement (QI) initiative was a retrospective chart review of the antibiotic treatment differences and recurrence of genital Ureaplasma at a corporate owned obstetrical and gynecologic outpatient clinic in the metro-Denver area. This paper includes a description of the practice problem with an articulated review of supporting literature and evidenced based practice guidelines. The paper also presents a market/risk analysis for conducting the project, the project objectives and methodology and evaluation plan, as well as an analysis of project findings and results and a discussion of limitations, recommendations and implications for change.

### **Problem Recognition and Definition**

#### **Project Purpose**

The purpose of this capstone project, which is a quality improvement (QI) initiative, was to investigate if there is a statistical difference in the incidence of symptomatic recurrence of genital Ureaplasmas in the female patient when treating the patient and partner as compared to treating the patient alone with antibiotic therapy. The primary investigator used a retrospective chart review to identify symptoms of genital Ureaplasma and antibiotic

treatment, to determine if the female patient alone or the patient and partner were treated for Ureaplasma, and measured rates of symptomatic recurrence of genital Ureaplasma in the intervention and the comparison groups.

### **Problem Statement**

The problem statement for the proposed project was as follows: Lack of treatment of partners who test positive for Ureaplasma may increase sexual transmission of this microorganism. The problem statement for the capstone project was identified when the primary investigator recognized the antibiotic treatment differences, in women with positive Ureaplasma culture, between 13 providers in an obstetric and gynecologic clinic in the metro-Denver area. The primary investigator suspected that treatment inconsistencies among providers were due to the lack of knowledge of genital Ureaplasma signs, symptoms, and negative effects, as well as preferred antibiotic treatment options. The primary investigator and another seasoned nurse practitioner became concerned with the number of female patients that returned to the clinic with recurrent symptoms of genital Ureaplasma.

The risks of genital Ureaplasma if left untreated in symptomatic patients, is known to lead to pelvic inflammatory disease (PID), ectopic pregnancy, infertility by blocking fallopian tubes, and recurrent vaginosis in the non-pregnant female. In a pregnant patient, Ureaplasma can lead to preterm rupture of membranes and preterm labor/delivery (Diaz, et al., 2013).

The Center for Disease Control (2015) guidelines recommend antibiotic treatment for male urethritis and female cervicitis. Genital Ureaplasma falls into this category. With the aforementioned risk of genital Ureaplasma, it is important for clinicians to provide antibiotic treatment in a timely manner.

**PICO**

The capstone project utilized the “PICO” question format rather than a formal research hypothesis. The PICO acronym stands for: Population or Patient (P), Intervention (I), Comparative Intervention (C), and Outcome (O) (Houser & Oman, 2011). The question the project sought to address was: Do women with symptomatic genital Ureaplasmas have a decreased incidence of symptomatic recurrence when both the patient and the partner are treated with antibiotic therapy than treatment of the patient alone?

In the PICO format, the question reads:

P (patient): Women with symptomatic genital Ureaplasmas

I (Intervention): Treating patient and partner with antibiotic therapy

C (comparison): Treating the patient alone

O (outcome): Decrease the incidence of symptomatic recurrence

**Project Significance, Scope, and Rationale**

Genital Ureaplasma species have gained more attention as being an attributing bacterium associated with adverse effects to the health of men, women, and neonates. In women, genital Ureaplasma can cause pelvic inflammatory disease (PID), leading to potential ectopic pregnancy or infertility. According to the CDC (2017), an estimated 2.5 million women aged 18–44 years in the United States reported a history of PID diagnosis within their lifetime. This quality improvement project may have a financial impact by decreasing the rate of PID seen in a clinical setting, as well as decreasing cost of potential adverse effects from the Ureaplasma species.

The scope of this project was a quality improvement project internal to a large obstetrics and gynecology clinic in the metropolitan Denver area. This study was not meant

to develop new knowledge or to be generalized outside of the agency where the QI project took place.

The rationale for the project was to inform providers within the practice of antibiotic treatment for genital Ureaplasma. The investigator identified the capstone project with DNP Essential II: *Organizational and Systems Leadership for Quality Improvement and Systems Thinking* (AACN, 2006). This project focused on the direct care of patients who had symptomatic Ureaplasma and their partners. It provided the investigator with an opportunity to apply evidence-based guidelines/policies that could potentially improve the quality of health care for this population.

### **Foundational Theory**

The investigator used two theories for the theoretical framework for the capstone project, which were the Neuman Systems Model and Lewin's Theory of Change.

Betty Neuman (1924-2008), introduced her Neuman Systems Model in 1970 while she was a professor at UCLA. Her background in nursing included Community and Mental Public Health. "The goal of the model was to provide a holistic overview of the physiological, psychological, sociocultural, and developmental aspects of human beings" ("Betty Neuman", 2010). The theory developed over time with adaptability for use in the classroom, community, and clinical practice. The purpose of the Neuman Systems Model is viewing the patient, or client as termed by Dr. Neuman in her theory, as an open system that reacts to stressors. Stressors may include environmental, psychological, developmental, physiological, and spiritual sources.

One of the major concepts of the model was identifying the client as having "rings" representing each component of the model. The inner "ring" is the central circle, which is the

basic vital signs, genetics, strengths and weakness of the system (client). The next ring is the line of resistance. This protects the client from outside factors/stressors and maintains a healthy system. The next ring is the flexible line of defense, which serves as a protective buffer to prevent stressors from invading the client (Ume-Nwagbo et al., 2006). This line is seen as being fluid and can move away or towards the line of resistance. The normal line of defense completes the Neuman Systems Model and is thought to be developed over time as the system learns coping mechanisms, as well as outside influences and beliefs.

The Neuman Systems model is a middle-range theory that can be applied to the Capstone problem statement: As a nurse or provider, their function is to assess an individual's reaction to a stressor (as in this case, symptoms consistent with genital Ureaplasma) has on the system (or the patient). The primary care provider can use primary (education), secondary or preventative measures (antibiotic treatment to patient and partner), and tertiary measures (management/treatment of recurrent symptoms) to return the client to health and stability. See Appendix A for The Neuman Systems Model.

Kurt Lewin (1890-1947) was a German-American social psychologist. Lewin's Change Theory consists of three levels: unfreezing, changing/transition, and refreezing. The *unfreezing* stage begins after the problem or the needs for change is identified. In unfreezing, "physicians and staff must be motivated to change by means of exposure to new ideas and creating a sense of urgency around the shared vision of how patient care outcomes and the work environment could be enhanced by the proposed change" (Stichler, 2011, p. 9). During the *unfreezing* stage, in this case, providers must be prepared for change by treatment of patient and partner in light of positive Ureaplasma. The *transition* or *moving* phase consists of a plan of action that is developed to engage "people to try out the proposed change"



(Shirey, 2013, p. 70). The last phase, the *refreezing* stage, consists of acceptance of change into routine practice. Lewin's model is found to be versatile, simple to implement, and easy to understand (Shirey, 2013).

Applying Lewin's Change Theory in context with the problem statement, the problem was identified within one OB/Gyn practice where providers are treating women with positive genital *Ureaplasma* inconsistently. Patients returning to the clinic with recurrent symptoms of genital *Ureaplasma* promoted the Unfreezing phase. The Transition phase may evolve over time during the Capstone project, depending on the results of the study and recommendations made by this investigator. Refreezing or acceptance of a different way of treating the patient and partner may occur if the results point to a change in routine practice of managing *Ureaplasma* infections (see Appendix B for Lewin's Theory of Change model).

### **Literature Selection/Systematic Process**

A systematic review of the literature was conducted using CINAHL, Google Scholar, PubMed, Ovid, and Sage databases between the dates of September 2018 through September 2019. The search was limited to articles dated after 2009 and publications in English language, but were from several countries including Italy, India, Brazil, Switzerland, and the United States. Exclusion criteria included articles more than 7 years old, written in language other than English, focus on pregnancy, and pediatrics. Keywords for the literature review included: Genital *Ureaplasma*, *Ureaplasma parvum*, *Ureaplasma urealyticum*, real-time PCR, antibiotic susceptibility, vaginal discharge, *Mycoplasmas*, asymptomatic infection, NGU, cervicitis, urethritis, diagnosis, management, and partner treatment. By using a combination of the keywords, the investigator found 50 articles that was later narrowed to 30 articles

pertaining to the project. In addition, the investigator selected information from the Centers for Disease Control and Prevention as well as UpToDate.

### **Scope of Evidence**

There were several types of studies used in the literature, including: quasi-experimental, systematic review, retrospective analysis, experimental, and correlational. Melnyk and Fineout-Overhalt's (2015) table was used to identify the level of evidence using four of seven levels for the 30 articles and are identified as follows:

- Level I- systematic review or meta-analysis of randomized control trials- 11 articles,
- Level II- evidence from one or more randomized control trials- 3 articles,
- Level III- controlled trial with no randomization- 12 articles, and
- Level IV- case controlled or cohort studies- 4 articles.

### **Background of Problem**

Ureaplasma is considered a normal flora residing in the respiratory and urogenital tract of humans. According to Saigal, Dhawan, Rawre, Khanna, and Chaundry (2016), approximately 60-80% of sexually active women have been exposed to genital Ureaplasma before they are 40 years old, and remain asymptomatic in both developed and developing countries. Symptomatic Ureaplasma are bacteria known to cause adverse effects in men, women, and neonates.

Combaz-Sochnchen and Kuhn (2017) found limited literature regarding women and urogenital Ureaplasma. The authors noted women experiencing chronic urinary tract symptoms, including urethritis, overactive bladder, and interstitial cystitis, should be tested by PCR assay for Ureaplasma spp.

After the investigator conducted a search for applicable research articles related to the PICO question, a systematic review of evidence table was created (see Appendix C for an example). Emerging themes from the search resulted in five categories: biology and transmission of genital *Ureaplasmas*, urethritis and cervicitis, microbiology of diagnosis and detection, antibiotic susceptibility, and clinical guidelines.

### **Review of Evidence**

#### **Systematic Review of the Literature**

**Biology and transmission of genital *Ureaplasmas*.** Genital *Ureaplasma* belong in the smallest, free-living self-replicating organisms of Mollicutes, and can also be found in the general category of genital *Mycoplasmas* (Kokkoyail & Dhawan, 2015). There are two known genital biovars, those being *Ureaplasma urealyticum* (Biovar 1) and *Ureaplasma parvum* (Biovar 2). Together, these biovars identified under the category of *Ureaplasma* species (spp.). For the purpose of the project, the investigator did not differentiate findings into the two biovars, but as *Ureaplasma* species.

*Ureaplasma* spp. is transmitted by direct host contact including genital to genital, genital to oral, as well as vertical transmission (mother to fetus), or by transplanted tissue (Waites & Bronze, 2019). Genital *Ureaplasma* is not considered a sexually transmitted infection since it is found as a normal flora in humans.

In transmission from male to female partner, men “act as asymptomatic carriers and function as reservoirs and vectors” (Silva, Cerqueira, Teixeira, Bicho, Campinha, Amorin, & Medeiros, 2018, p. 1003). *Ureaplasma* pathogens may be introduced into a healthy vagina through intercourse causing lysis of healthy *Lactobacillus*.

Neonates who are colonized with *Ureaplasma* are presumably exposed during a vaginal delivery, since colonization is less common in infants born via cesarean section (Baum, 2018). In this case, *Mycoplasmas* (*Mycoplasma* and *Ureaplasma* spp.) adhere to mucosal epithelial cells of the respiratory tract. It can disseminate to other sites when there is a disruption of the mucosa or an underlying immunity of the host, in this instance, the neonate (Baum, 2018).

**Urethritis and cervicitis.** Symptoms of urethritis or cervicitis are what often prompts the patient to seek medical care. Clinical complaints for women are abnormal vaginal discharge, pelvic pain, vaginal burning, dyspareunia, and abnormal uterine bleeding (Centers for Disease Control and Prevention, 2015). The CDC (2015) defines the symptoms of males and females as experiencing dysuria, urethral pruritus, and mucoid, mucopurulent, or purulent discharge.

Co-infections can be seen in the presence of genital *Ureaplasma*. *Ureaplasma* will thrive in a favorable pH environment, with better survival rate in the symbiotic relationship with anaerobic bacterial vaginosis (Rumyantseva, et al., 2018). Frolund et al. (2019) found bacterial vaginosis is often present in *Ureaplasma* positive samples speculating that production of urea from *Ureaplasma* increases vaginal pH, which in turn leads to an increased bacterial load of bacterial vaginosis.

The prevalence of genital *Ureaplasma* spp. suggest sexually active adults should be screened for these pathogens and condoms should be promoted. "Though coinfections were not associated with increase in severity of clinical manifestations, however, these infections could be transmitted to their partners contributing to clinical morbidity" (Saiga, Dhawan, Rawre, Khanna, Chaudhry, 2016, p. 195). If left untreated, symptomatic *Ureaplasma* spp. are

associated with pelvic inflammatory disease (PID) and infertility. Obstetric complications include chorioamnionitis, spontaneous abortion/miscarriage, stillbirth, and premature rupture of membranes (Verteramo, Patella, Calzolari, Recine, Marcone, Osborn, & Degener, 2013).

**Microbiology of diagnosis and detection.** The incubation period of genital Ureaplasmas is approximately 10-20 days (Kimberlin, Brady, & Jackson, 2018). Symptomatic genital Ureaplasma on exam and microscopically may include mucopurulent discharge, first void urine with >10 WBC's on high power field of microscopic assessment, and gram staining of >2WBC's per oil immersion field. Symptomatic cervicitis characteristics include a purulent or mucopurulent discharge visible to the examiner in the endocervical canal or on an endocervical swab specimen and a friable cervix or bleeding of the endocervix when touched with a cervical swab (Liu, Cao, Zhao, Zhao, & Huang, 2014).

Since Mollicutes lack a cell wall, the organism cannot be visualized by Gram stain. Nucleic-acid amplification tests (NAAT), including PCR and DNA chip assay, are used for detection of Mycoplasmas (Baum, 2018). Polymerase chain reaction (PCR) is the test of choice when testing for Ureaplasma due to affordability and timeliness of results. PCR testing is collected from the urethra or endocervix with a polyester or nylon tipped swab, which is then placed in the liquid transport material for laboratory assessment.

**Antibiotic susceptibility.** Four classes of antibiotics are recognized for treatment of urogenital Ureaplasma: fluoroquinolones, tetracycline, chloramphenicol, and macrolide classes (Beeton, & Spiller, 2016). Based on CDC (2015) guidelines, the first-line treatment is azithromycin 1gram or doxycycline 100mg/day for 7 days. In the United States, doxycycline is available with high antibiotic susceptibility rate at 76%, whereas ciprofloxacin showed resistance to Ureaplasma at 82% (Kasprzykowska, et al., 2017). Other susceptible antibiotics

to *Ureaplasma* available in the U.S. are minocycline with 74.7% susceptibility and clindamycin with 74% susceptibility. Diaz, et al., (2015) found a high resistance against fluoroquinolones due to their overuse for treatment of urinary tract infections and upper respiratory infections. The number of therapeutic options are limited in pregnancy and neonates' due to the accumulation of tetracycline in developing bones. During pregnancy, azithromycin 1 gram for a single dose is preferred. Erythromycin can also be administered with a 42% susceptibility rate. (Al-Khadfaji, 2017).

**Clinical guidelines and recommendations.** Initiating treatment of *Ureaplasma* spp. infection is imperative to prevent occurrences of potential future complications. There are inconsistent partner treatment guidelines found between countries, without any substantial empirical data to inform treatment decision (Ong, et al., 2017). The recommendations in the United States for treatment of *Ureaplasma* is found through the CDC. For treatment of non-gonococcal urethritis or cervicitis, the Centers for Disease Control and Prevention currently recommends azithromycin, 1g orally in a single dose or doxycycline, 100mg twice a day for 7 days (Terris & Kim, 2018). This recommendation reflects all genital pathogens and is not exclusive to *Ureaplasma* spp.

Waites and Bronze (2019) states "successful treatment hinges on promptly considering *Mycoplasma* and *Ureaplasma* species as potential etiologic agents, performing proper diagnostic tests for their detection, and providing appropriate antimicrobial coverage" (p. 8). *Ureaplasma* spp. are opportunistic organisms that may be present simultaneously with other pathogens, such as bacterial vaginosis. Treatment decisions should reflect this.

The literature review supported the investigator's PICO question of antibiotic treatment options and provides guidelines on treating both partners for symptomatic genital

Ureaplasma. With risk factors of untreated Ureaplasma, including infertility in women at 21-32%, pregnancy risks, and PID, it is important to consider proper antibiotic treatment (Tandon, Munne, Chauhan, & Patil, 2019). By providing a quality initiative, supported by the literature, the project may increase provider knowledge at the obstetric/gynecologic practice site for the capstone project.

### **Market Risk Analysis**

#### **SWOT Analysis**

To perform an analysis of the market where the capstone project was completed, a SWOT Analysis was conducted identifying the Strengths, Weaknesses, Opportunities, and Threats (See Appendix D). There were a number of *strengths* identified for this project, including evidenced based practice and guidelines as reviewed in the systematic review of literature. Nucleic Acid Amplification Tests (NAAT) are readily available in the clinical setting, and there was clinical support from providers for a quality initiative project.

The investigator identified *weaknesses* to the project as well. One of the hurdles encountered was the investigator was no longer employed at the site the capstone project was to take place. This led to early written approval of a letter of intent submitted to the health care corporation for review. The site is now a midwife only practice; however, they are able to provide obstetrical and gynecologic care at the capstone site. Another weakness identified was potential resistance to change provider practice of treatment of genital Ureaplasma. The final weakness identified was data collection being limited to one area located in the metro-Denver area.

The project allowed for recognition and staff development *opportunity* to providers in the clinical site by providing an evidenced based literature review and guidelines, as well as

acknowledging an easily identified microorganism through NAAT collection to prevent future obstetrical and gynecologic morbidities. This can decrease the overall cost to health insurance companies and the patient by providing early detection and treatment, rather than the costliness of such morbidities such as PID.

There were three *threats* identified to the project. The first threat is the current unstable state of the corporate run clinic that was dismantled within a 6-week period, laying off two physicians and 4 nurse practitioners, and closing two of the three locations. This also led to the second threat of the current office being short-staffed, therefore, all remaining providers may not be able to attend the QI presentation due to days off and call schedule. This may result in providers continuing to practice with inconsistent treatment measures. The final threat was COVID-19, which delayed collection of the data due to the reduction of work hours for both the biller printing out the patients fitting the ICD-10 parameters, as well as the clinical mentor collecting the data.

### **Driving and Restraining Forces**

The *driving force* behind the capstone project was the rate of recurrent vaginal infections, intermenstrual bleeding, and pelvic pain that was seen when *Ureaplasma* was positively identified on NAAT. The investigator began to notice a pattern of antibiotic treatment of the patient versus treatment of the patient and the partner. Associated cost with the return office visits was also a driving force for the project. At this time, the PICO question was formed and the QI was developed in order to increase staff knowledge of symptoms associated with *Ureaplasma*, testing method, antibiotic susceptibility, and guidelines.



One of the *restraining forces* noted by the investigator was possible lack of provider knowledge of providers on Ureaplasma treatment guidelines. This may lead into a second restraining force of resistance to change their practice, even with evidence supported by the literature review. A third restraining force was lack of time in the providers schedule for the investigator to present the findings to the group during a single session. The presentation may have to take place on the provider's day off, which the provider may not agree to attend the presentation.

### **Needs, Resources and Sustainability**

**Needs.** The need for the capstone project was first identified in the clinic setting by the investigator and another nurse practitioner within in the clinic, with a combined experience as advanced nurse practitioners of 50 years. As testing for genital Ureaplasma became widely available, pathologists from Metropolitan Pathologists would attend "lunch and learn" sessions educating the available clinicians on the collection process for genital Ureaplasma, reporting sheets, and treatment options. Not all clinicians attended the sessions, while other clinics within the practice did not desire a pathologist to discuss any new testing options. In time, the two experienced nurse practitioners noticed treatment differences between clinicians as patients returned to the clinic for recurrent vaginitis symptoms. The investigator began looking into available treatment guidelines, which was reviewed in the literature review.

Due to the prevalence of recurrent genital Ureaplasma symptoms and inconsistent antibiotic treatment, there was a need to implement an educational intervention for clinicians within the practice.

**Resources.** The resources needed to complete the project were minimal. NAAT testing through PCR, including through NuSwab and Thinprep, are available at no cost to the clinic or patient. Personnel used for the project included the Capstone Chair, clinical mentor, HCA contract administrator and security officer, and investigator. The clinical mentor collected data for the project during her time away from work and had agreed to assist in the project free of cost. The electronic medical record (EMR) system, Electronic Clinical Works, is already used nationally through the HCA system. See Appendix E for the cost to replicate the study.

**Sustainability.** A *sustaining force* the investigator planned on implementing was an evidenced-based practice guideline for the chosen clinic based on project findings, as well as existing guidelines from the CDC. In order to accomplish this, the investigator used a Power Point Presentation to educate the providers on guidelines and findings. The investigator also included laboratory testing that was readily available (NAAT testing through ThinPrep and NuSwab) to the provider that already exists in the clinical setting as well as the appointed laboratory used (LabCorp).

### **Feasibility/Risks/Unintended Consequences**

**Feasibility.** The implementation of the evidence-based project was feasible at HCA Mountain Vista Midwifery due to the former connection the investigator had as an employee for several years at the mentioned site. The investigator maintained a positive relationship with the management team, as well as the providers when exiting the practice. The availability of the existing positive standing between the investigator and mentor and the resources available, made this capstone project feasible.

**Risks.** There was no risk of harm to human subjects or animals with this quality improvement (QI) project. The project only collected information that was recorded in the electronic health record and was given to the investigator by the mentor using aggregated data. The consent was waived, as the waiver will not adversely affect the rights and/or welfare of the subjects. The intention of this QI project was to explore best practice for consistency in antibiotic treatment in patients with positive genital *Ureaplasma* on genital culture to promote health of the patient.

**Unintended Consequences.** The investigator did not have control of the antibiotic that was prescribed to patients by other providers in the clinic. The investigator also had no control of whether the patient or patient and partner was compliant and completed the course of antibiotic therapy prescribed. Other unintended consequences are discussed later in this paper under findings.

### **Stakeholders and Project Team**

The stakeholders that benefited from the capstone project included the health corporation that owns the clinic used for the project, providers, patients, their partners, and the community. The investigator discussed the plan via email for this project with the stakeholders/health corporation (see Appendix F, Letter of Intent) and worked closely with the HCA contracts coordinator to obtain site approval for conducting the project.

The project team included the Regis University faculty project chair, the Regis University DNP student (investigator), and the capstone clinical mentor.

### **Cost-Benefit Analysis**

A retrospective data analysis was used, and therefore, data was readily available at no cost to the investigator. Charts were readily available to the clinical mentor who assisted in

gathering data for compliance with HIPAA. The clinical mentor agreed to review patient charts on her time away from the work place.

The cost that was incurred for the patient who is seen in the clinic for symptoms of vaginitis, pelvic pain, dyspareunia, and intermenstrual bleeding, and/or history of Ureaplasma was charged a co-payment, which usually ranges from \$2.00-\$50.00. The insurance is billed a CPT charge at a 99203 (new patient with a detailed history, detailed exam, and low complexity decision making) or 99213 (existing patient with a detailed history, detailed exam, and low complexity decision making). The reimbursement from a 99203 and 99213 visit is \$109.46 and \$72.70 (E/M University, 2017). The transport media used through LabCorp was free of charge to the clinic. The cost of running the testing for genital Ureaplasma and Mycoplasma is \$122.75 through LabCorp. The out of pocket cost of oral doxycycline 100mg twice a day for 7 days is \$7.68-\$14.17 when using the GoodRx phone application (2019). For the uninsured patient, the total cost to the patient is estimated at \$203.13 for an existing patient and \$239.89 for a new patient.

In comparison, the average cost of treatment for pelvic inflammatory disease per the CDC (2017) is \$3,202. Since PID can lead to future complication, such as an increased risk of ectopic pregnancy and infertility, the cost of untreated genital Ureaplasma can be an economic burden to the patient.

### **Project Objectives**

#### **Mission and Vision**

The mission was an evidenced based project to determine if there was a relationship between antibiotic treatment differences and recurrence of symptomatic Ureaplasma. By determining a relationship between antibiotic treatment of the female patient and their

partner, it allowed the primary researcher to identify patients at risk and prevent further disease by proper treatment. The investigator's vision was to have a standardized testing and treatment for patients with a positive genital *Ureaplasma* spp. culture.

### **Goals**

The goal of this project was to determine whether the relationship between treatment differences and recurrence of symptomatic genital *Ureaplasma* was statistically significant. Another goal was to explore the recommendations of evidenced-based guidelines related to urethritis and cervicitis caused by *Ureaplasma*.

### **Process/Outcome Objectives**

The focused outcome objective for this project was to perform a retrospective chart review for patients seen in the clinic from 2018 through 2019, in order to measure rates of symptomatic recurrence of genital *Ureaplasma* in the intervention (treating patient and partner with antibiotic therapy) and comparison groups (treating the patient alone). This time period was selected to give data for a one-year period, in addition to a three-month time period for recurring symptoms. The investigator followed a specific project timeline, shown in Appendix G, to achieve completion of the project.

### **Logic Model**

A logic model template adapted from Zaccagnini & White (2017) was used to outline the target short-term and long-term goals and benchmarks for the investigator (see Appendix H). The first step on of the conceptual model, was to establish a close working relationship with the DNP clinical mentor and the DNP project chair at Regis University. Developing a relationship helped the investigator identify and implement an achievable outline for the

project. The Logic Model also helped the investigator determine activities to conduct the project with expected outputs.

### **Methodology and Evaluation**

#### **QI Project Study Design**

The capstone quality improvement initiative required the investigator to use a non-experimental quantitative study design using a retrospective chart review. Using a retrospective chart review for the project allowed the investigator to have quick and readily available access to patient records, allowing less loss of follow up of recurrent symptoms (Nickson, 2019). Other advantages of using RCR include providing a cost-effective and efficient means to collect (Gregory & Radovinsky, 2012). Disadvantages of a retrospective chart review included inconsistent and incomplete or missing entry in the EMR and using a convenience sample may not be representative of the general population (Gregory & Radovinsky, 2012)

The independent variables of the project identified were 1) antibiotic treatment of the patient and partner and 2) antibiotic treatment of the patient alone with doxycycline, azithromycin, or “other” antibiotic. The dependent variable or outcome was a decrease in the incidence of symptomatic recurrence as measured by the difference in means between the two groups (patient treated alone versus treatment of patient and partner). Dependent variables were identified by 1) test of cure results when both patient or patient and partner are treated with antibiotics or 2) resolution of symptoms measured by no return clinical visit for symptoms within a 3-month time period.

Extraneous variables that the researcher encountered was lack of patient follow up for a test of cure, co-infections, treating provider that is treating the patient and the choice of

antibiotics, patient compliance in completing the antibiotic regime, and form of contraception.

### **Data Collection and Treatment Procedure**

The primary investigator followed the steps below when conducting the retrospective chart review:

- 1) Obtained approval to conduct QI project from Regis University IRB after submitting *QI Checklist and Summary* as well as approval from HCA (for example contracts personnel, IT security officer).
- 2) The primary investigator was responsible for overseeing data collection by providing ICD-10 codes to the clinical mentor to identify patients with positive genital Ureaplasma. The clinical mentor was the only one that collected data from the clinic patient EHRs.
  - a. Identified ICD-10 codes of symptomatic signs of genital Ureaplasma in female patients.
  - b. Collected NAAT testing results for genital Ureaplasma spp.
  - c. Identified treatment of patient (comparison) versus treatment of patient and partner (intervention).
  - d. Identified patients that returned for recurrent symptoms of genital Ureaplasma in a three-month time period or returned for a test of cure after treatment.
  - e. Identified which antibiotic was used for treatment.
- 3) Measured the difference between patients that were treated with antibiotics alone versus the treatment of the patient and partner.
- 4) Shared results of QI project with stakeholders (obstetric/gynecologic providers) after the DNP project defense.

**Population and Sampling Parameters**

The sample population used for the capstone project included a convenience sample of a total of 128 subjects where only the patient was treated with antibiotics or the patient and partner were treated with antibiotics between 2018 and 2019. The sampling size was calculated using the G\*Power software (Department of Psychology, 2019) with the alpha of 0.05 and power of 0.80.

The investigator used ICD-10 codes to identify patients that had been seen for possible genital Ureaplasma. The ICD-10 codes that were used are: N76.1 (chronic vaginitis), R01.2 (pelvic pain), N89.8 (Other specified non-inflammatory disorders of vagina), N93.9 (abnormal uterine and vaginal bleeding), and N94.1 (dyspareunia) (ICD.codes, 2020). Inclusion criteria were: the patient will have a positive PCR testing for Ureaplasma species, regardless of co-infections, as well as antibiotic treatment, including azithromycin, doxycycline, and clindamycin. Exclusion criteria included subject's having an IUD in place and not having a current partner for treatment. The reasoning for the exclusion is to eliminate the variable of a new partner within the 3-month time frame and the lack of comparison of patient and partner treatment versus patient treatment only with the same sexual partner. The reason for excluding patients with IUD's is antibiotics cannot penetrate non-living tissue/devices, therefore Ureaplasma can continue to inhabit the IUD device causing recurrence of Ureaplasma. Pregnant women are considered a vulnerable population; therefore, they were excluded from the project.

**Setting**

The setting for the capstone project was a three clinic, corporate owned obstetrics and gynecology office located in three cities in the metro-Denver area. During the period of time



that will be used for the retrospective chart review, there were thirteen providers (six physicians, three midwives, and four nurse practitioners. An estimated 1,500-2,000 patient visits were documented per month in all three offices.

The site since downsized to a midwife clinic with three full-time and one part-time certified nurse midwives. Currently, there are approximately 300-400 patient visits per month. The current location, located in Englewood, Colorado, consist of a main medical office, as well as a procedure office where ultrasound and colposcopy is performed. The main office has six exam rooms and two rooms used for fetal monitoring.

### **Study Instrument: Description, Validity and Reliability**

Reliability and validity were essential to validate the project. The data collection tool consisted of the Hologic Aptima Mycoplasma genitalium Assay. The Hologic website defines the Aptima Mycoplasma genitalium assay as an in-vitro nucleic acid amplification test (NAAT) used as the detection of ribosomal RNA (rRNA) from Mycoplasma and Ureaplasma species (Hologic, 2016). The test is able to categorize the microorganisms into *M. hominis*, *M. genitalium*, *Ureaplasma urealyticum*, and *Ureaplasma parvum*. The test results are automatically interpreted by the Panther system Aptima Mycoplasma genitalium Assay software. The software does not quantify the amount of the microorganism present, but provides a qualitative measure (presence of genital Ureaplasma per microscopic field) of genital Ureaplasma found on the vaginal or endocervical culture. Control testing is run to establish validity by completion of an assay calibration, which is valid for up to 48 hours. Per Hologic (2016), “one positive calibrator tube and one negative calibrator tube are run in duplicate each time a reagent kit is loaded on the Panther system. Software on the Panther system alerts the operator when a new calibrator set is required” (p. 17).

The data collection tool utilized in this study was created by the investigator and content validity was assessed by the clinical mentor. A detailed data dictionary, found in Appendix I, defines each datum that will be collected from the EMR. This dictionary served as a guide for the chart reviewer to use when using the data collection tool (see Appendix J). The investigator used numbers 1-128 to identify participants. The PCR testing, collected from NuSwab and ThinPrep media was sent to LabCorp for positive identification of Ureaplasma species. Also included on the data table are descriptions for presenting symptoms using select ICD-10 codes, treatment of partner.

### **Protection of Human Subjects**

Before seeking approval from the IRB from Regis University, the investigator completed the Collaborative Institutional Training Initiative (CITI) courses (Certificate # 34972066) to ensure participants safety (see Appendix K). A letter of intent was submitted by the investigator and was granted approval by HCA Healthcare on March 27, 2020 (see Appendix L, HCA Approval Email).

The primary investigator was responsible for maintaining integrity of the project and patient confidentiality. There were minimal to no risk to the patient because the data was gathered from existing medical records following the treatment of genital Ureaplasma. In order to maintain patient confidentiality, the clinical mentor collected data by using ICD-10 codes and patient identifiers such as name, date of birth (DOB), address, or medical record number were not included in the data collection process. The clinical mentor already had HCA's permission for remote secure access to the electronic medical records outside of work hours (see Appendix M, Data Use Agreement). The clinical mentor collected data over a four-week time period. The de-identified data was delivered to the primary investigator via

the secure Regis University email system. Once all information was gathered, the investigator organized the results on a Microsoft Excel spreadsheet.

The results were reported as de-identified, aggregate data. The clinical mentor and the investigator have been in the medical field over 20 years and stayed within compliance of the Health Insurance and Portability Accountability Act (U.S. Department of Health and Human Services, 2015).

The investigator sought approval for the QI project with assistance from the Capstone Chair. The investigator was granted approval to conduct the project as non-research (QI) from the IRB on April 16, 2020 (see Appendix N, IRB Net Board Action Email).

### **Data Collection and Statistical Test**

The investigator used percentage change as the descriptive analysis for the Capstone project. Percentage change is a mathematical calculation determining the percentage difference between two scores. The statistical tool was chosen to specifically measure the percentage difference between Group A: Ureaplasma positive patient alone was treated with antibiotic therapy and Group B: Ureaplasma positive patient and partner was treated with antibiotic therapy. The investigator also used Kendall's tau as the inferential statistic. Kendall's tau is a nonparametric, inferential test measuring the correlation between two variables (Polit, 2010).

There were two levels of data used in the project. Nominal data is the lowest form of measurement and can be divided into categories (Polit, 2010). Identified nominal data were the antibiotic prescribed to the patient and test of cure findings. The other level of data used for the project was ordinal data, which classifies variables relative to the dimension of

interest (Polit, 2010). Ordinal data identified were partner treatment with antibiotics and recurrence of symptoms.

### **Project Findings**

The investigator asked the clinical mentor to collect data by using a retrospective chart review from 2018 through 2019 using a convenience sample of 128 subjects that were seen in the clinical setting with positive genital *Ureaplasma* cultures.

The results of the data led the investigator to address the PICO statement. In addition, the investigator unintentionally identified the recurrence of genital *Ureaplasma* with and without partner treatment and comparing azithromycin, doxycycline, and clindamycin.

### **Project Objective**

The primary objective identified was to assess the rate of symptomatic recurrence of genital *Ureaplasma* in the intervention (treating patient and partner with antibiotic therapy) and comparison groups (treating the patient alone).

### **Statistical Data**

Pie charts were used to represent the number of cases where the partner was treated with antibiotic therapy, antibiotic prescribed, and symptoms of recurrence (Figure 1).

The first pie chart represents whether the patient's partner was treated (n=59, 47%) or not treated (n=69, 53%) with antibiotics.

The second pie chart identifies the percentage rate of antibiotics prescribed for the patient. Doxycycline was prescribed the most out of all the antibiotics, where n=116, 91%. Followed by azithromycin (n=9, 7%). Lastly is clindamycin, where it was prescribed to three subjects (2%).

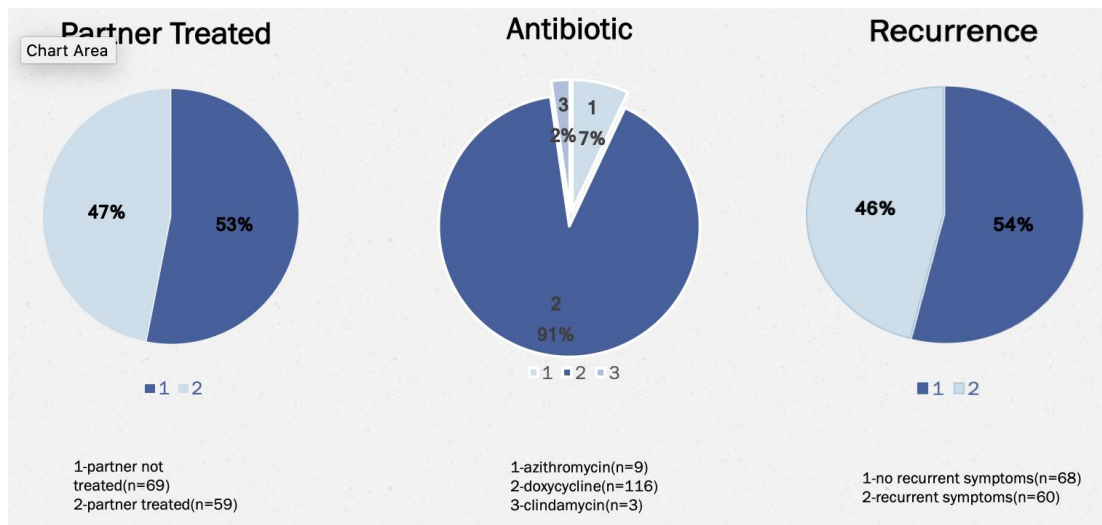
The last pie chart shows the rate of patient recurrence of symptomatic genital

Ureaplasma after initial treatment. Recurrence rate in a three-month period was 46% (n=60).

The rate of lack of symptoms occurred in 54% (n=60) of the subjects identified.

*Figure 1*

*Statistical Pie Charts*



All raw data was converted from a “yes/no” format to a numerical format in order to use SPSS for this project. When running the data “1” equates to “no,” which included the partner not being treated with an antibiotic and recurrence in a three-month timeframe. The number “2” identified partner treatment and recurrence of symptoms.

Test of cure (TOC) was labelled as:

0=TOC not done

1=TOC with negative result

2=TOC with positive result

The investigator did collect the data for TOC; however, the investigator did not analyze data pertaining to this variable as it was not seen as a factor in the recurrence of symptomatic genital Ureaplasma.

## Results

The interpretation of the table below recognizes the frequency of recurrent symptoms of the patient. In “1” (partner not treated), 53.9% of patients returned for recurrent symptoms if their partner was not treated for genital Ureaplasma. In “2,” 46.1% of the patients did not return in a three-month period of time for recurrent symptoms. Using the percentage change equation, the difference between the two scores is 14.47% (Table 1).

Table 1

### *Partner Treatment and Recurrence Rate*

		Recurrence			Cumulative
		Frequency	Percent	Valid Percent	Percent
Valid	1	69	53.9	53.9	53.9
	2	59	46.1	46.1	100.0
	Total	128	100.0	100.0	

Percentage:  $(46.1 - 53.9 / 53.9) * 100 = 14.47\%$

Using Kendall’s tau to measure correlation, the investigator found that there was no statistical difference whether the patient’s partner was or was not treated with antibiotic therapy and recurrence of symptoms with  $p < 0.05$  (Table 2).

Table 2

### *Kendall’s Tau*

Kendall’s Tau (Sig. 2-tailed)	Antibiotic	Partner Treated	TOC	Recurrence
Antibiotic	.	.292	.862	.190
Partner Treated	.292	.	.547	.816
TOC	.862	.547	.	.520
Recurrence	.190	.816	.520	.

Further data was run using SPSS for nominal and ordinal levels of collected.

Unintentional findings of antibiotic effectiveness of patient treatment versus patient and partner treatment were analyzed as the investigator and statistical mentor used the percentage change (see Table 3).

Using the percentage change mathematical equation, the investigator found that when the patient was treated with azithromycin (n=9) and the partner was not treated, there was a 50.07% recurrence rate of symptomatic Ureaplasma. The exact same percentage of the recurrence rate applies if both the patient and partner were treated with azithromycin,

If the patient was treated with doxycycline (n=116), and the partner was not treated with antibiotics, the rate of recurrent symptoms was 20.47%. If both the patient and the partner were treated with doxycycline, the rate of symptomatic recurrence drops to 16.59% (Table 3).

Only three patients received Clindamycin and all three patients had a symptomatic recurrence regardless if the partner was treated or not. Comparing the antibiotic treatment, the results show the antibiotic of choice at this obstetric-gynecological practice was doxycycline for symptomatic genital Ureaplasma, with azithromycin as a secondary choice. The findings support the recommendations from the CDC and UpToDate.

Table 3

*Evaluating Partner Treatment, Antibiotic, and Recurrence*

Partner Treated(1=not treated;2=treated)	Antibiotic(1=azith; 2=doxy; 3=clinda)	Recurrence(1=no; 2=yes)	Frequency	Percent	Percentage Change
1-Partner not treated	1-Azithromycin	1	2	33.3	
1-Partner not treated	1-Azithromycin	2	4	66.7	50.07
1-Partner not treated	2-Doxycycline	1	34	55.7	
1-Partner not treated	2-Doxycycline	2	27	44.3	20.47
1-Partner not treated	3-Clindamycin	2	1	100	N/A
2-Partner treated	1-Azithromycin	1	1	33.3	
2-Partner treated	1-Azithromycin	2	2	66.7	50.07
2-Partner treated	2-Doxycycline	1	30	54.5	
2-Partner treated	2-Doxycycline	2	25	45.5	16.59
2-Partner treated	3-Clindamycin	1	1	100	N/A

**Limitations, Recommendations, and Implications****Limitations**

Limitations of this study included a small sample size and a single area in Colorado, therefore the findings cannot be applied to the general population. Another limitation noted are the number of subjects that were prescribed doxycycline were at a higher rate than azithromycin and clindamycin. A third limitation identified is the lack of interrater reliability with the collection tool. Lastly, the project did not include pregnant women or include contraception measures. In the clinical setting, it was noted that women with IUD's had recurrent symptoms of genital Ureaplasma whether the partner was treated or not treated with antibiotics.

**Recommendations**

The investigator recommends using a larger sample size to test for statistical significance of the treatment of the partner for genital Ureaplasma as per the current CDC



guidelines. The investigator also recommends a follow-up project to assess the use of doxycycline only to identify recurrence rate with the larger sample size. Lastly, the investigator recommends a project addressing IUD's and recurrence of genital Mycoplasma. Polymer implants have been associated with infections resulting from bacteria and biofilm adhesion to an implant surface. Ribeiro et al., 2012 noted that once biofilm bacteria inhabit the implant, there is a high resistance to conventional antibiotics therapy.

### **Implications**

While this study did not generate new phenomenon, the antibiotic findings were consistent with CDC guidelines. It appears that doxycycline has a higher success rate for treatment of genital Ureaplasma.

The results showed there was not a statistical improvement of recurrence of genital Ureaplasma, however; there was improvement of 14.47% between patient partner versus patient and partner treatment. Therefore, even though not statistically significant, consideration to clinical significance when looking at percent change can be significant in terms of cost and quality of life to the patient. When presenting to the stakeholders, the investigator will recommend a trial study in which both patient and partner are treated with antibiotic therapy and analyze the results using the percentage differences to identify if there is a further decrease in recurrence.

### **Summary**

The proposed quality improvement project is specific to three metro-Denver area outpatient obstetrics and gynecology offices owned by a national corporation. The investigator explored the use of evidence-based guidelines related to treatment of female

patients with a positive genital Ureaplasma culture identified by PCR testing, with and without partner treatment.

The investigator addressed the PICO question for this project by using a retrospective chart review and a percentage difference for descriptive analysis. Even though the investigator did not find statistical significance between patient and patient and partner antibiotic treatment and recurrent Ureaplasma, the investigator observed a possible relationship between recurrent symptoms and the prescribed antibiotic. Further studies would be indicated based on the clinical considerations to the patient's quality of life and partner treatment for symptomatic genital Ureaplasma. The clinical importance of the study, though not statistically significant, support the CDC guidelines of patient treatment of genital Ureaplasma with doxycycline or azithromycin, as well as partner treatment.

## References

- Al-Khadfaji, G. K. (2017). Susceptibility and antimicrobial resistance of genital *Ureaplasma parvum*. *Journal of Nano Biomedicine and Engineering*, 9(3), 236-241.
- American Association of the College of Nursing. (2006). *DNP essentials*. Retrieved from <https://www.aacnnursing.org/dnp/dnp-essentials>
- Baum (2018). *Mycoplasma hominis* and *Ureaplasma urealyticum* infections. *UpToDate*. Retrieved from <https://www.uptodate.com/contents/mycoplasma-hominis-and-ureaplasma-infections/print>
- Beeton, M. L., & Spiller, O. B. (2016). October Antibiotic resistance among *Ureaplasma* spp. Isolates: Cause for concern? *Journal of Antimicrobial Chemotherapy*, 72, 330-337.
- Betty Neuman (2010). Retrieved from [http://www.nurses.info/nursing\\_theory\\_person\\_neuman\\_betty.htm](http://www.nurses.info/nursing_theory_person_neuman_betty.htm)
- Centers for Disease Control and Prevention. (2015). *Diseases characterized by urethritis and cervicitis*. Retrieved from <https://www.cdc.gov/std/tg2015/urethritis-and-cervicitis.htm>
- Centers for Disease Control and Prevention. (2017). *Pelvic inflammatory disease*. Retrieved from <https://www.cdc.gov/std/pid/stdfact-pid-detailed.htm>
- Combaz-Sochnchen, N. & Kuhn, A. (2017). *A systematic review of Mycoplasma and Ureaplasma in urogynaecology*. *Guburtshilfe und Frauenheilkunde*, 77(12), 1299-1303.
- Department of Psychology. (2019). G\*Power (version 3.1.9.4). Retrieved from [https://download.cnet.com/G-Power/3000-2054\\_4-10647044.html#full-specs](https://download.cnet.com/G-Power/3000-2054_4-10647044.html#full-specs)
- Diaz, L., Carberra, L. E., Fernandez, T., Ibanez, I., Torrez, Y, Obregon, Y., & Rivero, Y.

- (2013). Frequency and antimicrobial sensitivity of ureaplasma urealyticum and mycoplasma hominis in patients with vaginal discharge. *MEDICC Review*, 15(4), p. 45-47.
- E/M University. (2020). *Level 3 new office visit*. Retrieved from <https://emuniversity.com/Level3NewOfficePatient.html>
- Flaherty, K. M. (2017). *Neuman systems model in nursing practice*. Retrieved from <https://nursekey.com/neuman-systems-model-in-nursing-practice/>
- Frolund, M., Falk, L., Ahrens, P., Jensen, J. S. (2019, April) Detection of Ureaplasmas and bacterial vaginosis associated bacteria and their association with non-gonococcal urethritis in men. *Public Library of Science*, 1-13.
- GoodRx. (2019). Good Rx-Save on Prescriptions (Version 5.5.1). Retrieved from <http://itunes.apple.com>
- Hologic. (2016). Aptima Mycoplasma genitalium assay. Retrieved from [https://www.hologic.com/sites/default/files/2019-07/AW-17946\\_002\\_01.pdf](https://www.hologic.com/sites/default/files/2019-07/AW-17946_002_01.pdf)
- Houser, J., & Oman, K. S. (2011). *Evidenced-based practice: An implementation guide to healthcare organizations*. Sudbury, MA: Johns & Bartlett.
- ICD.codes. (2020). *ICD-10-CM*. Retrieved from <https://icd.codes/>
- Kasprzykowska, U., Sobieszczanska, B., Duda-Madej, A., Secewicz, A., Nowicka, J., Gosciniak, G. (2017). Colonization of lower urogenital tract with Ureaplasma parvum can cause asymptomatic infection of the upper reproductive system in women: a preliminary study. *Archives of Gynecology and Obstetrics*, 289, 1129-1134.

- Gregory, K. E. & Radovinsky, L. (2012). Research strategies that result in optimal data collection from the patient medical record. *Applied Nursing Research*, 25 (2), 108-116.
- Kimberlin, D. W., Brady, M. T., & Jackson, M. A. (2018). *Red book: 2018-2021 report of the committee of infectious disease*. (31st ed). Itasca, IL: American Academy of Pediatrics.
- Kokkayil, P. & Dhawan, B. (2015). Ureaplasma: Current perspectives. *Indian Journal of Medical Microbiology*, 33(2), 205-214.
- Leli, C., Mencacci, A., Latino, M. A., Clerici, P., Rassu, M., Perito, S., Pistoni, R., Luciano, E., De Maria, E., Morazzoni, M., Pascarella, S., Bozza, M., & Sensini, A. (2018). Prevalence of cervical colonization by Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis and Mycoplasma genitalium in childbearing age women by a commercially available multiplex real-time PCR: An Italian observational multicentre study.
- Liu, L., Cao, G., Zhao, Z., Zhao, F., & Huang, Y. (2014). High bacterial loads of Ureaplasma may be associated with non-specific cervicitis. *Scandinavian Journal of Infectious Disease*, 46, 637-641. *Journal of Microbiology, Immunology, and Infection*, 51, 220-225.
- Melnyk, B.M. & Fineout-Overholt, E. (2015). "Box 1.3: Rating system for the hierarchy of evidence for intervention/treatment questions" in *Evidence-based practice in nursing & healthcare: A guide to best practice (3rd ed.)* (pp. 11). Philadelphia, PA: Wolters Kluwer Health.
- Ong, J. J., Saumpaet, A., Chow, E. P., Bradshaw, C., Chen, M., Read, T., Fairley, C. K.

- (2017). Should female partners of men with non-gonococcal urethritis, negative for Chlamydia trachomatis and Mycoplasma genitalium, be informed and treated? Clinical outcomes from a partner study of heterosexual men with NGU. *Sexually Transmitted Diseases*, 44(2), 126-130
- Polit, D. F. (2010). *Statistics and data analysis for nursing research*. (2<sup>nd</sup> ed.). Pearson.
- Riberio, M., Monteiro, F. J., & Ferraz, M. P. (2012). Infection of orthopedic implants with emphasis on bacterial adhesion process and techniques used in studying bacterial-material interactions. *Biomatter*, 2(4), 176-194.
- Rumyantseva, T., Khayrullina, G., Guschin, A., & Donders, G. (2018). Prevalence of Ureaplasma spp. and Mycoplasma hominis in healthy women and patients with flora alterations. *Diagnostic Microbiology & Infectious Disease*, 93(3), 227-231.
- Saigal, K., Dhawan, B., Rawre, J., Khanna, N., Chaudhry, R. (2016). Genital Mycoplasma and Chlamydia trachomatis infections in patients with genital tract infections attending a tertiary care hospital of North India. *Indian Journal of Pathology and Microbiology*, 59(2), 194-196.
- Schneider, S. C., Tinguely, R., Droz, S., Hilty, M., Dona, V., Bodmer, T., & Endimiani, A. (2015, October). Antibiotic susceptibility and sequence type distribution of Ureaplasma species isolated from genital samples in Switzerland. *Antimicrobial Agents and Chemotherapy*, 59(10), 6026-6031.
- Shirey, M. R. (2013). Lewin's theory of planned change as a strategic resource. *Strategic Leadership for Organizational Change*, 43(2), p. 69-72.
- Silva, J., Cerqueira, F., Teixeira, A. L., Bicho, M. C., Campinha, R., Amorin, J., and

- Medeiros, R. (2018). Genital mycoplasmas and ureaplasmas in cervicovaginal self-collected samples of reproductive-age women: prevalence and risk factors. *Internal Journal of STD's & AIDS*, 29(10), 999-1006.
- Stichler, J. F. (2011). Adapting to change. *Health Environments Research & Design Journal*, 4(4), 8-11.
- Tandon, D., Munne, K., Chauhan, S., & Patil, A. D. (2019). An update on prevalence, diagnosis, treatment and emerging issues of genital mycoplasma infection in Indian women: A narrative review. *Indian Journal of Dermatology, Venereology and Leprology*, 85(5), 441-447.
- Ume-Nwagbo, P. N., Dewan, S. A., & Lowry, L. W. (2006). Using the Neuman systems model for best practices. *Nursing Science Quarterly*, 19(1), p. 31-35.
- University of Wisconsin-Madison. (2016). *Division of business services*. Retrieved from <https://www.bussvc.wisc.edu/purch/contract/wp5555.html>
- U.S. Department of Health and Human Services. (2015). *The HIPAA privacy rule*. Retrieved from <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>
- Verteramo, R., Patella, A., Calzolari, E., Recine, N., Marcone, V., Osborn, J., and Degener, A.M. (2013). An epidemiological survey and Mycoplasma hominis and Ureaplasma urealyticum in gynaecological outpatients, Rome, Italy. *Epidemiology and Infection*, 141(12), 2650-2657.
- Waites, K. B. & Bronze, M.S. (2019, July). Ureaplasma infection. *Medscape*. Retrieved from <https://emedicine.medscape.com/article/231470-overview>
- Wojciechowski, E., Pearsall, T., Murphy, P., & French, E. (2016). A case review: Integrating Lewin's theory with lean's system approach for change. *The*

*Online Journal of Issues in Nursing*, 21(2). Retrieved

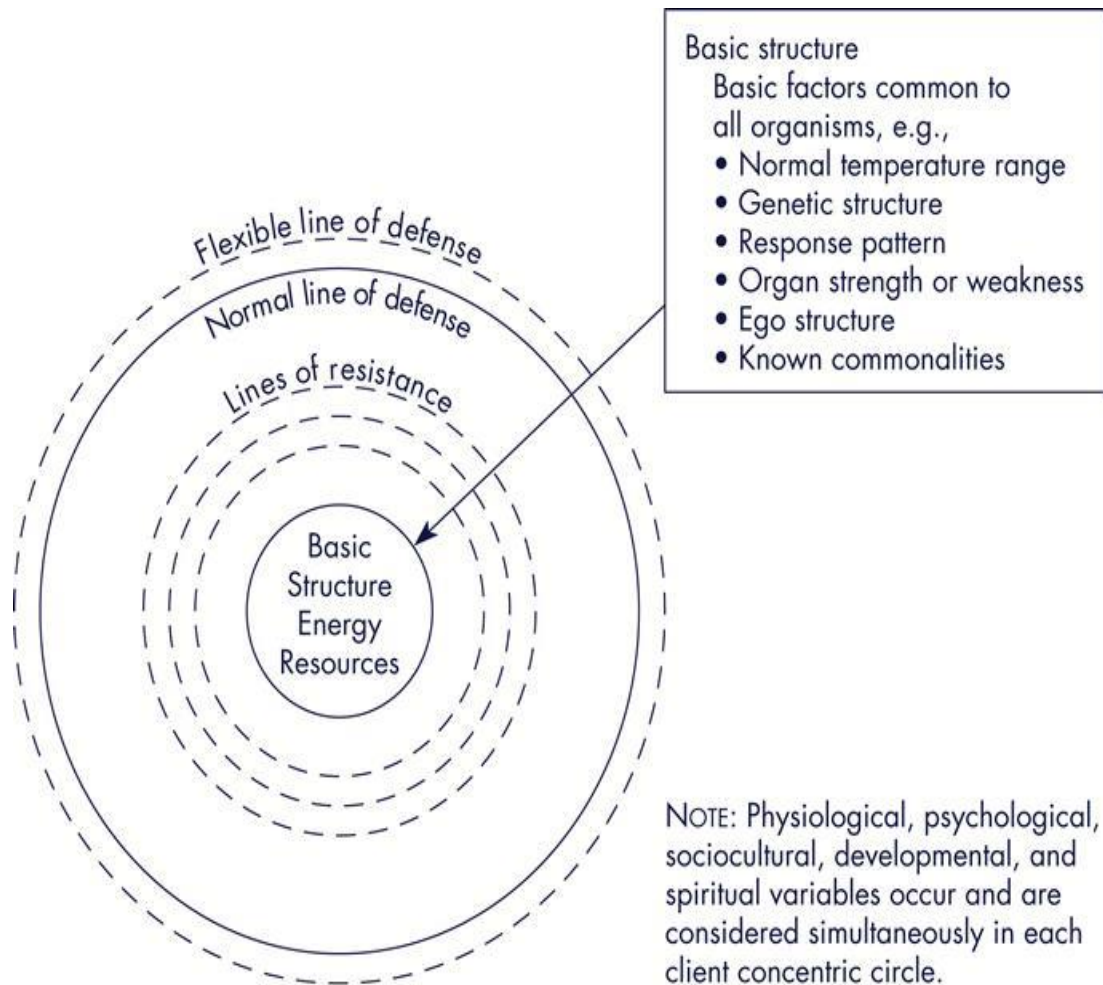
from <https://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-21-2016/No2-May-2016/Integrating-Lewins-Theory-with-Leans-System-Approach.html>

Zaccagnini, M. E., & White, K. W. (2017). *The doctor of nursing practice essentials: a new model for advanced practice nursing*. (3<sup>rd</sup> edition). Jones & Bartlett Learning.



## Appendix A

## Neuman's Systems Model



(Flaherty, 2017)

Appendix B

Lewin's Theory of Change



Wojciechowski et al, 2016

## Appendix C

## Literature Review Example

Article Title and Journal	Susceptibility and antimicrobial resistance of genital ureaplasma parvum. <i>Nano Biomedicine and Engineering</i> , 9 (3), 236-241.
Author/Year	Al-Khadfaji, G. K. (2017).
Database and Keywords	Database: Ovid. Keywords: Genital and ureaplasma
Research Design	Quasi-experimental
Level of Evidence	Level III
Study Aim/Purpose	Investigating the antimicrobial susceptibility of Ureaplasma parvum to determine the best course of antibiotic treatment.
Population Studied/Sample Size/Criteria/ Power	35 samples of Ureaplasma parvum. No criteria or power identified.
Methods/Study Appraisal/ Synthesis Methods	1)Fixed amount of Ureaplasma parvum was cultured in broth medium in sterile test tubes. 2) Concentrations were numbered for addition of each antibiotic and stored at 37 Celsius x 48hours 3) Agar medium was then inoculated and stored at 37 Celsius x 24 hours 4) Amount of bacterial growth was then analyzed.
Primary Outcome Measures and Results	80% of Ureaplasma parvum isolates were susceptible to doxycycline at the highest with 0% susceptible to gentamycin and azithromycin.
Author Conclusions/ Implications of Key Findings	For treatment of Ureaplasma parvum, doxycycline (80% susceptible), clarithromycin (71.4% susceptible), and levofloxacin (65.7% susceptible) should be the antibiotics of choice.
Strengths/ Limitations	Strengths: controlled environment of test tubes and culture growth. Susceptibility was performed using 6 different antibiotics. Limitation: Small sample size, no mention of how collection of Ureaplasma parvum was obtained, and presence of the growth of bacteria was measured by turbidity only.
Funding Source	None listed
Comments	Erythromycin was recommended for treatment during pregnancy, which has a 42% susceptibility rate.

## Appendix D

## SWOT Analysis

<p><b><u>Strengths</u></b></p> <ul style="list-style-type: none"> <li>• Evidenced based practice and guidelines supported by the systematic review of literature</li> <li>• Favorable Nucleic Acid Amplification Tests (NAAT) readily available in the clinical setting</li> <li>• Clinical support from providers for a quality initiative project</li> </ul>	<p><b><u>Weaknesses</u></b></p> <ul style="list-style-type: none"> <li>• Investigator is no longer employed at the site the capstone project</li> <li>• Capstone site is now a midwife-only practice with five practicing providers</li> <li>• Potential resistance to change provider practice of treatment of genital Ureaplasma</li> <li>• Data collection is limited to one area located in the metro-Denver area</li> </ul>
<p><b><u>Opportunities</u></b></p> <ul style="list-style-type: none"> <li>• Provide evidenced based literature review and guidelines to existing providers</li> <li>• Providing information of NAAT collection to identify Ureaplasma</li> <li>• Decrease future obstetrical and gynecologic morbidities caused by genital Ureaplasma</li> <li>• Decrease the overall cost to health insurance companies and the patient through early detection</li> </ul>	<p><b><u>Threats</u></b></p> <ul style="list-style-type: none"> <li>• Unstable state of the corporate run clinic</li> <li>• Remaining five providers may not be able to attend the QI presentation resulting in providers continuing to practice with inconsistent treatment measures</li> </ul>

## Appendix E

## Budget and Resources

Items	Cost	Cost to Replicate
Investigator Time: \$50/hour x 80 hours	\$0	\$4,000
Collection time \$50/hour x 40 hours	\$0	\$2,000
EMR/provider/month (estimate)	\$0	\$175
NAAT (Thin prep, 500 count)	\$0	\$2750*
G*Power Software (free download)	\$0	\$0
<b>Total</b>	<b>\$0</b>	<b>\$8,925</b>

\*University of Wisconsin-Madison, 2016

## Personnel:

- Investigator
- Patients
- Clinical mentor
- Capstone chair

## Time:

- Retrospective Chart Review

## Equipment:

- EMR
- NAAT

## Appendix F

## Letter of Intent

**DNP Quality Improvement Project Letter of Intent****To: Laura Collison****From: Shelbie Paul****Subject: DNP Project****Date: December 11, 2019**

I am writing to obtain permission to conduct a quality improvement (QI) project in your facility (Mountain Vista Midwifery) with the purpose of using a retrospective chart review study design to investigate if there is a difference in the incidence of symptomatic recurrence of genital Ureaplasma in the female patient, when treating the patient and partner as compared to treating the patient alone with antibiotics. This project will be done to fulfill requirements for completion of the Doctor of Nursing Practice degree at Regis University, Denver, CO. The following information will review the study:

This project will employ a **Population-Intervention-Comparative-Outcome (PICO)** format for development of the DNP project question to be investigated:

**Population:** Women with symptomatic genital Ureaplasma

**Intervention:** Treating patient and partner with antibiotic therapy

**Comparative:** Treating the patient alone

**Outcome:** Decrease in the incidence of symptomatic recurrence of genital Ureaplasma

**Quality Improvement Project Question:** Do women with symptomatic genital Ureaplasma have a decreased incidence of symptomatic recurrence when both the patient and the partner are treated with antibiotic therapy than treatment of the patient alone?

**Project Significance:** Untreated, genital Ureaplasma can lead to pelvic inflammatory disease, infertility, premature rupture of membranes, preterm delivery, and infection in the neonate (Verteramo et al., 2013).

The Centers for Disease Control and Prevention (CDC, 2015) recommends treatment with azithromycin and doxycycline; however, the efficacy of azithromycin is declining. Women treated for cervicitis, should abstain from intercourse until their partners have completed treatment with antibiotic therapy.

Findings in this QI project may support the creation of a standard approach based on the CDC guidelines in managing the care of women with symptomatic Ureaplasma.

**Type of Quality Improvement Project Study Design:** A retrospective chart review using a convenience sample

**Participant Requirement:** None, as the data collected already exists in the chart. While conducting the retrospective chart review, I will be working with my clinical mentor, Shana Martin, CNM, in using ICD 10 codes to identify the diagnosis of Ureaplasma, and its treatment and recurrence.

**Risks, Cost, and Benefits:**

- **Risks:** Risks are minimal to none for the participants. The project will use existing data in the electronic health record. Data collected will be de-identified. I will submit an

application to the Regis University IRB and HealthOne IRB (if required) prior to conducting this quality improvement project.

- **Costs:** The cost will be minimal to none to conduct the retrospective chart review.
- **Benefits:** If all providers treat the patient and partner, there may be a decrease in cost to the insurance company and patient related to long-term issues caused by genital Ureaplasma pathogens.

**Project Goals and Objectives:**

The main goal of this project is to explore if there is a difference in the incidence of symptomatic recurrence of genital Ureaplasma based on two treatment modalities; treating the patient only or treating the patient and partner with antibiotics.

**Objectives:**

1. Identify symptoms of vaginitis
2. Identify antibiotic treatment
3. Identify if the patient alone or the patient and partner were treated for Ureaplasma.
4. Measure rates of symptomatic recurrence of genital Ureaplasma in the intervention and comparison groups
5. After DNP Capstone defense, share results of QI project with leadership at site of study

Permission is requested to conduct this quality improvement project at Mountain Vista Midwifery located at 701 E. Hampden Ave. Suite 110 Englewood, CO 80113.

I have included a template for the brief site approval letter that is required on letterhead from you.

Thank you for your assistance with completing my DNP Quality Improvement Project.

Sincerely,

Shelbie Paul, DNP Student

## Appendix G

## Timeline

2018-2019	January	February	March	April	May	June	July/August
8/2018 12/2018	Proposal: Intro to Problem/Market Analysis	Objectives and Evaluation	Complete written proposal and Power Point Presentation	IRB approval/Evidence	Analyze Data	Statistics/paper /PPP	PPP/Defend
Identify Problem for Improvement	Statement of purpose	Mission/ Vision		Start Regis University's IRB approval process	Start statistics course	Complete "Methods" section of paper	Review power point
Explore PICO	Problem statement	Goals	Final edits on paper per Dr. Whalen's recommendations	Make any corrections to Capstone paper	Analyze data	Write conclusion	Set time to defend Capstone
Nursing Theories course	PICO	Outcome objectives				Edit per Dr. Whalen's recommendations	Present findings to clinic
1/2019-12/2019	Concepts and Definition	Logic Model	Begin organizing presentation	IRB Approval!		Work on final power point presentation	
PICO Identified	Theory	Methods (sampling parameter and research design)	Set date for presentation	Get ICD 10 codes to preceptor to begin collecting data			
Theme selection	Lit Review	Protection of Human Rights	Presentation	Arrange table/graphs per data			
Literature review	Scope of Evidence	Reliability/Validity	Review feedback and make appropriate corrections				
CITI course	SWOT						
Email Letter of Intent to HCA to approve project	Identify stakeholders						
	Cost/benefit analysis						



## Appendix H

## Logic Model

	Constraints	Activities	Outputs	Short term	Long term	Impact
<b>Personnel</b>	<p>Establish working relationship with project chair and clinical mentor.</p> <p>Identify providers that are testing for Ureaplasma</p> <p>Treatment regimen</p>	<p>Staff reporting positive Ureaplasma cx</p> <p>Training providers to identify patients for appropriate testing</p> <p>Collection of appropriate genital swabs</p> <p>Identify antibiotic used for treatment</p>	<p>Test for ureaplasma species</p> <p>Identify the appropriate patient for testing</p> <p>Inconsistency of treatment of patient and partner vs patient only</p>	<p>Identify appropriate patient for testing (pelvic pain, reoccurrence of BV, increase in vaginal discharge, dyspareunia, urethritis, history of infertility)</p> <p>Identify appropriate course of antibiotic treatment by CDC guidelines</p> <p>Present evidence to providers</p>	<p>Develop consistency of care within a HCA Ob/Gyn practice</p> <p>Decrease the incidence of recurrent Ureaplasma</p>	<p>Providers identifying the patient on the first visit that should be tested for ureaplasma</p> <p>Treatment per CDC guidelines</p>
<b>Financial</b>	Lab costs to patient depending on insurance coverage		Lab costs to patient depending on insurance coverage	Cost of antibiotics for the patient	Decrease cost of return visits for patient for recurrent symptoms	Decreasing the number of visits for patients for recurrent symptoms
<b>Time</b>	<p>IRB approval time</p> <p>Time Restraint of retrospective chart review</p>	<p>Retrospective study</p> <p>Collecting data</p> <p>Identifying patient's that return to the office within 3 months with reoccurring symptoms</p> <p>Comparison of antibiotic treatment of patient vs treatment of patient and partner for reoccurrence of ureaplasma and mycoplasma</p>	Time lapse between positive culture, calling and treating patient and partner	Course of antibiotic treatment (7 days)	Not identified	Not identified
<b>Materials</b>	PCR or Thin Prep transport media	Review reports received from laboratory	Prescription for antibiotics (verbal or electronically sent to the pharmacy)	Patient compliance in taking full course of antibiotics	Not identified	Not identified
<b>Equipment</b>	Electronic Health Records downtime, lack of internet connectivity	Electronic Health Records	HER	None	None	None
<b>Facilities</b>	<p>HCA clinic services (OB/gyn only)</p> <p>HCA approval</p>	HCA clinic services	Not identified	Not identified	Not identified	HCA clinic services

Adapted from "The Doctor of Nursing Practice Essentials," by M. E. Zaccagnini and K. W. White, 2017.

## Appendix I

## Data Dictionary

NAME	DESCRIPTION	FORMAT
NAAT testing: NuSwab or Thinprep (PCR: polymerase chain reaction)	Positive or negative	Nucleic Acid Amplification Test collected from the endocervical canal/vaginally. PCR will be resulted as “positive” or “negative” and identify Ureaplasma species.
Subject	Numeric identification	A number between 1-128 will be assigned to each subject
Test site	N/A	Healthone clinic services
Presenting symptoms	ICD-10 codes	N76.1 (chronic vaginitis) R01.2 (pelvic pain) N89.8 (Other specified non-inflammatory disorders of vagina) N93.9 (abnormal uterine and vaginal bleeding) N94.1 (dyspareunia)
Treatment of partner	Yes or no	Telephone encounters to patients will need to be looked at to see if the partner was treated or not
Antibiotic prescribed	Numeric 1)Azithromycin 2)Doxycycline 3)Other	Type of antibiotic used will be identified
TOC on follow-up visit	Positive, negative, not done	NAAT test results after completion of antibiotic therapy (8-21 days)
Recurrence in 3-month period (Y/N)	See ICD-10 “Presenting symptoms”	NAAT test with positive results

## Appendix J

## Collection Instrument for Retrospective Chart Review

<b>Sample Number</b>	<b>ICD-10 Visit Code Associated with Ureaplasma</b>	<b>NAAT Test Results</b>	<b>Name of Antibiotic Prescribed</b>	<b>Partner Treated (Y/N)</b>	<b>TOC (positive, negative, or not done)</b>	<b>Recurrence in 3 Month Period (Y/N)</b>
1						
2						

## Appendix K

## CITI Training Certificate



Completion Date 21-Jan-2020  
Expiration Date 20-Jan-2023  
Record ID 34972066

This is to certify that:

**Shelbie Paul**

Has completed the following CITI Program course:

<b>Human Research</b>	(Curriculum Group)
<b>Biomedical Research Investigators</b>	(Course Learner Group)
<b>0 - Refresher Course</b>	(Stage)

Under requirements set by:

**Regis University**

**CITI**  
Collaborative Institutional Training Initiative

Verify at [www.citiprogram.org/verify/?wf9b4635f-34b5-4f12-bc1f-3b3e0f314d0f-34972066](http://www.citiprogram.org/verify/?wf9b4635f-34b5-4f12-bc1f-3b3e0f314d0f-34972066)



Completion Date 10-Feb-2019  
Expiration Date 09-Feb-2022  
Record ID 30484281

This is to certify that:

**Shelbie Paul**

Has completed the following CITI Program course:

**Human Research**

(Curriculum Group)

**Social Behavioral Research Investigators**

(Course Learner Group)

**1 - Basic Course**

(Stage)

Under requirements set by:

**Regis University**



Verify at [www.citiprogram.org/verify/?wd6b9c641-51fb-4113-8437-401b0f151674-30484281](http://www.citiprogram.org/verify/?wd6b9c641-51fb-4113-8437-401b0f151674-30484281)

## Appendix L

## HCA Approval Email

---

**From:** Collison Laura <Laura.Collison@HealthONEcares.com>

**Sent:** Friday, March 27, 2020 2:20 PM

**To:** Lopez, Shelby R <lopez716@regis.edu>

**Subject:** Shelby Lopez/ Capstone

Hi Shelby –

Please see the attached agreement that needs to be signed before you can start your project. Shana Martin has an agreement the she needs to sign also. If you agree, please sign the Agreement and e-mail it back to me. As soon as I have both agreements back, you can start working with Shana.

Thank you,

**Laura Collison** | Contracts Administrator

(d) 303-584-8262 | (f) 866-458-1860

4900 S. Monaco St., Suite 210 Denver, CO 80237 | [bit.ly/19hITSh]Map

[www.healthONEcares.com](http://www.healthONEcares.com)



*Caution: This email and any files transmitted with it may contain PRIVILEGED or CONFIDENTIAL information and may be read or used only by the intended recipient. If you are not the intended recipient of the email or any of its attachments, please be advised that you have received this email in error and that any use, dissemination, distribution, forwarding, printing, or copying of this email or any attached files is strictly prohibited. If you have received this email in error, please immediately purge it and all attachments and notify the sender by reply email or contact the sender at the number listed.*

## Appendix M

## Data Use Agreement

**DATA USE AGREEMENT**

This Agreement is entered into as of March 26, 2020 (the "Effective Date"), by and between Mountain Vista Midwifery ("Practice") and Shelbie Paul ("User"). User is pursuing a Doctor of Nursing Practice degree at Regis University and desires to access certain patient-related data of Practice for research required in order to complete such degree. In connection therewith, the parties wish to exchange a limited data set as permitted by the HIPAA Privacy Rules (45 CFR Part 160 and Part 164, Subparts A and E) for research purposes in accordance with the terms and conditions set forth in this Agreement. In consideration of the mutual promises hereinafter recited, the parties hereto agree as follows:

1. Definitions. Limited Data Set shall have the same meaning as the term "limited data set" in 45 C.F.R. §164.512(e)(2), as amended from time to time. Any remaining terms used, but not otherwise defined, in this Agreement, shall have the same meaning as those terms in the HIPAA Privacy Rule, as amended from time to time.
2. Permitted Uses and Disclosures. Practice will provide data as described on Exhibit A ("Data") to User. The Data will constitute a Limited Data Set. User agrees to only use the Data for the purposes of the research described on Exhibit A consistent with the HIPAA Privacy Rule. User shall not disclose the Data to any third party unless agreed in writing in advance by Practice or unless the Data has been further de-identified so that it complies with the de-identification safe harbor set forth at 45 CFR §164.514(b), which among other things requires that any dates or portions of dates (other than year) be removed, including dates of service.
3. Other Obligations. User will
  - a. only use and disclose the Data as permitted by this Agreement or as Required By Law;
  - b. use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement;
  - c. report to Practice in writing immediately any use or disclosure of the Data not provided for by this Agreement of which User becomes aware;
  - d. ensure that any Subcontractors or agents to whom User provides the Data agree to the same restrictions and conditions that apply to User with respect to such information; and
  - e. not identify or attempt to identify the Data nor contact or attempt to contact the individuals who are the subject of the Data.
4. Term. This Agreement shall be effective as of the Effective Date and remain in effect until terminated by either party or one year from the Effective Date, whichever is earlier. Either

party may terminate this Agreement upon thirty (30) days' written notice to the other party. Upon termination of this Agreement, User shall destroy the Data if feasible. User's obligations set forth in Sections 2 through 3 shall survive any termination of this Agreement for so long as User maintains any of the Data.

5. Notice. All notices and other communications required or permitted to be given shall be made in writing and shall be considered given and received when deposited in the United States mail, postage prepaid, return receipt requested and addressed as set forth below or at such other address such party shall have specified by notice given in accordance with the provisions of this Section:

**If to PRACTICE, to:**

**If to USER, to:**

Mountain Vista Midwifery  
701 E. Hampden Ave,  
Suite 110 Englewood, CO  
80113  
Attn: Shana Martin

6. Confidentiality. User acknowledges that information regarding Practice's business operations, including, but not limited to, procedures, programs, formularies and reimbursement schedules are proprietary and confidential, and agrees to hold such information in strict confidence and not to disclose or make available such information to any third party, except as required by law. This provision shall survive termination of this Agreement.
7. Miscellaneous. None of the provisions of this Agreement are intended to create any relationship between the parties other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. The parties agree to amend this Agreement as necessary to comply with the HIPAA Privacy Rule and other applicable law. This Agreement constitutes the entire written agreement of the parties with respect to the subject matter of this Agreement and supersedes any prior written agreements of the parties regarding the subject matter of this Agreement. Any ambiguity in this Agreement shall be resolved to permit Practice to comply with the HIPAA Privacy Rule. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities, whatsoever.

**IN WITNESS WHEREOF**, the parties have executed this Agreement as of the date and year first above written.

**USER:**

**B Y :**



PRACTICE:

By:

William Smitham

Title:

Vice President

---

---

**EXHIBIT A**

The Data consists of the following:

- ICD-10 Visit Code
- results of culture
- antibiotic prescribed
- partner treated (yes/no)
- TOC/recurrence in 3 month period

Practice will collect data that will constitute a Limited Data Set from its records and provide the Data to User. The Data is provided for the following research project which involves collecting data from medical charts on a retrospective basis. User certifies that the description of the research project set forth below is accurate and complete.

This project will employ a Population-Intervention-Comparative-Outcome (PICO) format for development of the doctor of nurse practice project question to be investigated:

Population: Women with symptomatic genital Ureaplasma

Intervention: Treating patient and partner with antibiotic therapy

Comparative: Treating the patient alone

Outcome: Decrease the incidence of symptomatic recurrence of genital Ureaplasma

Quality Improvement Project Question: Do women with symptomatic genital Ureaplasma have a decreased incidence of symptomatic recurrence when both the patient and the partner are treated with antibiotic therapy than treatment of the patient alone?

Project Title: Considerations of antibiotic treatment for genital Ureaplasma.

Project Significance: Untreated, genital Ureaplasma can lead to pelvic inflammatory disease, infertility, premature rupture of membranes, preterm delivery, and infection in the neonate.

Type of Quality Improvement Project Study Design: Retrospective

Participant Requirement: None. User will receive Data from Practice.

Risks, Cost, and Benefits: If all providers treat the patient and partner, there will be a decrease in cost to the insurance company and patient related to long-term issues caused by genital Ureaplasma pathogens.

Project Goals and Objectives: The main goal of this project is to apply standard of care to women with symptomatic Ureaplasma.

Objectives:

1. Identify symptoms of genital *Ureaplasma* species.
2. Identify antibiotic treatment.
3. Identify if the patient alone or the patient and partner were treated for *Ureaplasma*.
4. Prevent recurrence of genital *Ureaplasma* with proper antibiotic treatment.

## Appendix N

## IRB Net Board Action Email



REGIS.EDU

**Institutional Review Board**

DATE: April 16, 2020

TO: Shelby Paul, MSN

FROM: Regis University Human Subjects IRB

PROJECT TITLE: [1590977-1] Considerations of Antibiotic Treatment for Genital Ureaplasma

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF NOT RESEARCH

DECISION DATE: April 16, 2020

Thank you for your submission of New Project materials for this project. The Regis University Human Subjects IRB has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

The project may proceed as written.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact the Institutional Review Board at [irb@regis.edu](mailto:irb@regis.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 Regis University Human Subjects IRB's records.