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# A PARADIGM SHIFT IN THE DIAGNOSIS AND TREATMENT OF POLYCYSTIC OVARIAN SYNDROME: A PRACTICE CHANGE IN PRIMARY CARE

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# A PARADIGM SHIFT IN THE DIAGNOSIS AND TREATMENT OF POLYCYSTIC OVARIAN SYNDROME: A PRACTICE CHANGE IN PRIMARY CARE

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An Abstract of the Scholarly Project by
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The purpose of this DNP Scholarly Project was to determine whether participants' knowledge of the updated guidelines on the diagnosis and treatment of the obese patient with polycystic ovarian syndrome (PCOS) is increased following a continuing education presentation. The increase in the knowledge of PCOS guidelines for an obese patient is documented using a pretest/ posttest method following the continuing education program which utilizes a PowerPoint presentation. Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder in women. This Doctor of Nursing Practice (DNP) capstone project was designed to provide a literature review and best practice guidelines delivered through the use of an educational PowerPoint presentation for the purpose of educating nurse practitioners and nurse practitioner students on the inflammatory complexity of a PCOS diagnosis. A portion of the presentation discussed the role of FDA approved liraglutide in the treatment of obese women with a co-morbidity of PCOS. A quasi-experimental one-group pretest/posttest design instrument in the form of an index was created for this study. The index included four dimensions with four questions each. The dimensions involved the four research questions for this project. The sample of convenience included 16 nurse practitioners and 2 nurse practitioner students. The results did provide data that a learning curve exists by analyzing the pretest and posttest scores

for the PowerPoint presentation. This study did reflect the need for increased education in nurse practitioners to more appropriately diagnose and treat the obese PCOS patient.

*Keywords*: PCOS, GLP I, Insulin Resistance, PCOS and Obesity, TNF-α

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# CHAPTER I

# INTRODUCTION

*"For us who nurse, our nursing is a thing which, unless we are making progress in nursing every year, every month, every week, take my word for it, we are going back",*

Florence Nightingale, 1872.

## Introduction

Polycystic Ovarian Syndrome (PCOS) is the most common endocrine disease affecting women of childbearing age (Roe & Dokras, 2011). The Department of Health and Human Services (DHHS) reports there are more than 5 million women suffering from Polycystic Ovarian Syndrome currently (2014). According to a recent study published in the Endocrine Society's March 2015 issue of *Journal of Clinical Endocrinology & Metabolism,* women diagnosed with PCOS are twice as likely to be hospitalized for heart disease, diabetes, mental-health conditions, reproductive disorders', and cancer of the uterine lining due to an underlying inflammatory etiology. The cost of evaluating and providing care to women with PCOS is approximately $4.36 billion per

year (Hart & Dorghty, 2015). Similar inflammatory correlations have been identified in obesity and PCOS (Gonzalez, Sia, Shepard, Rote, & Minium, 2014).

The National Center for Health Statistics reported in 2013 that an approximate 68 percent of Americans over the age of 18 are overweight or obese. In the past, obesity was merely looked upon as a caloric matter versus hormonal and inflammatory causes (NCHS, 2013). In 2013, the American Medical Association (AMA) addressed this symptom of obesity and finally categorized it for the first time as a chronic disease state involving gut hormone inflammatory dysregulation rather than a mere symptom (AMA, 2013).

Treatment options for obesity in the PCOS patient are limited. These limitations include the complexity of the disorder, an unknown etiology, and lack of financial backing for research (NIH, 2012). Both metabolic and reproductive abnormalities are amplified in PCOS similar to the obese patient (Franks, 2011). In turn, obesity in the PCOS patient exacerbates objective and subjective findings due to an increase in insulin resistance, androgens, and inflammatory markers. These findings are already elevated at baseline in PCOS, independent of a co-morbidity of obesity (Gonzalez, 2015). Adipose tissue becomes a catalyst to PCOS (2015).

Genetic and epigenetic influences are linked to PCOS (Gonzalez, 2015). It is likely that epigenetics is more of a facilitator to the disease rather than solely from genetic inheritance (Franks et al., 1997). In the research, evidence based findings report dietary habits such as increase glucose adds to the epigenetic expressions. Recent findings in the study of PCOS report that metabolic deviations and ovarian dysregulation are caused by

insulin resistance and inflammation (Gonzalez, 2015). This is the linkage which associates the obese patient without PCOS and the effects of an increase in adipose tissue enhancing insulin resistance and inflammation.

Identifying and treating PCOS is ambiguous among many health care professionals (NIH, 2012). This is due to the similarities of objective and subjective findings in other endocrine disorders (Boyle & Teede, 2011). Current PCOS guidelines recommend lifestyle changes in caloric intake and exercise for weight loss. No medication recommendation is offered (Endocrine Society, 2013). Research finds lifestyle modifications have limited outcomes in PCOS with weight loss (2013). New obesity guidelines offer a novel treatment for weight loss in PCOS which also impedes inflammatory markers. These inflammatory markers are key in exacerbation of the disease process (AACE/ACE, 2016). This therapy contradicts the previous guidelines from the Endocrine Society on weight loss in the PCOS patient.

In December 2012, a PCOS workshop was sponsored by the Office of Disease Prevention and the Eunice Kennedy Shriver National Institute of Child Health and Human Development through the NIH. Invited experts came together to discuss independent and unbiased evidence to facilitate discussion. An executive summary indicated for most of the twentieth century PCOS has been a poorly understood condition. Also, the distractive title limited the assumptions of the disease to an isolated gynecological state. It also allowed for an underdevelopment in education for clinicians and need for funded research in discovery of the metabolic causes and pathologies of the disease state (NIH, 2012).

In a final position paper written by the NIH selected committee, they recommended a change in the name of the disorder. The name change would further reflect the complex inflammatory, metabolic, hypothalamic, pituitary, ovarian and adrenal interactions which characterize this disease state. The experts also recommended future translational research on mechanisms which alter the hormone functions. This would allow for the establishment of models to be developed in identifying innovative therapies for the treatment of PCOS due to the underlying inflammatory and metabolic components with PCOS (NIH, 2012).

At the American Diabetes Association Scientific Conference June, 2016, an Australian Endocrinologist presented a lecture entitled, *"Clinical Update and Implications – Renaming PCOS*." The changed name to be considered is "Metabolic Reproductive Syndrome" (Teede, 2016).

The purpose of this research is to disseminate updated knowledge and correlations between inflammatory and metabolic dysregulation research findings with PCOS. The more interesting aspect is to strongly support a paradigm shift in treatment of the obese patient with a co-morbidity of PCOS. Documented antiquated guidelines are causing missed diagnosis and sub-therapeutic treatment options for this misunderstood population (NIH, 2012). In turn, research allows for opportunities to increase future funded research for metabolic treatments despite the BMI. This syndrome deserves further exploration in order to find a cause.

**Description of the Need for Clinical Practice Guidelines**

In 2013, The Endocrine Society appointed a Task Force of experts to formulate

practice guidelines for the diagnosis and treatment of PCOS. The Clinical Guide Subcommittee deemed the diagnosis and treatment of PCOS a priority area in need of practice guidelines (p. 4570). Primary and secondary causes along with correct diagnosis is imperative for treatment options (Jensterle, Kocjan, Pfeifer, Kravos, & Janez, 2010; NIH, 2012). Implementing this guideline of recommendations assists in an appropriate diagnosis consistent with evidence in order to treat appropriately each patient based on the diagnosis and co-morbidities. These guidelines are aimed at helping physicians and patients understand a complex condition which often has diverse symptoms (2013).

Inflammation is hallmark in the pathophysiology of PCOS (Gonzalez, 2011). The effect of inflammatory markers like Tumor Necrosis Factor-alpha (TNF-α), among others are responsible for these symptoms and co-morbidities. Similarities of increased inflammatory markers are seen between obesity alone and the obese, PCOS patients (Gonzalez, Sia, Shepard, Rote, & Minium, 2014). A further discovery from the research is an elevation in these inflammatory markers being responsible in part for the decreased expression of a gut hormone, GLP-1, from the L cells in the small intestine. Decreased GLP-1 is associated with insulin resistance which further increases adipose production (Gonzalez, 2013). For us who nurse, our nursing is a thing which, unless we are making progress every year, every month, every week, take my word for it, we are going back (Nightingale, 1872)

GLP-1 agonists, like liraglutide, are a class of medications that allow for insulin-glucose homeostasis by promoting insulin secretion and limiting glycogen release (Franks, 2011). GLP-1 levels in PCOS patients were found to be significantly lower

when compared to healthy women (Wang, Liu, Chen, Li & Qu, 2015). GLP-1 medications are often misrepresented as an insulin sensitizer because of the improved glucose and loss of adipose tissue results with the medication. This medication has been proven to assist in weight loss for patients with Type II Diabetes (T2DM) (Franks, 2011). Early GLP-1 therapy may preserve pancreatic beta cell function in subjects with Impaired Glucose Tolerance (IGT) and PCOS by reducing TNF-α. GLP-1 agonists have been FDA approved for obesity (Whitten, 2016). This allows for the FDA approval to prescribe liraglutide for obesity despite other co-morbidities (AACE/ACE, 2016).

The purpose of this research includes delineation of the inflammatory pathophysiology of obesity and similarities to the obese PCOS patient. This links these correlations with a treatment option through these guidelines. This therapeutic option improves many outcomes of the disease. These outcomes involve an ability to decrease key inflammatory markers and weight in these women in order to improve hormone levels which complicate the symptoms of PCOS.

**Significance to Nursing and the Role of the Family Nurse Practitioner**

Nursing as a profession continues to evolve from its inception. Florence Nightingale was the change agent of her time, moving the nursing concept from a vocation to a profession (Ulrich, 1992). A famous quote from her is, "Unless we are making progress in nursing every year, every month, every week, take my word for it, we are going back" (Ulrich, 1992). Discussions across the United States in Doctoral nursing programs are focused on the current paradigm shift this profession is facing in the fluidity of current healthcare challenges (Sullivan, 2013). The need for clinical based nursing as

clinicians, researchers, and scientists is at the forefront as the DNP gains leadership in the healthcare community (2013). The significance to nursing parallels Florence Nightingale on the challenge to evolve.

A paradigm shift in 2013 classifying obesity as a disease rather a than symptom allows nursing the ability to treat obese patients the same as treating hypertension, diabetes, and all other disease states (AMA, 2013). This permits a new level of care and therapeutic treatment options gradually being covered by insurance companies for the overweight and obese patient population. Along with obesity, treatment guidelines established for PCOS potentially expedites the diagnosis and treatment to allow for a decrease in potential chronic co-morbidities that are associated with PCOS (NIH, 2012 )

**Specific Aims/Purpose**

This research accomplishes the following DNP essentials in disseminating the paradigm shift in the diagnosis and treatment of PCOS by: 1) completing an exhaustive literature review integrating the link between liraglutide, inflammatory marker similarities in obesity and PCOS, improvement of hormone levels, and weight reduction as treatment for obese patients with PCOS; 2) Developing an educational PowerPoint with one CE credit hour through American Academy of Nurse Practitioners (AANP) regarding obese patients with PCOS for providers. Along with this, updated practice guidelines for the diagnosis and treatment of PCOS; 3) conducting a pretest and posttest for the continuing education program; and 4) summarize the impact of the project on practice and recommendations for future opportunities.

**Theoretical Framework**

Albert Einstein was quoted

> *"... creating a new theory is not like destroying an old barn and erecting a skyscraper in its place. It is rather like climbing a mountain, gaining new and wider views, discovering un-expected connections between our starting point and its rich environment. But the point from which we started out still exists and can be seen, although it appears smaller and forms a tiny part of our broad view gained by the mastery of the obstacles on our adventurous way up" (Einstein, 1938).*

**Chaos Theory**

Conceptual shifts are occurring in many areas of healthcare and medicine based on the premises of the chaos theory (Hoffman, 2000). Complexity science utilizes the Chaos theory to expand on knowledge rather than discovering new knowledge (2000).

The chaos theory summarizes the undertones of order in a state of total disorganization hammering the healthcare system in the United States currently. Chaos Theory frames the understanding with nursing in being willing to adjust and being malleable in this current paradigm shift with medicine (Grossman & Valiga 2013). Clark (2008) states in her book, *Classroom Skills for Nurse Educators*, the application of the chaos theory for nurse educators helps students during simulations that allows for a purpose of uncertainty. This theory helps students understand the uncertainty of a new patient. At that juncture varied appropriate interventions can be identified and adjusted as the simulated patient changes (2008).

This is similar to the uncertainty of a patient with PCOS. Diverse epigenetic challenges arise with multiple variables altering the patient's symptoms and treatments at any given time (Gonzalez, 2015). Epigenetic variables include the patient's diet, lifestyle, and environment among other gene altering stimuli (2015). Treatment algorithms and protocols are limited and guideline attempt to force all patients with PCOS into "boxes" that may not be appropriate with each unique presentation (NIH, 2012).

Grossman and Valiga (2013) incorporates a discussion allowing the chaos theory to be applied to patient-centeredness, critical thinking, and creativity during this time for improved patient outcomes (2013). The conceptual terms consistent within this theoretical framework allow for a comparison applicable to this research. Definitions of concepts in relation to the chaos theory are in the following table. A second table following defines the parallel of these definitions to PCOS.

**Table 1.** Chaos Theory Conceptual Definitions (Oestreicher, 2007)

| | |
|---|---|
| Causality Principle | Every effect has an antecedent proximate cause. |
| Characteristic Lyapynov time | The characteristic time of a system is defined as the delay when changes from the initial point are multiplied by 10 in a phase space |
| Feedback | A response to information, that either increases effects (positive) or decreases them (negative), or induces a cyclic phenomenon |
| Determinism | A philosophical proposition that every event is physically determined by an unbroken chain of prior occurrences |
| Predictability | This refers to the degree that a correct forecast of a system's state can be made either qualitatively or quantitatively. |
| Model | A patter, plan, representation, or description designed to show the structure or workings of an object, system, or concept. |
| Dynamical system | A system that changes over time in both a causal and a deterministic manner; i.e, its future depends only on |

| | |
|---|---|
| | phenomena from its past and its present and each given initial condition will lead to only one given later state of the System (determinism). Systems that are noisy or stochastic, in the sense of showing randomness, are not dynamical Systems, and the probability theory is the one to apply to their analysis. |
| Phase space | An abstract space in which all possible states of a System are represented, which, each possible state of the System corresponding to one unique point in the phase space. |
| Integral System | In mathematics, this refers to a System of differential equations for which solutions can be found. In mechanics, this refers to a system that is quasiperiodic. |
| Linear System | A system is said to be linear when the whole is exactly equal to the sum of components. |
| Attractor | A set to which a dynamical System evolves after a long enough time. |
| Sensitivity to initial conditions. | This is when a change in one variable has the consequence of an exponential change in the System. |

In reviewing the conceptual terms describing the chaos theory, this research identifies a parallel description of the terms as themes. These themes resonate through the PCOS disease state and symptomology of the females with this disorder. The purpose of this research is to focus on the obese PCOS patient and inflammatory marker elevations. These elevations could potentially have devastating outcomes if not harnessed. The diversity of the symptoms and treatments depend on genetic and epigenetic factors influencing a multitude of cause and affect exchanges with each patient (Gonzalez, 2015). In the following diagram correlations are identified with the conceptual definitions paralleling this research.

**Definition of Terms:**

This section describes the definitions for the terms utilized in this study:

*Polycystic Ovarian Syndrome* – A condition in some women of abnormal hormone levels

**Table 2.** PCOS Conceptual Definitions in Relation to the Chaos Theory

| | |
|---|---|
| Causality Principle | Elevated inflammatory markers, GLP-1 and adiponectin abnormality, insulin resistance. |
| Characteristic Lyapynov time | The time a patient with PCOS increases adipose tissue causing worsening of symptoms from the initial symptoms. |
| Feedback | Increased Inflammatory markers, worsening insulin resistance, elevated androgens, obesity, infertility, acne, excessive body hair, male pattern hair loss, diabetes, etc. |
| Determinism | Polycystic Ovarian Syndrome |
| Predictability | Hypothesis of elevation of adipose tissue and the symptoms of PCOS in obese females. |
| Model | Adipose tissue |
| Dynamical system | Hormonal changes that are consistent with the probability of a diagnosis of PCOS |
| Phase space | An abstract space in which all possible presentation of an obese patient with PCOS is represented which, each possible presentation of the symptoms correspond to one unique point in the parameters of this space. |
| Integral System | Domino effect of dysregulation of female hormones secondary to inflammatory markers from an increase in adipose tissue. |
| Linear System | The perfect hormone regulation that does not deviate from normal |
| Attractor | Elevated inflammatory markers, Insulin resistance, Amenorrhea, Ovarian Follicles. |
| Sensitivity to initial conditions. | Elevated inflammatory markers, Insulin resistance, Polycystic Ovarian Syndrome, hypertension, diabetes, vasculopathies, infertility. |

resulting in irregular menstruation, hirsutism, acne, ovarian cyst, and infertility. Treatment involves weight loss and hormones (Sell, Rothenburg, & Chapman, 2012)

*Liraglutide* is marketed under the trademark Victoza© and Saxenda© (Whitten, 2016).

*TNF-α* – is directly proportional to fat mass and has been shown to be involved in the development of insulin resistance. It decreases insulin receptors and down-regulates several steps in the insulin-signaling pathway. It is a protein which is produced chiefly by monocytes and macrophages in response to endotoxins that mediate inflammation. It

is an inhibitor of insulin on the insulin receptor increasing insulin resistance. This is elevated in PCOS and worsens insulin resistance, GLP-1 resistance, and GLP-1 production (Gagnon et. al., 2015)

*Insulin resistance* – A reduction to the sensitivity of insulin by the body's insulin-dependent processes such as glucose uptake and lipolysis (Franks, 2011).

Epigenetics - Epigenetics describe the alterations of gene expression despite any alterations to the genetic sequence (Chuang & Jones, 2007)

*GLP-1* – one of two intestinal hormones secreted when nutrients such as carbohydrates and lipids are present in the small intestine. It stimulates the release of insulin from pancreatic beta cells in conjunction with carbohydrates that are absorbed from the gut while inhibiting glucagon secretion, stomach emptying and food intake. It regulates postprandial glucose homeostasis. PCOS hormone dysregulation involves a decreased production and sensitivity of GLP-1 which leads to worsening symptoms of the disease.

*Body mass index (BMI)* – A useful tool to calculate body fat. It is a measurement of weight (kilograms) divided by the height (meters) (Institute for Clinical Systems Improvement, 2013). It is useful to correlate with coexisting health problems (2013).

*Clinical Practice Guidelines* – Reports which include recommendations for improving patient care and outcomes through disseminating a systematic review of evidence and an association of the benefits and harms of treatment options (National Guideline Clearinghouse, 2011).

**Chapter Summary**

PCOS is the number one endocrine disorder in women. Coupled with obesity, inflammation worsens the disease process. Many studies have looked at the long term effects of the obese PCOS patient. New guidelines were implemented in May, 2016 for obesity associated with PCOS and in 2013 for PCOS. Nurse practitioners in the primary care setting must be educated on to appropriate diagnosis and treatment of PCOS. Chapter II presents a literature review on the updated guidelines as well as multiple research studies utilizing medication to treat the obese PCOS patient. It goes on to highlight key guidelines that are FDA approved in treating PCOS.

# CHAPTER II

# REVIEW OF THE LITERATURE

## Introduction

This chapter discusses research and guidelines on the diagnosis and management of PCOS with a focus on the obese PCOS patient. The purpose of this research is to disseminate imperative knowledge to support a paradigm shift in the diagnosis and treatment of PCOS with obesity. This is achieved by blending current evidence based guidelines for PCOS and Obesity along with supportive research studies reinforcing novel trends in pathophysiology and treatment.

The review of literature is achieved through multiple online databases. The research is generally limited to the last five years. Due to the diagnosis classification being a rare disease, some research exceeds the five year mark to allow the reader full bodied research from the inception of the diagnosis.

The phrases being used for search includes “PCOS,” “obesity,” “GLP-1 agonists and obesity,” “Clinical practice guidelines in PCOS” and “inflammatory markers with PCOS”. The statistical information from the website of the Centers for Disease Control and Prevention and the National Institutes of Health are reviewed. In searching these different words and phrases, there are over 30 peer-reviewed articles with information

being utilized for this scholarly project. The following categories distinctly satisfy a portion of necessary essentials for the DNP program. The first category is a literature review correlating obesity, PCOS, inflammatory markers, and lirglutide. The second category involves developing a one hour CE, through AANP, Power Point presentation. A pretest and posttest comparison involving area nurse practitioners and nurse practitioner students is conducted. The CE includes the pathophysiology, diagnosis, and treatment of obesity in the PCOS patient. The third category is further dissemination of the information from this research in future state and national conferences. This allows for updated practice changes in the primary care setting to be the rule and not the exception in treating PCOS.

**Practice Change Guidelines**

The Endocrine Society 2013 guidelines, *Diagnosis and Treatment of Polycystic Ovarian Syndrome: An Endocrine Society Clinical Practice Guideline,"* recommends three primary recommendations which delineate into 32 more precise recommendations for the diagnosis, co-morbidities, and treatment of PCOS. The Endocrine Society appoints a Task Force of experts to formulate practice guidelines for the diagnosis and treatment of PCOS. The Clinical Guide Subcommittee deems the diagnosis and treatment of PCOS a priority area in need of practice guidelines (p. 4570). Primary and secondary causes along with correct diagnosis is imperative for the correct treatment of PCOS (Jensterle, Kocjan, Pfeifer, Kravos, & Janez, 2010).

Implementing this guideline and bundle of recommendations is to individually diagnose appropriately each patient according to the severity of the disease and co-

morbidities. These guidelines are aimed at helping physicians and patients understand a complex condition that often has diverse symptoms (2013). PCOS continues to be underdiagnosed in adolescents and adults due to the complexity and diverse subjective and objective findings (March et. Al., 2012).

Under diagnosis of PCOS is concerning due to the long term reproductive health consequences and associated cardio metabolic risks. These women have increased risk of metabolic syndrome, diabetes, heart disease, and death (Coviello, Legro & Dunaif, 2006). Due to this, assessing and establishing the diagnosis is important for further counseling and treatment.

Three evidenced based diagnostic criteria protocols have been available but tend to be under-utilized by healthcare providers and medical professions currently. This is due to variations and confusion among the different specialties involved in treating PCOS (Bonny et. Al., 2012). These protocols include the NIH 1990, Rotterdam 2003, and Androgen and Endocrine (AE)-PCOS Society 2006. The following tables will identify key criteria for each protocol.

**Table 3.** Guidelines for the Diagnosis of PCOS

| NIH 1990 | Rotterdam 2003 | AE-PCOS Society 2006 |
|---|---|---|
| Chronic anovulation<br>Clinical and/or biochemical signs of Hyperandrogenism (with exclusion of other etiologies, e.g., congenital | Oligo-and/or anovulation<br>Clinical and/or biochemical signs of Hyperandrogenism<br>Polycystic ovaries<br>(Two of three criteria | Clinical and/or biochemical signs of Hyperandrogenism<br>Ovarian dysfunction (Oligo-anovulation and/or polycystic ovarian |

| | | |
|---|---|---|
| adrenal hyperplasia)<br><br>(Both criteria) | needed) | morphology)<br><br>(Both criteria needed) |

**Practice Change Recommendations for Implementation**

The Endocrine Society published updated recommendations for PCOS in 2013. Obesity is addressed. Treatment options for the obese PCOS patient in the guidelines. These guidelines are limited and state that benefits to the patients are uncertain in improving PCOS symptoms (Endocrine Society, 2013). Research clearly identifies that weight loss decreases inflammatory markers in patients with PCOS (Gonzales, 2015). In 2016, the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) introduced updated clinical practice guidelines for comprehensive medical care of patients with obesity. PCOS is listed as a co-morbidity of obesity and offers liraglutide as a treatment option for PCOS (AACE, 2016). The Endocrine Society in 2013 offered no medication as a treatment for obesity in the PCOS patient (2013).

Diagnosing and Treating PCOS, the Endocrine Society recommendations contain three primary recommendations with a total of 32 separate detailed recommendations divided within the three primary guidelines. The delineation of these being outlined (See Table 4). The highlighted guidelines are the focus of this research.

**Table 4.** Endocrine Society Practice Change Guidelines

| | |
|---|---|
| 1.0 Diagnosis of PCOS | 1.1 Diagnosis Criteria<br>1.2 Diagnosis Criteria for adolescents<br>1.3 Diagnosis Criteria for perimenopause or menopause with presumptive symptoms |

| | |
|---|---|
| 2.0 Associated morbidity and evaluation | 2.1 Documented cutaneous manifestations<br>2.2 Screening ovulatory status<br>2.3 Exclusion of other causes of if infertility<br>2.4 Preconception assessment of BMI, B.P., and OGTT<br>2.5 No intervention for prevention of PCOS in offspring<br>2.6 Against routine ultrasound screening for endothelial strip<br>**2.7 Screening PCOS females for adiposity by BMI and waist circumference**<br>2.8 Screening for Depression<br>2.9 Screen for Obstructive Sleep Apnea<br>2.10 Awareness of Fatty Liver Disease, but no screening<br>2.11 Recommend OGTT to screen for glucose intolerance and type II diabetes<br>2.12 Screening for CVD |
| 3.0 Treatment | 3.1 Oral Contraceptives as first-line management of PCOS symptoms<br>3.2 Screening for contraindications of Oral Contraceptives<br>**3.3 Exercise management in the treatment of obesity in PCOS**<br>**3.4 Suggest calorie-restricted diets for weight loss in PCOS**<br>3.5 Suggest against first line therapy for treatment of cutaneous manifestations of PCOS<br>3.6 Recommend metformin in women who fail first line therapy for T2DM or IGT<br>3.7 Recommend clomiphene citrate as first-line for infertility |

| | |
|---|---|
| | 3.8 Metformin suggested as an adjuvant therapy for infertility to prevent ovarian hyper stimulation syndrome in women with PCOS undergoing IVF<br>3.9 Recommend against use of insulin sensitizer such as inositol's or thiazolidineses for treatment of PCOS<br>3.10 Recommend against using statins for treatment of hyperandrogenism and anovulation in PCOS<br>3.11 Suggest OCs first line treatment in adolescents<br>3.12 Premenarcheal girls with advanced pubertal development, suggest OC's |

The 2016 updated obesity guidelines from the AACE/ACE allow for a paradigm shift in the treatment of obesity in PCOS. The guidelines specific for obesity and the co-morbidity of PCOS state, "*What are the weight-related complications that are either caused or exacerbated by excess adiposity?* (AACE, 2016). It lists PCOS as one of 15 co-morbidities of obesity. Each recommendation is graded according to the strength of each recommendation. Grade A and B indicate a strong or intermediate level of scientific substantiation. The strength of evidence is graded one through four with one being strong and four being no clinical evidence (2016).

**Table 5.** 2016 AACE Clinical Guidelines for Obesity with Co-Morbidity of PCOS (AACE/ACE, 2016)

| | |
|---|---|
| Screening for Co-morbidity of Obesity | Premenopausal female patients with overweight or obesity and/or metabolic syndrome should be screened for polycystic ovary syndrome by history and physical examination; all patients with PCOS should be evaluated for the presence of overweight or obesity. **(Grade B; BEL 2)** |
| Treatment: Is weight loss effective to treat | **R48**. Women with overweight or obesity |

| | |
|---|---|
| PCOS? How much weight loss would be required? | and PCOS should be treated with lifestyle therapy with the goal of achieving five percent to 15 percent weigh loss or more to improve hyperandrogenism, oligomenorrhea, anovulation, insulin resistance, and hyperlipidemia; clinical efficacy can vary among individual patients **(Grade A; BEL 1)**<br><br>**R49**. Patients with overweight or obesity and PCOS should be considered for treatment with orlistat, metformin, or liraglutide, alone or in combination, since these medications can be effective in decreasing weight or improving PCOS manifestations including insulin resistance, glucose tolerance, dyslipidemia, hyperandrogenemia, oligomennorrhea, and anovulation **(Grade A; BEL 1).**<br><br>**R50**. Selected patients with obesity and PCOS should e considered for laparoscopic Roux-en-Y gastric bypass to improve symptomatology including restoration of menses and ovulation **(Grade B; BEL 2)** |
| Treatment Goals for overweight or obese patients with PCOS with BMI> 24: | Decrease of weight by 5-15 percent<br><br>Ovulation<br><br>Regularization of menses<br><br>Reduced hirsuitism<br><br>Enhanced insulin sensitivity<br><br>Reduced serum androgen levels |

**Implementation Plan**

In an attempt to understanding the disease process of PCOS with obesity, it is difficult to have a one size fits all treatment algorithm. In saying that, a basic evidenced template allows for consistency to distinguish a depth of credibility for the diagnosis and treatment of PCOS. Initiating new guidelines in a primary care practice can be difficult

due to the complexity and multiple symptoms of PCOS. Utilizing an implementation guideline could facilitate an easier transition in the practice change for PCOS.

The Registered Nurses' Association of Ontario (RNAO) environmental scan from the Toolkit: Implementation of Clinical Practice Guidelines (2013) assesses the potential readiness of a primary care practice to implement change in PCOS guidelines. Results of the findings are located in Table six that discusses barriers and facilitators.

**Table 6.** Primary Care Practice Readiness to Change in the Treatment of PCOS

| Element | Question | Facilitators | Barriers |
|---|---|---|---|
| Structure | To what extent does decision-making occur in a decentralized manner? Is there enough staff to support the change process? | Recognition of collaborating physician and mid-level in need of specific guidelines for PCOS patients | Various protocols from different specialties for PCOS, some contradicting |
| Workplace Culture | To what extent is the CPG consistent with the values, attitudes and beliefs of the practice environment? To what degree does the culture support change and value evidence? | The reputation and specialty of the providers in each practice. | Inconsistent protocols used due to types of patients, insurance, family support, etc. |
| Communication | Are there adequate (formal and informal) communication systems to support information exchange relative to the CPG and the CPG | Communication involves the mid-level and physician along with educating patients | Not educated on PCOS. "Not knowing what you don't know" |

| | | | |
|---|---|---|---|
| | implementation process? | | |
| Leadership | To what extent do the leaders within the practice environment support (both visibly and behind the scenes) the implementation of the CPG? | The support of the staff and other providers in the office. | Decrease level of education and close-mindedness towards the disease. |
| Knowledge skills and attitudes of target group(Includes Nursing Leadership, Staff Nurses and Nurse Educators) | Does the staff have the necessary knowledge and skills? Which potential target group is open to change and new ideas? To what extent are they motivated to implement the CPG? | The continued education undergone by the physicians and mid-levels the experience with PCOS and ability to utilize the guidelines appropriately | Lack of interest or education to provide appropriate care |
| Commitment to quality management | Do quality improvement processes and systems exist to measure results of implementation | Quality improvement has being a part of office infrastructure | Lack of resources on PCOS and Obesity and need for quality management |
| Availability of resources | Are the necessary human, physical and financial resources available to support implementation? | Resources are readily available with involvement of the diagnosis and treatment of PCOS | Unclear of updated guidelines for obesity and PCOS |
| Interdisciplinary relationships | Are there positive relationships and trust between the disciplines that will be involved or affected by the CPG? | Support and use of these guidelines will allow for other disciplines to be educated on this disease | Misunderstanding of the disease process across different specialties causes mixed focus of the diagnosis and treatment of PCOS |

| | | | |
|---|---|---|---|
| Patients | Are patients happy with results of new guidelines | Results of patient evaluations | Lack of desire for the patients to fill out evaluations |

According to the Endocrine Society, treatment of obesity in the PCOS patient is not associated with improvement in symptoms (Endocrine Society, 2013). The purpose of this literature review is to present research to substantiate the importance of weight loss in PCOS in the reduction of symptoms. It then continues to discuss improvement in co-morbidities with the introduction of liraglutide as a treatment. Weight loss as well as the use of liraglutide decrease inflammatory markers, especially TNF-a, which are key in the pathophysiology of PCOS (Gonzalez, 2015; Gagnon et. al, 2015).

**Tumor Necrosis Factor-alpha**

Tumor Necrosis Factor-alpha (TNF-α) is a pro-inflammation cytokine which encourages a wide range of reproduction related disorders (Gagnon et. al., 2015). Genetic and epigenetic expressions of this inflammatory marker lead to excess production of TNF-α. Because of excessive TNF-α, elevated production of other androgens in the system produce the classical symptoms of PCOS (Fauser et. Al, 2012). These androgens include testosterone, DHEA-S, insulin among others.

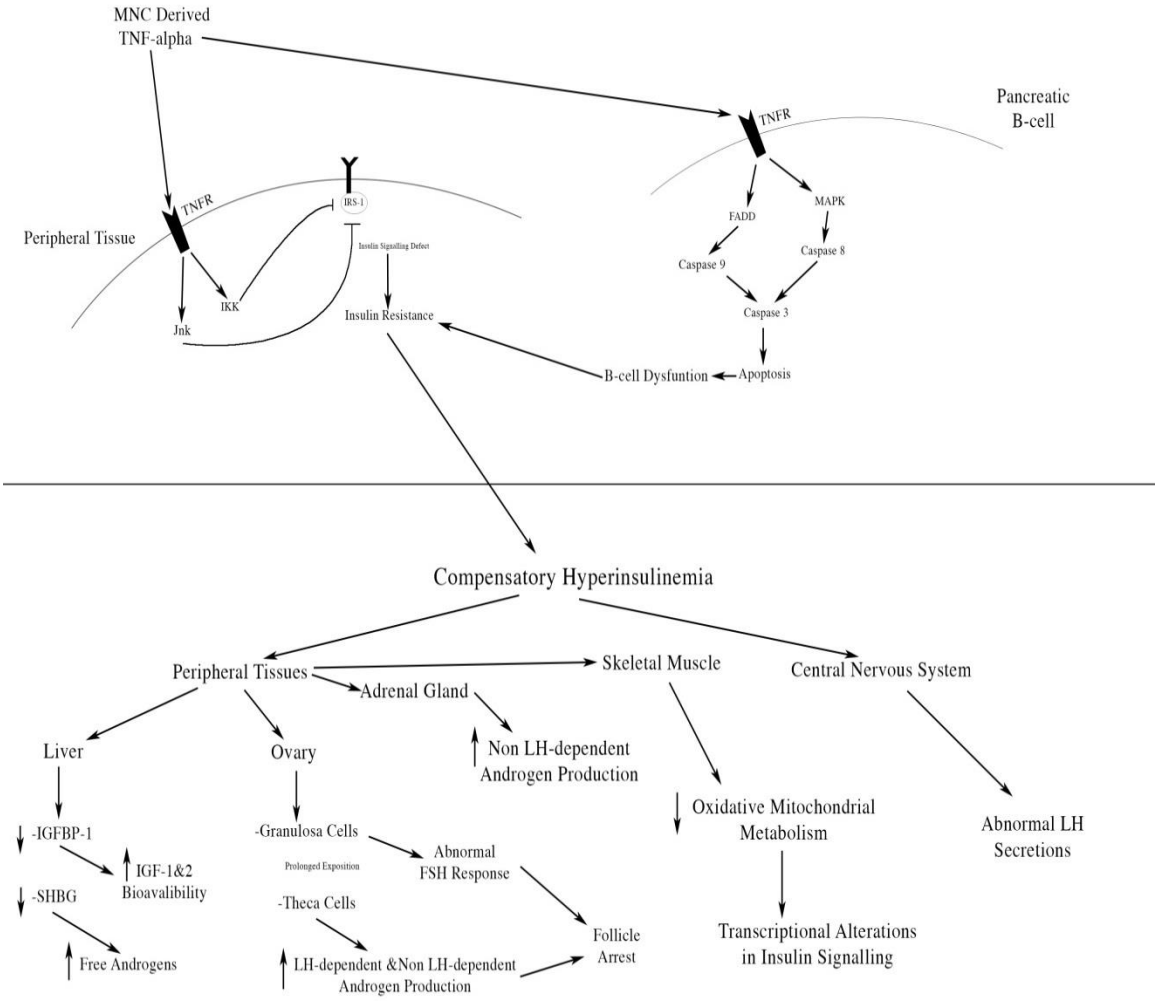
While obesity is well known to create a pro-inflammatory state, with increased levels of TNF-α, recent literature suggests PCOS patients exhibit increased levels of these inflammatory markers independent of obesity (Gonzalez, 2015). Inflammatory markers also secrete abnormally in response to dietary components, such as glucose. This promotes a greater pro-inflammatory and oxidative state, which is elevated when obesity is present (Gonzalez, Sia, Shepard, Rote & Minium,2014).

Genetic and Epigenetic Polymorphisms of TNF-α in PCOS patients have been confirmed versus control groups in recent studies (Gan & Nalliah, 2015). Hector et. Al (2001) demonstrates high serum levels of TNF-α in PCOS patients. TNF-a biomarkers have been identified as a screening for potential candidates and their risk for developing PCOS (2015). The following diagram is a simplified algorithm to how TNF-a causes insulin resistance.

Elevated levels of TNF-α contribute to insulin resistance through post receptor restraint of insulin receptors. TNF-α impedes insulin uptake leading to a decrease in insulin sensitivity. Consequently, hyperinsulinemia occurs as a compensatory mechanism, which in return, promotes an elevated androgen state and increase in adiposity (Gonzalez, F., 2015).

Since the discovery of TNF-α, the understanding of the various effects on the human body is increasing. The pathophysiology of diseases linked with this marker

**Figure 1.** Inflammatory Marker Effects on Insulin and the Cell (Taylor, 2016)




involves multiple organ systems. TNF-α receptors can be located on virtually every cell of the body. With this increase in understanding the role of TNF-α in diseases an increase in therapeutic agents rise (LaDuca & Gaspari, 2001)

In 1999 Dr. Gonzalez states that circulating TNF-a is elevated independent of obesity in PCOS (Gonzalez et. al., 1999). Dr. Gonzalez discusses multiple connections to PCOS and TNF-a in his peer reviewed article, *Inflammation on Polycystic Ovary Syndrome: Underpinning of insulin resistance and ovarian dysfunction* (2012). Along

with this, research continues to have no definite etiology of PCOS. Recent literature points toward a pattern consistent with inflammatory markers' response to genetic mutations and epigenetic factors which could support an etiology to this syndrome (2012).

PCOS subjects have been shown to produce elevated levels of TNF-α in response to glucose independent of obesity. Glucose intake along with acute hyperglycemia causes insulin resistance. Insulin resistance becomes a potent activator of several inflammatory cellular pathways (Khodabandehloo et al., 2015). Of significant importance, physiological changes occur in the presence of excess insulin, resulting in a greater luteinizing hormone (LH) response. This increase in LH function contributes to the abnormal ovulation and increase in androgens observed in PCOS patients (Franks, 2011).

Further research involving the pathophysiology of PCOS is the elevation of TNF-α from the ovaries that elevate insulin and androgen levels (Hector et. Al, 2001). Recent genetic research is on the brink of identifying TNF-α mutations in the genetic sequences that are unique to PCOS patients (Gan & Nalliah, 2015). Gan and Nalliah (2015) have verified this TNF-α mutation could potentially be related to lowering GLP-1 production and uptake in the cells initiating the PCOS disease process.

**GLP-1 Agonists**

The purpose of this project is focused research regarding the parallel between obesity and the obese PCOS patient in the therapeutic benefit of liraglutide, a GLP-1 agonist. An important parallel in treating with liraglutide is a decrease in inflammatory markers, like TNF-α, and weight. Elevated TNF-α levels lower GLP-1 production in the

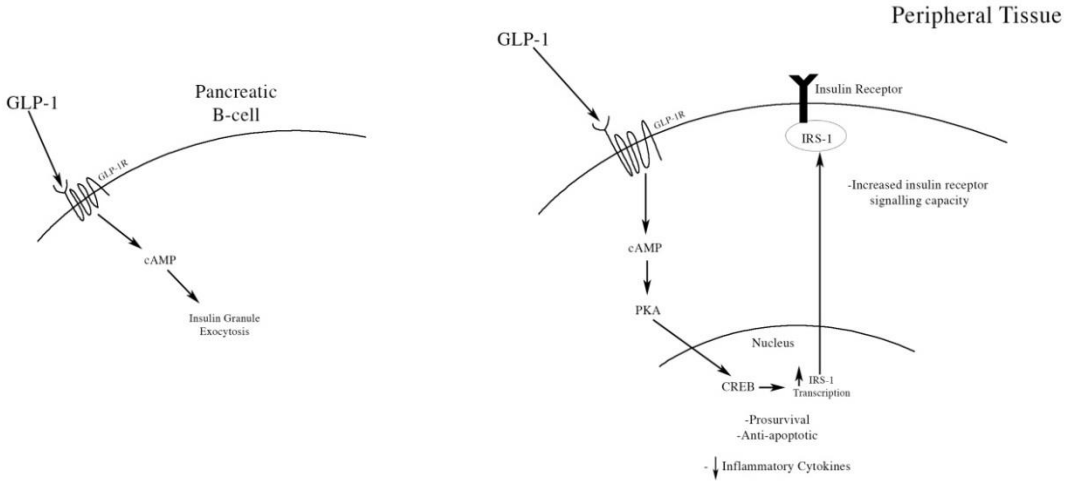
gut as well as GLP-1 uptake in the peripheral organs (Gagnon, 2015). An observational research study concludes that GLP-1 inhibition occurs in PCOS patients independent of BMI or oral contraceptive use during a three hour glucose tolerance test. TNF-α was not tested in this research (Aydin, Arusoglu, Koksalt, Cinar, Aksoy & Yildiz, 2014 )

Molecular cardiologists published a study in 2013 correlating GLP-1 agonists with a decrease in the over-expression of TNF-α in mice who were fed a high fat diet for up to 32 weeks versus the mice control group (Noyan-Ashraf et. al., 2013). Their conclusion supports GLP-1 in the activation of several cardio-protective pathways in vitro (2013).

The research for GLP-1 agonist treatment of weight loss in PCOS, independent of BMI is limited and the subject numbers are small. In the literature review, GLP-1 agonists have been extensively researched for T2DM, obesity and non- alcoholic steatohepatitis (NASH). Other research supports GLP-1 agonists with treatment for hypertension, metabolic therapy, Alzheimer's disease and antipsychotic medication induced obesity (Hoang et. al., 2015; Ishoy, Fliip, Vilsboll, Glenthoj, & Bjorn, 2013). The following diagram in Figure two demonstrates GLP-1 and insulin on the cell receptors.

Multiple peer-reviewed research outcomes identify similar results involving GLP-1 induced weight loss in patients who have diagnoses other than PCOS. In 2013, a randomized controlled trial compares antidiabetic medications, including GLP-1 agonists for treatment of T2DM (Brady, Davies, Gray, Saeed, Smith, Hanif & Khunti, 2013).

**Figure 2:** GLP-1 and insulin at the Cell Receptors (Taylor, 2016)




Although weight loss is a secondary outcome liraglutide, which is a GLP-1 agonist, did statistically find weight loss in this group (>-1kg). This was the first randomized controlled trial comparing a sulfonurea to a GLP-1 receptor agonist in patients with diagnosed T2DM who were fasting during Ramadan. It is a 12 week study with 70 subjects finishing the trial (2013).

The second review is a study involving long-term efficacy and safety in comparing liraglutide, glimepiride and placebo with T2DM. It is randomized to liraglutide, placebo, or glimepiride with all to include metformin. It is a two year retrospective study from patients who enroll in the LEAD-2 study and continues after the 26 week trial was complete. Weight loss with liraglutide is significantly greater than with metformin therapy (p=0.0378) (Nauck, Hermansen, Thomsen, During, Shah, Tankova, Miltha & Matthews, 2013).

The third review involves a 12-week prospective randomized open-label study involving metformin or liraglutide with a primary endpoint of weight loss. The PCOS subjects are diagnosed by Rotterdam criteria. A statistical weight loss is observed (Sever et. al., 2015).

The fourth review involves an observational study from Denmark. The aim is to evaluate liraglutide on weight loss with obese and overweight women with PCOS. Treatment is significant in the overweight and obese women on liraglutide. A mean decrease of the BMI of 3.2 kg/m2 is found (Rasmussen & Lindenberg, 2014).

The fifth review involves liraglutide and improvement of hypertension and metabolic perturbation in a rat model of PCOS. A secondary outcome involves noted weight loss. A significant decrease in body weight ($p<0.01$) is measured. Utilizing research in a very controlled setting allows for more accurate results in the endpoints being studied (Hoang et. al., 2015).

The sixth review is conducted as a randomized control trial to research the question involving GLP-1 receptor agonist and maintenance of weight loss due to a decrease in plasma leptin. This is an interesting description of leptin in the methodology and results. The subjects are randomized, after a 12 percent weight loss into the treatment with GLP-1 agonist and the control being without treatment. The study is able to conclude that GLP-1 agonists maintain the 12 percent weight loss for one year and could prevent prediabetes and obesity (Iepsen, Lundgren, Dirksen, Jensen, Pedersen, Hansen, Madsbab, Holst & Torekov, 2014).

**Assimilating the Research**

This researcher begins to review case studies of patients and gather evidence based research to cultivate a trend of family history, genetics, epigenetics, medical histories, lifestyle failures and past medical therapies corresponding with the diagnosis of obesity and co-morbidity of PCOS. A common theme in the research involves gut hormones and the effect of insulin resistance in these women. This research leads to the connection of insulin resistance (IR) to GLP-1 (Drucker, 2006).

Next, this research attempts to integrate the similarities of inflammatory markers and insulin resistance in PCOS and obesity. This integration leads to a consistent theme. These patients with increasing inflammatory markers complicate the ability to improve without intervention. Once the weight gain begins, increased adipose tissue complicates the overall hormone dysregulation with the inflammatory markers produced from the tissue. It is like a train leaving the station. Because of this hormone dysregulation, if affected women exercise and eat minimally, the insulin resistance will not allow for metabolism of adipose. Lifestyle changes have shown little result (Endocrine Society, 2013).

This is where GLP-1 comes into play. GLP-1 is an incretin hormone secreted in a nutrient dependent dose. It stimulates glucose dependent insulin secretion (Drucker, 2006). GLP-1 receptors are not only located in the pancreas, but also the kidney, lung, heart, and the peripheral and central nervous system (2006). These are all the areas affected by obesity and PCOS as mentioned earlier in the literature review.

Both lean and obese women with PCOS show mutated alterations in the secretion of GLP-1 both fasting and post-prandial (Aydin, Arusoglu, Koksai, Cinar, Aksoy, &

Yidliz, 2014). Recently researchers have found a strong link with PCOS to IR, a genetic condition often associated with diabetes (Hoffman et. al., 2016). IR is a condition in which muscle, fat, and liver cells do not respond properly to insulin and thus cannot easily absorb glucose from the bloodstream. This causes production of increasingly higher levels of insulin to assist with entry of glucose into the cell. This exacerbates the disease process causing more insulin resistance, potential weight gain, and worsening of hormone dysregulation (Gonzalez, 2015; Gonzalez, Sia, Shepard, Rote, & Minium, 2014).

**Chapter Summary**

The purpose of this literature review is to educate the reader on updated research and paradigm shifts in the diagnosis and treatment of the obese PCOS patient. The disease process is a culmination of both genetic and epigenetic expressions of each affected female. Treatment options have been limited as the true etiologies have not been identified at this juncture. This research delineates the links between obesity and PCOS in order to educate nurse practitioners on a new treatment option for PCOS.

Identification and understanding of the individualized hormone dysregulation in PCOS is vital. One size does not fit all with this disease process. Once the diagnosis is made, distinct treatment plans for each patient is imperative based on a very thorough history and physical. Laboratory studies and other diagnostics should be addressed. The necessity to align hormone regulation by lowering inflammation and restoring insulin sensitivity is the hallmark of PCOS (Gonzalez, 2015).

Once the initial inflammation has been addressed research is demonstrating that obesity, infertility, glucose dysregulation, and hormone dysregulation improves. The patient's overall self- esteem, quality of life and overall health improve. PCOS is a very complex disease process with divergent assumptions of causes and treatments. The origins of PCOS must be recognized. Chapter III discusses the research methodology, protection of human subjects, design of instruments, project procedure and outcomes.

# CHAPTER III

# METHODOLOGY

## Introduction

This chapter includes the research design, samples, instrument utilization, and the analysis of the statistical outcomes. This study is designed to evaluate primary care providers, specifically, nurse practitioners and family nurse practitioner students, in their knowledge of the obese patient with PCOS before and after a Continuing Education (CE) presentation on PCOS. The review of the literature discloses the updated research and paradigm shifts in the diagnosis and treatment of the obese PCOS patient.

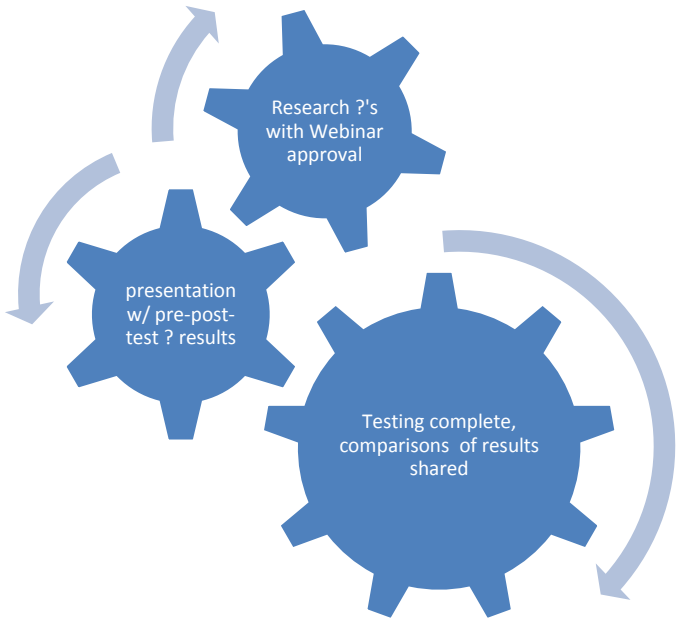
## Research Design, Conceptualization and Measurement

The study utilizes a quasi-experimental design for measuring knowledge of the participating learner and their understanding of PCOS based on recent guidelines for diagnosis, assessment, and treatment of this disorder. Two practice guidelines are bridged in order to apply up-to-date treatment in the obese, PCOS patient. Implementation of the quantitative study allows for the review of how participating learners are improving their education of obesity in PCOS after participating in the presentation (Hoy & Adams, 2016). Using this style of statistical analysis allows for an

objective approach and decreases the chance of the researcher becoming overly involved. It also decreases potential complications early in the study (2016).

The decision to utilize a quasi-experimental design allows for testing and analysis evaluation to identify the strength and dissemination of the education presented during the CE. There is no control group. This study utilizes a randomized sample due to the potential small size of the participant group. The questionnaire includes a demographic section in order to identify the representation of the sample.

**Figure 3.** Project Algorithm




The Continuing Education program, which is presented as face-to-face presentation with the use of PowerPoint slides, introduces an updated approach in PCOS diagnosis and treatment in the overweight/obese population. It is anticipated that the goals of this project will be met. It is anticipated that 100 percent of the learners will be able to

process and synthesize the information in order to contemplate practice changes at their place of employment**.**

**Research Questions**

The following questions are the focus of the results from the evaluation of the pre-post-test and diagnosing and treating PCOS:

1. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of the correlations between obesity and PCOS?
2. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of diagnosing the patient with PCOS and obesity?
3. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of inflammatory co-morbidities and PCOS?
4. Will the Continuing Education presentation on the new PCOS Guideline increase the provider's knowledge of prescribing weight loss medications for the obese patient with PCOS?

**Settings and Participants**

The participants' involvement in this research project includes attendance at the Continuing Education presentation on the new PCOS Guideline by licensed practicing nurse practitioners, as well as Family Nurse Practitioner (FNP) students enrolled in a Master of Science in Nursing FNP program. These attendees are members of the "4 State APN Group" which is a group of Nurse Practitioners in the Kansas, Missouri, Oklahoma and Arkansas areas who meet to discuss the latest issues on a monthly basis.

Additionally, nurse practitioner students from the same areas are invited to join this group each month.

In order to complete and receive CE's for the presentation, the pretest and posttest are mandatory. The level of knowledge each participant possesses previous to the presentation is important in order to validate the increase in knowledge base after listening to the PCOS Guideline presentation. The participants are able to disseminate the information and utilize it in their daily practice in order to have the confidence to appropriately diagnose and treat the female obese patient with PCOS.

**Inclusion/Exclusion Criteria**

Inclusion criteria for this study involved all licensed practicing nurse practitioners, as well as Family Nurse Practitioner (FNP) students enrolled in a Master of Science in Nursing FNP program who attended the 4 State APN Group monthly meeting. The monthly meeting of the 4 State APRN Group was held at The Sullivan Clinic. The attendees completed the pretest, listened to the lecture with PowerPoint presentation and then completed the posttest. The participants were required to be a licensed nurse practitioner or a nurse practitioner student. No other exclusion criteria were recognized.

**Protection of Human Subjects**

This research capstone project falls under the status of exempt. The population of participants included adult nurse practitioners or nurse practitioner students over the age of 18. This study required a specific population which did not include children under 18, prisoners, specific ethnicity groups, or specific racial populations. There is no harassment or deception completed in order to obtain subjects for the continuing education offering.

In order to maintain confidentiality of the test results, each participant was given a specific code for the results. The participants are not placed at risk for a criminal or civil liable issue in completing the webinar and test questions. The participants are not placed at risk of damage to their reputation, finances, employment status or emotional health.

This research utilizes the criteria for the Committee for the Protection of Human Research Subjects (CPHRS) at Pittsburg State University, Pittsburg, Kansas. The information being obtained from the testing was utilized only for this research project. Completed test results are stored on a HIPPA compliant computer belonging to this researcher. Hard copies of the results will be stored in a locked filing cabinet in a locked room in the Irene Ransom Bradley School of Nursing. All data will be kept for a minimum of two years in a protected file then deleted from the hard drive.

**Ethical and Administrative Considerations**

Prior to seeking the consent of nurses agreeing to this research, authorization was be verified by an officer of the 4 State APN Group. Written informed consents were included prior to the first question of the demographic portion of the test. All data were considered confidential. Prior to the beginning of the presentation, all pretests and posttests were numbered to assure anonymity. Participants were verbally instructed they have a right to withdraw from the research at any time.

The ethical considerations potentially placing the participants in jeopardy for this capstone project were minimal. The design of the study was a quasi-experimental quantitative study involving the use of a pretest/posttest method. As previously stated, the demographics and results of the testing were handled in a confidential manner. The

anonymity code system was stored in a different secure file on this researcher's computer. A roster requiring name, state of licensure and Advanced Practice Registered Nurse (APRN) license number was utilized to confirm the validity of the participant as a licensed nurse practitioner and to document the status of the participant as a student.

**Instrument**

This quasi-experimental project utilized a lecture and PowerPoint presentation which is followed by a pretest and posttest. The instrument included an index of close-ended questions for each dimension with the pretest having additional demographic and professional practice questions not repeated on the posttest, (Appendix A). The original instrument utilized up-to-date evidence based literature from current guidelines and a comprehensive literature review (see Appendix A: Provider PCOS and Obesity Survey; pretest and posttest). The test questions were based on the literature review incorporating current practice guidelines along with research to support the inflammatory connection of PCOS and obesity. The pretest index was comprised of four main dimensions not including pretest professional demographic questions. These four categories were chosen to narrow the immense research on PCOS to be more focused on the connection of PCOS, obesity, inflammation, co-morbidities, diagnosis and treatment for weight loss in these patients.

These four dimensions included: (a) Inflammatory connections between obesity and PCOS; (b) diagnosis (c) inflammatory co-morbidities; and (d) medication management in the obese, PCOS patient. The posttest index followed the same format excluding the professional demographic questions. The style of questions included

multiple choice, True or False, and case studies. These questions addressed the following research questions. There were four questions per category. Each category included four related questions. Each correct answer will be given a one. An incorrect answer will be given a zero. Each category has a possibility of a zero to four in sum total.

**Dimensions**

A. Will the Continuing Education presentation on the new guideline for PCOS increase the knowledge of the inflammatory correlations of obesity and PCOS?

PCOS Index with Four Dimensions

1. Elevated Tumor Necrosis Factor Alpha is an inflammatory marker that is not associated with?

a. Obesity
b. Polycystic Ovarian Syndrome
c. Insulin Resistance
d. GLP-Production

2. Only patients who have both Polycystic Ovarian Syndrome and obesity have abnormalities in Tumor Necrosis Factor Alpha?

a. True
b. False

3. Glucose intake alters Tumor Necrosis Factor Alpha in Polycystic Ovarian Syndrome and causes:

a. A decrease in insulin
b. An elevation in androgens
c. A decrease in Luteinizing Hormone (LH)
d. None of the above

4. An elevation in Tumor Necrosis Factor Alpha decreases the production and increases the resistance of GLP-1 in PCOS. This correlation also occurs in obesity. This results in:

a. Insulin Resistance
b. Weight Gain
c. Glucose Elevation
d. All the Above

B. Will the Continuing Education presentation on the new guideline for PCOS increase the provider's knowledge base with diagnosing the patient with PCOS and obesity?

5. Current recommendations at the national American Diabetes Conference in 2016 involving a name change of PCOS would be?

   a. Complex Metabolic Syndrome
   b. Metabolic Reproductive Syndrome
   c. Reproductive Metabolic Syndrome
   d. Androgen Reproductive Syndrome
   e. None of the above

6. According to current practice guidelines for PCOS from the Endocrine Society, which guidelines are recommended in diagnosing PCOS?

   a. Rotterdam criteria
   b. NIH criteria
   c. AE-PCOS Society criteria
   d. None of the above

7. According to current practice guidelines for PCOS what screening measurements are assessed to screen for adiposity in PCOS?

   a. BMI
   b. Body Fat Composition
   c. Waist Circumference
   d. A and C

8. According to current practice guidelines what lab testing should be routinely ordered to diagnose patients with PCOS?

   a. TSH
   b. Hemoglobin A1C
   c. Lipid panel
   d. Insulin level

C. Will the Continuing Education presentation on the new PCOS guidelines increase the knowledge base of inflammatory co-morbidities and PCOS?

9. What is not considered a co-morbidity associated with PCOS?

a. Nonalcoholic fatty liver disease
b. Diabetes
c. Sleep apnea
d. Pancreatitis

10. According to the National Institute of Health, PCOS patients, with obesity have co-morbidities that worsen their disease state. These include:

a. Vitamin D deficiency
b. Prediabetes
c. Hypertension
d. All the Above

11. Mental health conditions are a co-morbidity of PCOS?

a. True
b. False

12. The following is a case study regarding co-morbidities in PCOS.

"Jane Doe," age 52 was recently released from the hospital with stage four uterine cancer after recently having both legs amputated from Insulin Dependent Diabetes Mellitus which is uncontrolled. She decided to not undergo any intervention for her cancer except for her Total Abdominal Hysterectomy. She tells the doctors and her family that she is just tired.

*..."I'm sorry family, friends, and health care providers. I have attempted to find someone since I was in high school to noticing my: missed periods, severe pelvic pain, weight gain, excessive hair, acne, insomnia, joint pain, edema, fatigue, episodes of rage, and low self-esteem. I ended up on lots of antidepressants and occasional in-patient psychiatric hospitalizations. But you know, they all said it was in my head. I was so confused because I literally ate like a bird but continued to gain weight. No one believed me. My parents took me to many specialists and they did say that I had Polycystic ovarian syndrome and prescribed birth control pills. I couldn't take them. Then I had someone prescribe 2000 mg of Metformin a day, 'tore my stomach up. Didn't want anything to do with that crap.*

*Years went by. Someone felt sorry for me and married me. We tried for years to have a baby; infertility drugs and all. We did in-vitro fertilization and after $50,000.00 and three attempts I did have a baby girl. She saved my life mentally. My focus was on her although I knew something was very wrong with me. This time in my life was hell. I was crazy most of the time, at least I thought. I kept gaining weight, feeling even more reclusive. I developed diabetes, hypertension, and fatty liver disease. I was prescribed so much medicine. And*

*since I hated metformin, my health care provider started me on insulin. That's when my life changed forever.*

*I kept gaining weight. I ended up with heart disease and multiple diagnoses with more medicine. Over 300 pounds at that point, I had a heart attack. Quadruple Bi-pass. Next, a divorce. My husband was done and told me that my health care providers said if I would just eat right and exercise that I would have been o.k. I was on diets and even had a gastric band. I felt so defeated.*

*My daughter was having the same problems and turned 18. She went to her local health care provider who sent her to someone who specializes in PCOS. She was 200 pounds, no periods, and excessive hair and acne. This provider started her on weight loss medicine, spironolactone for hyperandrogenism, liraglutide, and a low-glycemic food plan. In one year she lost 50 pounds, regained normal cycles, was sleeping, and developed a positive self- image.*

*Recently that health care provider sat down with me and cried with me after my decision to not undergo any treatment for my cancer. She told me if I would have been diagnosed and treated appropriately that I would probably have been a healthy and vibrant woman at this time. I just hope the new information on PCOS gets out so that women like me can be saved from this life imprisoned due to a misunderstood syndrome."*

12. When reading this case study consistent symptoms and health problems being a co-morbidity of PCOS, what appears to be the underlying issues causing this patient to fail?

    a. Self-Motivation
    b. Depression
    c. Inflammation
    d. Health Care Providers

D. Will the Continuing Education presentation on the new PCOS Guideline increase the provider's knowledge of prescribing weight loss medications for the obese patient with PCOS?

13. According to current practice guidelines in PCOS_____ is recommended for weight loss in the PCOS patient who is overweight or obese?

    a. Metformin
    b. Calorie restricted diet
    c. Phentermine
    d. Orlistat

14. Which is not recommended in the treatment of obesity in PCOS according to the current practice guidelines for PCOS?

a. Liraglutide
b. Exercise
c. Diet Control
d. Reduced calories

The following are **case studies**. Please read the following case study and respond to the questions based on the case.

15. "PR" is a 41-year-old female who comes to the clinic for a new patient consultation. At today's visit, she is 5 feet 3 inches tall and 140 pounds. Her body mass index is 25. She is not worried about her weight. She is more concerned with no menses and hair growth on her abdomen and back. She has severe acne that bothers her self-esteem. Only one pregnancy was induced by Clomid and weight loss. According to the 2016 AACE/ACE clinical practice guidelines for obesity and co-morbidity of PCOS, which in not a recommended treatment option?

    a. Liraglutide
    b. Metformin
    c. Bariatric Surgery
    d. Phentermine

You obtain "PR" family history. Her mother and grandmother are both obese and have been diagnosed with type 2 diabetes and hypertension. Both had a difficult time getting pregnant. They had severe issues with their cycles and losing weight. There was no family history of thyroid cancer or pancreatitis. Her previous history was free of those diagnoses as well. Her lab work showed elevated fasting insulin at 23, low B12 at 145, low Vitamin D at 17, Hgb A1c of 5.9 percent.

16. "PR" did not tolerate the Liraglutide, metformin, or orlistat. After six months she gained 30 pounds. What is the next intervention after lifestyle and diet according to the 2016 AACE/ACE obesity guidelines?

    a. Phentermine
    b. Bontril
    c. Roux-En-Y procedure
    d. Gastric Bi-Pass

**Content Validity**

Evaluating the validity of this index came from the literature review. The studies included areas of obesity and PCOS recently published which illustrated validity of each

test question in the instrument. This Index was developed to test the knowledge of best practice guidelines in PCOS and obesity. Three nurse practitioners working in the area of women's health or family practice were planned to evaluate the instrument based on their expertise. This was not completed due to the time frame available for presenting the study. An evaluation survey was offered to the initial presentation participants to test the validity of the instrument.

**Procedure**

The project consisted of a continuing education presentation utilizing a PowerPoint to describe current evidence based practice guidelines and a comprehensive literature review that related to PCOS in the obese patient. The participants were members of the 4 State APRN Group. Incentives were offered to gain voluntary participation in this project which included a pending one hour Continuing Education credit from the American Academy of Nurse Practitioners and a catered Italian dinner.

The continuing education presentation was delivered as the keynote presentation for the monthly 4 State APN Group. The continuing education program was presented in collaboration with American Academy of Nurse Practitioners, pending approval of the research for one hour of Continuing Education. The Sullivan Clinic provided a meal for the participants. The participants were given the pretest as they arrived for the meeting. The presentation was viewed during the dinner. After the dinner and the presentation was complete, the posttest was given followed by a question and answer session.

With completion of the education and posttest, an 11 question survey was given to validate the presentation and designed instrument for this study with two being open-

ended questions. The questionnaire was based on a four point Likert scale with 4 = strongly agree, 3 = agree, 2 = somewhat disagree, and 1 = strongly disagree. The questions included whether the participation in the activity allowed for better understanding of the four dimensions of the designed instrument. The second question evaluated how knowledge was presented. The third question evaluated the appropriateness of the presentation utilizing the design instrument. The fourth question evaluated the cohesiveness of the content topics with the designed instrument. The fifth question evaluated the fair and balanced coverage of the instrument. The sixth question evaluated the disclosure of any conflict of interest. The seventh question evaluated if the instrument was free from commercial bias. The eighth question evaluated the recommendation to colleagues. The ninth question evaluated the enhancement of current knowledge base with the use of the instrument.

After the confidential evaluation was completed by the 18 participants, the forms were placed in an envelope and secured in a safe at the Sullivan clinic. At a separate time, the 18 evaluations were tallied having 9 Likert scale questions. Scores were tallied. After totals of each questions were figured, Cronbach's Alpha was utilized to evaluate internal validity.

**Data Collection and Measurement**

This research consisted as a sample of convenience based on the quasi-experimental design for an index correlating four dimensions from the literature review. (Babbie, 2014). The population for this capstone project included nurse practitioners and nurse practitioner students from Kansas, Missouri, Oklahoma and Arkansas who attended the $

State APN Group's monthly meeting in October, 2016. The meeting was held at The Sullivan Clinic in Frontenac, KS. The 4-State APN is an area group of professionals that meet monthly. It was voluntary and no monetary compensation was offered to complete the webinar.

The pretest was secured in a confidential manner during the presentation. All data were kept confidential and all participants were kept anonymous. To measure the dependent variable, the correct response was valued as a one. The incorrect response was valued as zero. The total scores were tallied. The totals were divided by the number of correct answers to give a mean value. The highest total value was 16 with the lowest value being zero. There were four dimensions which had four questions each. Each dimension was tallied from a zero to four to evaluate the number of questions correct. These values were converted and presented as a percentage. Separating the total correct answers divided into four dimensions allowed for feedback analysis in the validity of the presentation and instrument.

Statistical analysis was performed utilizing *Excel* in spreadsheet format. Statistical significance allowed for a probability level acceptable as $p<0.05$. A paired t-test was conducted on the pretest and posttest results; one = yes, zero = no. Evaluation measures assessed within the parameters of each dimension of the overall project. Quantitative analysis used descriptive statistics and standard deviation to identify whether pre-test evaluations were statistically significant in comparison with post-test data. The correlation between different variables were determined again using *P* value $<0.05$ as an ANOVA/Spearman.

**Evaluation Measures Linked to Objectives**

Evaluation measures were linked to the objectives utilizing the logic model (Figure 2). This project measured the participants' knowledge of the diagnosis and treatment of obese PCOS patients with updated treatment guidelines before and after an educational program. The measured outcomes being evaluated were diagnostic criteria, diagnosis, pathophysiology, and treatment. A positive outcome was indicated by an increase in percentage of correct answers posttest. The long term goal of this research was to increase the awareness and knowledge of the diagnosis and treatment of the PCOS patient with obesity. Due to time this was not able to be measured with this research.

The research instrument was in a pretest and posttest format. The dependent variable consisted of 16 questions. A survey tool was established specific for this research since it involved a paradigm shift in the diagnosis and treatment of PCOS in obesity. It included multiple styles of questions including true and false, multiple choice, and case studies. An over-all score was utilized for the results. Table 7 describes the projected results of this research project.

**Table 7.** Objectives, Measurements and Outcomes

| Objective | Measurement | Outcome | Analysis |
|---|---|---|---|
| Participants will identify correctly the inflammatory correlations of obesity and PCOS. | Participants will have an increase in correct responses regarding inflammatory correlations between obesity and PCOS | Participants will choose the correct inflammatory correlations in the obesity and PCOS. | Paired t-test pretest/posttest format. |
| The continuing education presentation will | Participants increase correct answers concerning the | Participants will appropriately identify the correct | Paired t-test pretest/posttest format. |

| | | | |
|---|---|---|---|
| increase the provider's ability in diagnosing the patient with PCOS and obesity? | diagnosis of patients with PCOS and obesity. | diagnosis of patients with PCOS and obesity. | |
| The continuing education presentation will increase the knowledge of inflammatory co-morbidities with obesity and PCOS? | Participants increase correct answers concerning the increase the knowledge of inflammatory co-morbidities with obesity and PCOS. | Participants will recognize the inflammatory co-morbidities with PCOS and obesity. | Paired t-test pretest/posttest format. |
| The continuing education presentation will increase the provider's knowledge in prescribing weight-loss medications for the obese patient with PCOS? | Participants will have an increase in correct responses to questions regarding the treatment the obese patient with PCOS with weight loss medications | Participants will learn the correct treatment of the obese patient with PCOS with weight loss medications. | Paired t-test pretest/posttest format. |

**Conclusion**

With PCOS occurring in over 5 million women of childbearing age, continuous therapies and understanding of the cause is imperative. This researcher has witnessed hundreds of case studies personally with both positive and negative outcomes because of the lack of FDA approved therapies for treatment as well as a misunderstanding of the disease process alone.

GLP-1 agonists have been shown in small studies across the world to decrease weight and inflammation in these affected women. Hopefully through persistence and education, this research is part of the revolution of treatments and further research for this continued complex disease which has imprisoned the quality of life of millions of women thus far.

This project consisted of an educational program, the design of a pretest and posttest instrument in the form of an index, and validation of the instrument in the form of a 4 point Likert scale. Chapter IV discusses the results of the study.

# CHAPTER IV

# FINDINGS

## Introduction

The findings in this scholarly project were analyzed to determine if an increase in knowledge emerged. The potential increase in the knowledge acquired regarding PCOS practice guidelines following a continuing education presentation on new guidelines for obese, PCOS patients. A group of nurse practitioners and nurse practitioner students listened to the presentation and observed a PowerPoint presentation after a pretest over the contents of the presentation. A posttest was completed after the presentation was given. The sample included 18 total participants at this evening event. The data were analyzed providing quantitative data. The survey provided information on the educational offering and the posttest validated whether an increase in knowledge level of PCOS practice guidelines was observed. Following the collection of demographic data, the pretest data were collected regarding current guideline information and the pathophysiology of inflammation and PCOS. After the presentation, the same test was given to the subjects. The pretest and posttest contained sixteen questions separated into four distinct domains:

1. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of the correlations between obesity and PCOS?
2. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of diagnosing the patient with PCOS and obesity?
3. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of inflammatory co-morbidities and PCOS?
4. Will the Continuing Education presentation on the new PCOS Guideline increase the provider's knowledge of prescribing weight loss medications for the obese patient with PCOS?

**Demographic Data**

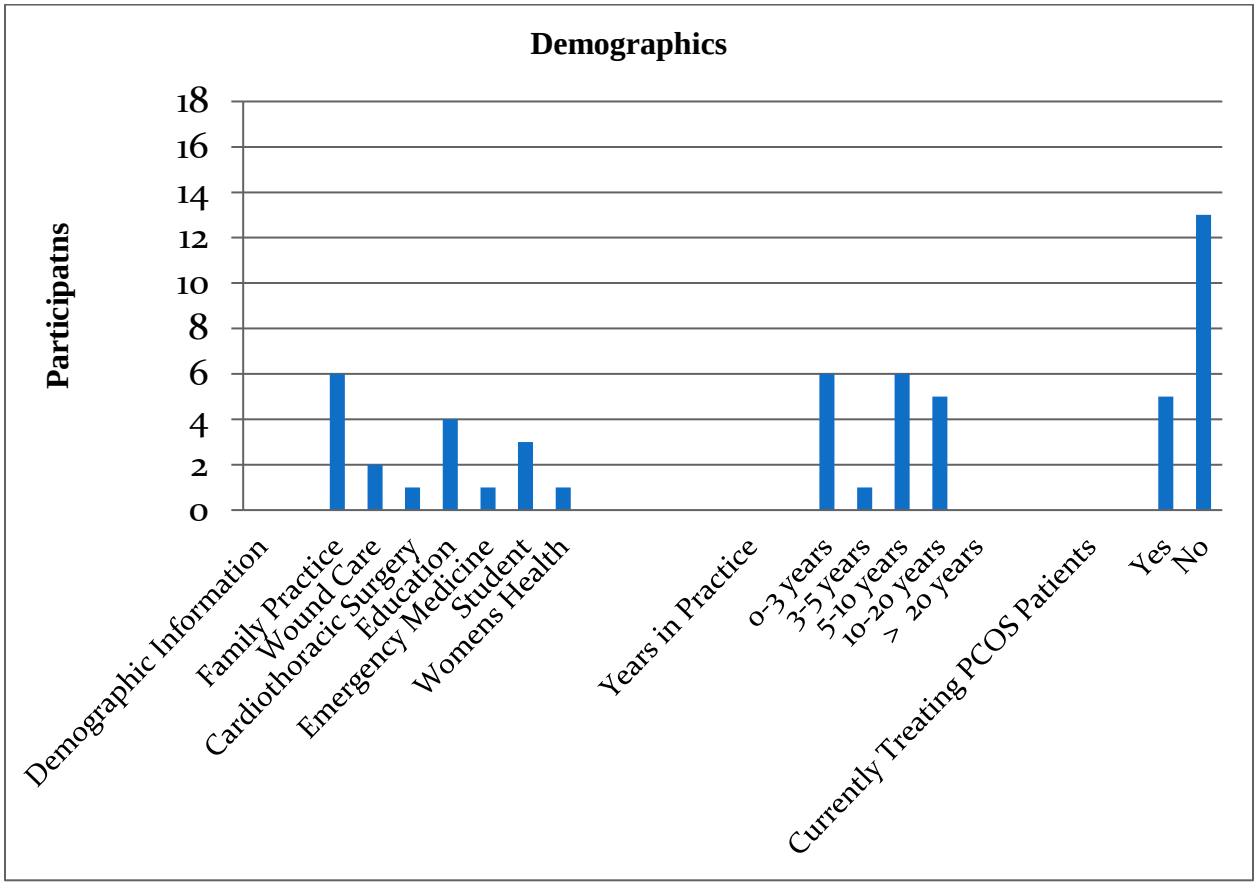
The demographic data gathered from the participants included practice setting and years of experience and is Presented in Table 5. Thirty-three percent (N=6) of practitioners were employed in a Family Practice setting. Nurse practitioners employed in Women's Health included one participant (N=1 or six percent). Six percent (n=1) were employed in the Emergency Department. The student participants consisted of 17 percent (n=3) of the subjects. Nurse Educators represented 22 percent (n=3). There was one Cardiothoracic Nurse Practitioner in the group of subjects which represented six percent of the population. Wound Care nurse practitioners represented eleven percent of the population (n=2).

The total years as a nurse practitioner was calculated from 0-3 years, 3-5 years, 5-10 years, and 10-20 years. Thirty-three percent represented 0-3 years of clinical

experience as a nurse practitioner. Six percent represented 3-5 years. Thirty-three percent represented 5-10 years and twenty-eight percent represented 10-20 years.

In a yes or no question, each participant was asked if they were currently taking care of patients with PCOS. The responses revealed that 28 percent of the subjects were currently taking care of patients with PCOS.

**Table 8.** Demographic Information of Attendance at Presentation




**Pretest and Posttest**

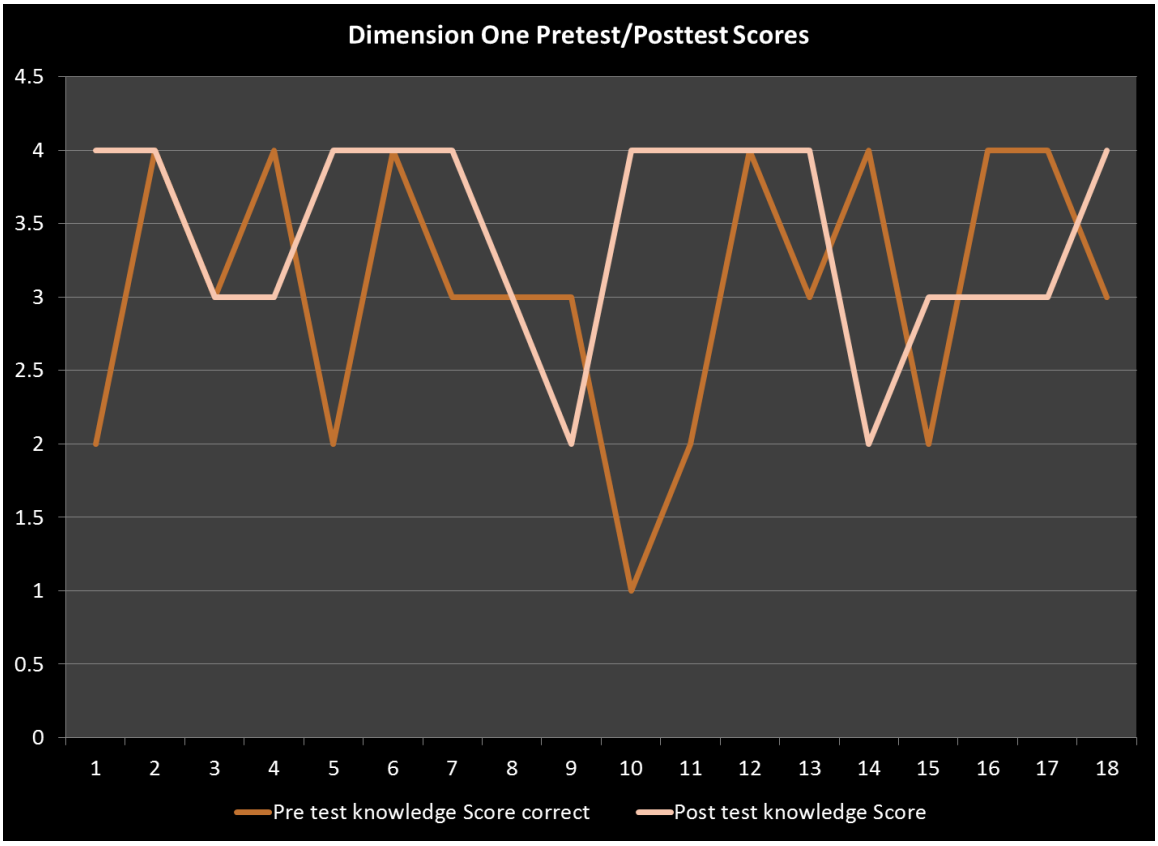
All of the subjects participating in the project were given a pretest prior to the presentation and a posttest followed. The testing was grouped according the name on the test giving permission to use the results in this project. Each test was identical in each of

the 16 questions. These questions were divided into four domains to make up an index. The first domain included questions on the inflammatory correlations of obesity and PCOS. The second domain included questions on the diagnosis of a patient with obesity and PCOS. The third domain included questions on the inflammatory co-morbidities and PCOS. The fourth domain included questions regarding the new guidelines in prescribing weight loss medication to the obese female with a co-morbidity of PCOS.

**Results**

**Quantitative data.** Each Dimension was tallied separately with 4 possible correct answers within each of the four categories. The mean pretest score for Dimension one was 3.0556 with a standard deviation of 0.9376 in the pretest group. The mean posttest score for Dimension one was 3.4444 with a standard deviation of 0.70479. The differences in the pretest score and the posttest score had a mean of -0.3889

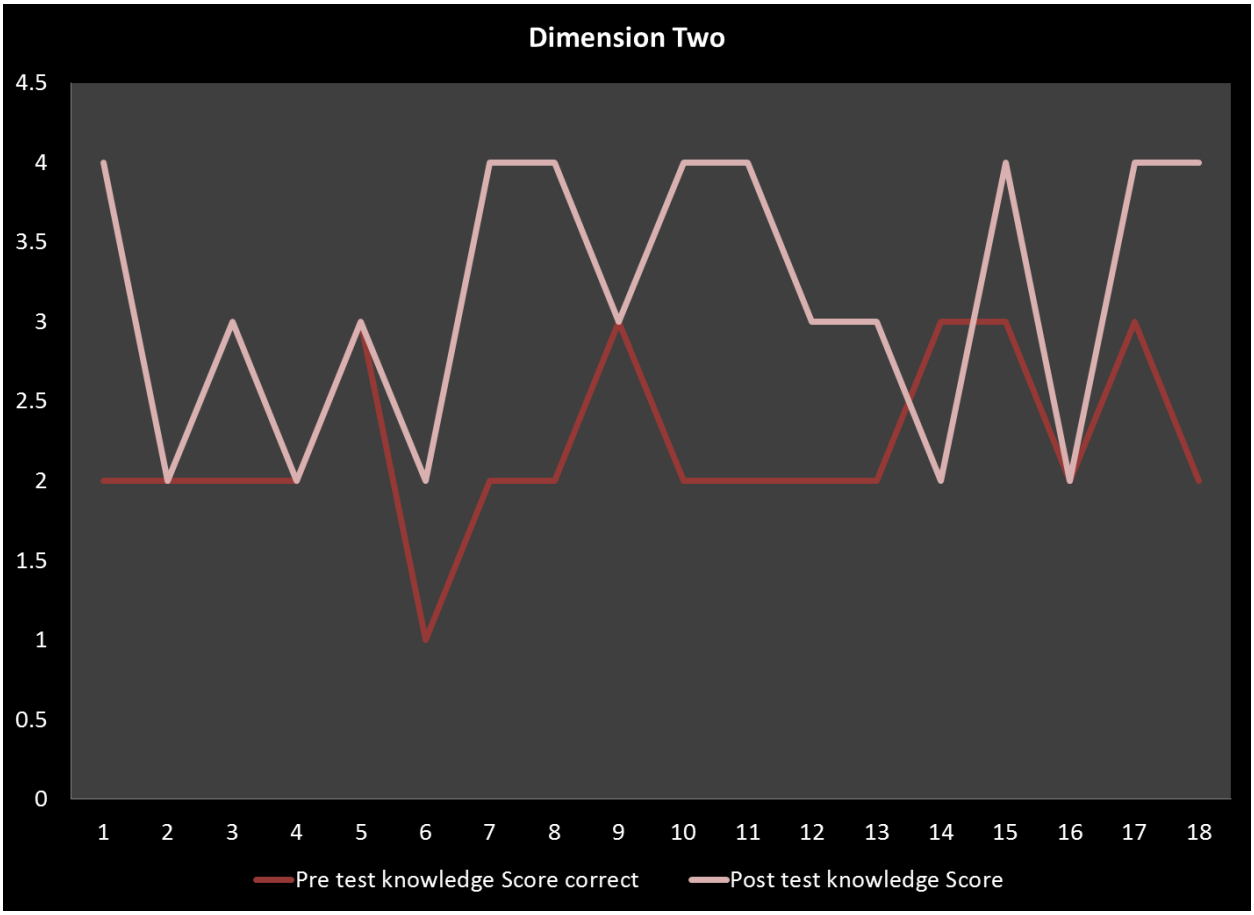
**Table 9.** Dimension One Pretest/Posttest Scores




with a standard deviation of 1.33456. The difference in test scores was not found to be statistically significant although most respondents had an increase in posttest scores as evidenced in Table 9.

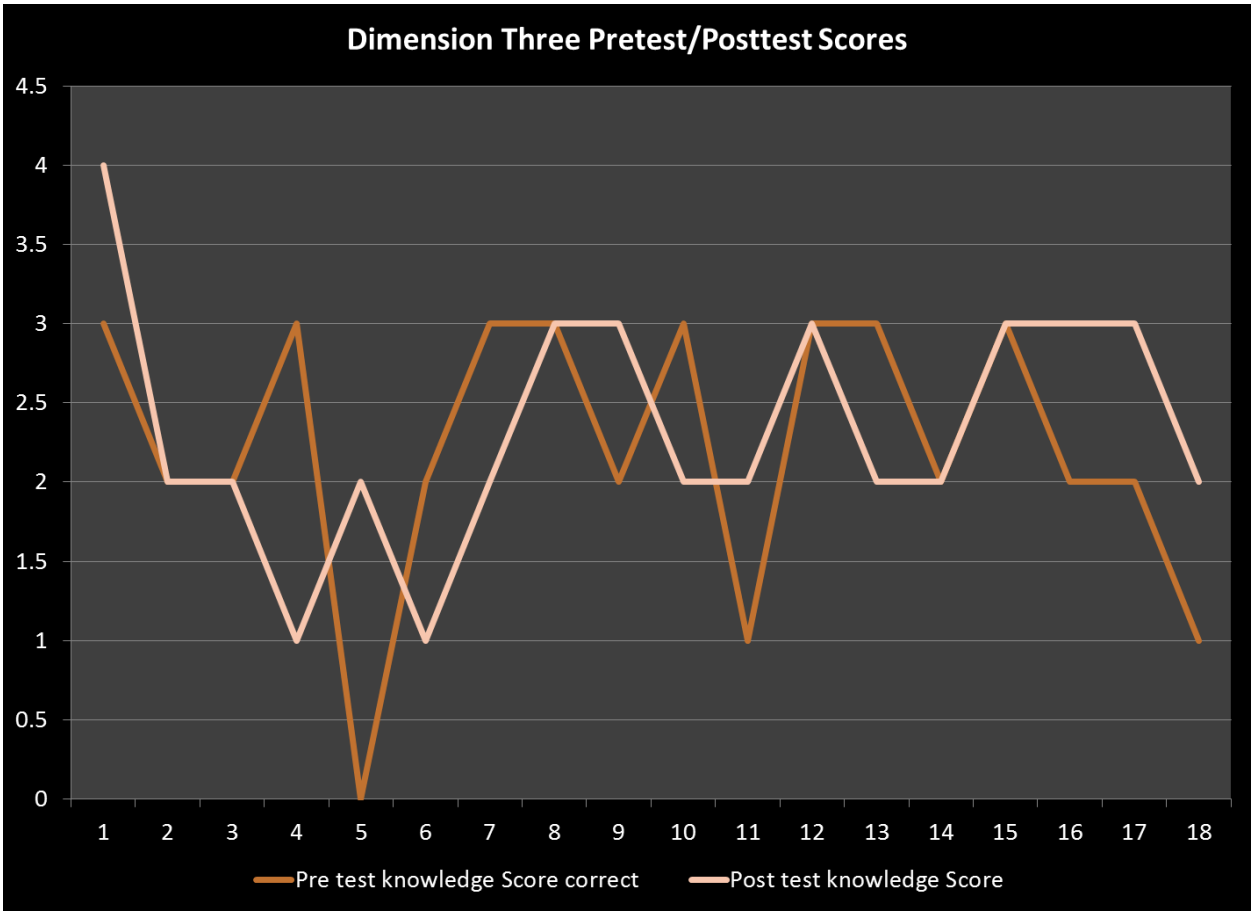
The mean pretest score for Dimension two was 2.2222 with a standard deviation of 0.54832 in the pretest group. The mean posttest score for Dimension one was 3.1667 with a standard deviation of 0.87549. The differences in the pretest score and the posttest score had a median of -0.9444 with a standard deviation of 0.93769. Statistical significance was found at $p<0.001$. The majority of respondents had an increase in posttest scores as evidenced in Table 10.

**Table 10.** Dimension Two pretest and posttest results



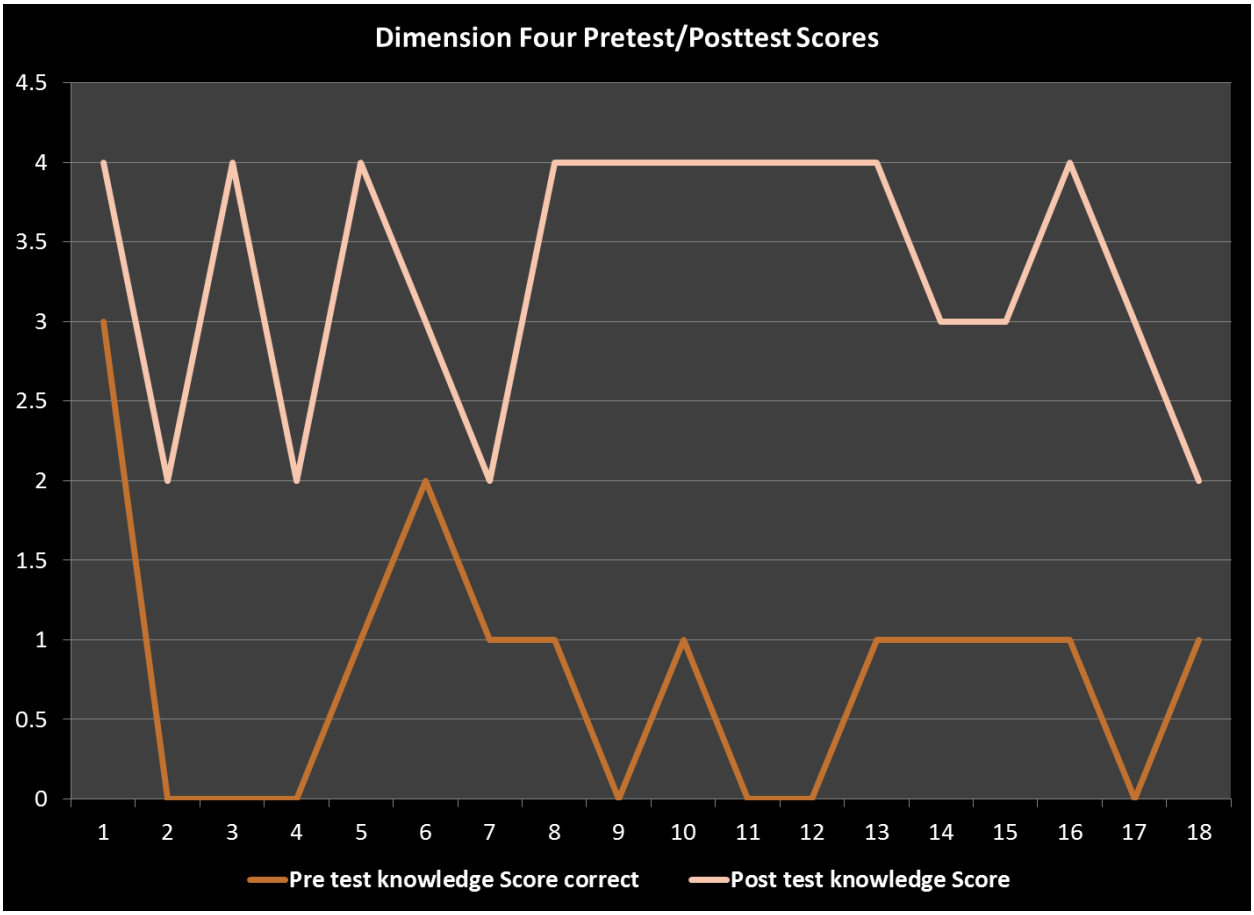

The mean pretest score for Dimension three was 2.2222 with a standard deviation of 0.8782 in the pretest group. The mean posttest score for Dimension one was 2.3333 with a standard deviation of 0.76696. The differences in the pretest score and the posttest score had a mean of -0.1111 with a standard deviation of 1.02262. Statistical significance was not found with a $p > 0.05$. Some respondents had a decrease in posttest scores as evidenced in table 11.

**Table 11.** Dimension Three Pretest/Posttest Scores




The mean pretest score for Dimension four was 0.7778 with a standard deviation of 0.80845 in the pretest group. The mean posttest score for Dimension one was 3.3333 with a standard deviation of 0.84017. The differences in the pretest score and the posttest score had a mean of -2.5556 with a standard deviation of 1.09664. All respondents had an increase in posttest scores as evidenced in table 12. Statistical Significance was found in this dimension at $p<0$.

**Table 12.** Dimension four Pretest/Posttest Scores




**Validity of the index.** Due to time constraints of the acceptance date of the proposal and the change of dates in the project presentation, validity of the index was tested at this presentation with all 18 subjects completing the 4 point Likert scale questionnaire with a place for open ended suggested changes. Nine questions were asked. There were no open ended suggestions noted. Cronbachs' Alpha was utilized to test the internal validity of the

**Table 13.** Paired t-test sampling revealing paired differences

| Paired Samples Test | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Paired Differences | | | | | | | |
| | | | | 95% Confidence Interval of the Difference | | | | |
| | Mean | Std. Deviation | Std. Mean Error | Lower | Upper | t | df | Sig. (2-tailed |
| Pair 1 Pretest-Posttest | -0.3889 | 1.33456 | 0.31456 | -1.0526 | 0.27477 | -1.236 | 17 | 0.233 |
| Pair 2 Pretest-Posttest | -0.9444 | 0.93769 | 0.22099 | -1.4107 | -0.47819 | -4.274 | 17 | 0.001 |
| Pair 3 Pretest-Posttest | -0.1111 | 1.02262 | 0.24103 | -0.6197 | 0.39743 | -0.461 | 17 | 0.651 |
| Pair 4 Pretest-Posttest | -2.5556 | 1.09664 | 0.25848 | -3.1009 | -2.01021 | -9.887 | 17 | 0 |

pretest, posttest and survey. The pretest results were 0.974532. The posttest results were 0.418406285. The 4 point Likert scale survey results were 0.658537. According to these results, the posttest did not score well according to Cronbachs' Alpha. Better presentation of the information should be considered in the future.

## Chapter Summary

Chapter four delineated the statistical analysis of the pretest and posttest of the capstone project. Overall, the learning objectives did show an increase in knowledge from the pretest to the posttest results. Each of the four research questions focused on the diagnosis, co-morbidity, and treatment of the obese, PCOS patient. The quantitative data gathered displayed an increase in the posttest scores with two out of the four dimensions showing a statistical significance with a p value at <0.000001. The findings of the study

did support the title being a paradigm shift in the diagnosis and treatment of PCOS. Continued education on recently updated guidelines in PCOS and obesity is warranted to continue dissemination of this knowledge in nursing. Chapter V discusses the future recommendations for research along with limitations of the project and conclusions.

**Table 14.** PCOS Descriptive Statistics

| PCOS Index Descriptive Statistics | | | | | |
|---|---|---|---|---|---|
| | N | Min. Correct | Max. Correct | Mean | Std. Deviation |
| | | | | | |
| Dimension 1 Pretest | 18 | 1 | 4 | 3.0556 | 0.9376 |
| Dimension 1 Posttest | 18 | 2 | 4 | 3.4444 | 0.70479 |
| | | | | | |
| Dimension 2 Pretest | 18 | 1 | 3 | 2.2222 | 0.54832 |
| Dimension 2 Posttest | 18 | 2 | 4 | 3.1667 | 0.87549 |
| | | | | | |
| Dimension 3 Pretest | 18 | 0 | 3 | 2.2222 | 0.8782 |
| Dimesnion 3 Posttest | 18 | 1 | 4 | 2.3333 | 0.76696 |
| | | | | | |
| Dimension 4 Posttest | 18 | 0 | 3 | 0.7778 | 0.80845 |
| Dimension 4 Posttest | 18 | 2 | 4 | 3.3333 | 0.84017 |

# CHAPTER V

# CONCLUSIONS

## Introduction

This project provided nurse practitioners and nurse practitioner students the opportunity to receive an education offering on the recently released practice guidelines on obesity and the PCOS patient. The continuing education offering was designed utilizing an instrument to test knowledge gained in a pretest and posttest fashion. The research design allowed the ability to conclude whether a statistically significant analysis was positive after the presentation to increase the knowledge in this subject area. The study focused on these four research questions:

1. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of the correlations between obesity and PCOS?
2. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of diagnosing the patient with PCOS and obesity?
3. Will the Continuing Education presentation on the new PCOS Guideline increase the knowledge base of inflammatory co-morbidities and PCOS?

4. Will the Continuing Education presentation on the new PCOS Guideline increase the provider's knowledge of prescribing weight loss medications for the obese patient with PCOS?

The nurse practitioner continuing education program was presented to a local group of nurse practitioners and nurse practitioner students. A pretest and posttest was completed prior to and immediately following the educational offering.

**Limitations**

The limitation of this project was the paradigm shift in how PCOS is diagnosed and treated in the obese population. It was difficult to attempt to present this information on the inflammatory connections between PCOS and obesity rather than just focusing on the gynecological aspect of PCOS. A second limitation involved having the information and results from a sample of convenience and would a different population setting produce similar results? All participants were female (n=18). A third limitation was the design of the instrument for this project. Due to limited time in the presentation and utilization of the instrument, the validity was not able to be completed prior to the educational PowerPoint presentation. This presentation was utilized for validation of the tool using a 4 point Likert scale survey. These questions were developed by the primary investigator and not standardized. All efforts were taken to validate the instrument for future educational opportunities.

Two out of four dimensions of the pretest and posttest comparison were found to be statistically significant. There needs to be better assimilation of education from the

PowerPoint for an increase in gained knowledge from the PowerPoint to increase statistical significance of test scores in all four dimensions.

**Future Research**

Due to the updated practice guidelines for PCOS and obesity, this project allows for a change in the approach to treating PCOS. Research validates the need for education at the provider level in the pathophysiology of PCOS. Even after the PowerPoint presentation, some questions continued to be answered incorrectly.

In May, 2016, it was suggested that PCOS should have a name change of the condition to Metabolic Reproductive Disorder. With representing a metabolic connection to the disease state, Nursing can begin to support this concept by educating and collaborating with other health care professions to assist in the positive outcomes in these women.

**Sustainability**

The sustainability of this research involves the continued search for opportunities to disseminate the information in this capstone project. With PCOS being the number one endocrine disorder in women, it is of great need for this approach with PCOS be supported. Opportunities for educating the public and healthcare professionals will be pursued. Television programs along with journal articles will be pursued.

**Dissemination of Information**

This project along with the statistical analysis of the increased knowledge in PCOS did find the need for more knowledge on this research in healthcare and the general public. For the medical community, updated guidelines in PCOS and obesity will need to be taught in schools and continuing education programs. For the public, allowing

a simple explanation of this research is needed to better understand the knowledge at a basic level. Acceptance of this change in the approach to PCOS is important across the board.

This PowerPoint presentation is pending approval for one Continuing Education credit through American Academy of Nurse Practitioners organization. This Continuing Education program has the potential to disseminate this knowledge across all forms of education pathways. Another potential idea for dissemination of information would include a policy brief for state and national legislatures which would allow for government backing in funding opportunities and government support.

**Chapter Summary**

This DNP Scholarly Project allowed for the participants to be given an opportunity to enjoy an Italian dinner along with a continuing education presentation regarding the updated guidelines for PCOS and obesity. In addition, the continuing education program provide education regarding the inflammatory connections of PCOS and obesity. Studies and current trends in PCOS reveal that updated education of current knowledge is lacking. The research also reveals the misleading name as it relates to an ovarian problem rather than a metabolic, inflammatory etiology. The research provided in this capstone project is vital to linking inflammation to PCOS and obesity in how the treatment of this disorder will be approached in the future. The co-morbidities of PCOS and obesity have the potential to increase the risk of multiple inflammatory disease such as diabetes, heart disease, and cancer. Primary care providers must be given the opportunity to continue understanding the paradigm shift in the diagnosis and treatment of obesity in the PCOS patient.

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# APPENDIX

## APPENDIX A

### A Paradigm Shift in the Diagnosis and Treatment of Polycystic Ovarian Syndrome: A Practice Change Index
### Four Dimensions

I, _____, authorize my consent to complete the pre/posttest in order to identify areas of improvement for this presentation. Recommendations will be written on the posttest.

## APPENDIX B

## PRETEST/POSTTEST

**PCOS Index with Four Dimensions**

**A. Will the Continuing Education presentation on the new guideline for PCOS increase the knowledge of the inflammatory correlations of obesity and PCOS?**

1. Elevated Tumor Necrosis Factor Alpha is an inflammatory marker that is not associated with?
    a. Obesity
    b. Polycystic Ovarian Syndrome
    c. Insulin Resistance
    d. Increased GLP-Production

2. Only patients who have both Polycystic Ovarian Syndrome and obesity have abnormalities in Tumor Necrosis Factor Alpha?
    a. True
    b. False

3. Glucose intake alters Tumor Necrosis Factor Alpha in Polycystic Ovarian Syndrome and causes:
    a. A decrease in insulin
    b. An elevation in androgens
    c. A decrease in Luteinizing Hormone (LH)
    d. None of the above

4. An elevation in Tumor Necrosis Factor Alpha decreases the production and increases the resistance of GLP-1 in PCOS. This correlation also occurs in obesity. This results in:
    a. Insulin Resistance
    b. Weight Gain
    c. Glucose Elevation
    d. All the Above

**B. Will the Continuing Education presentation on the new guideline for PCOS increase the provider's knowledge base with diagnosing the patient with PCOS and obesity?**

5. Current recommendations at the national American Diabetes Conference in 2016 involving a name change of PCOS would be?
    a. Complex Metabolic Syndrome
    b. Metabolic Reproductive Syndrome
    c. Reproductive Metabolic Syndrome
    d. Androgen Reproductive Syndrome
    e. None of the above

6. According to current practice guidelines for PCOS from the Endocrine Society, which guideline is recommended in diagnosing PCOS?
    a. Rotterdam criteria
    b. NIH criteria
    c. AE-PCOS Society criteria
    d. None of the above

7. According to current practice guidelines for PCOS what screening measurements are assessed to screen for adiposity in PCOS?
    a. BMI
    b. Body Fat Composition
    c. Waist Circumference
    d. A and C

8. According to current practice guidelines what lab testing should be routinely ordered to diagnose patients with PCOS?
    a. Free Testosterone
    b. Uric Acid
    c. ESR
    d. CBC

**C. Will the Continuing Education presentation on the new PCOS guidelines increase the knowledge base of inflammatory co-morbidities and PCOS?**

9. What is not considered a co-morbidity associated with PCOS?
    a. Nonalcoholic fatty liver disease
    b. Diabetes
    c. Sleep apnea
    d. Pancreatitis

10. According to the National Institute of Health, PCOS patients, with obesity have co-morbidities that worsen their disease state. These include:

    a. Insulin Resistance
    b. Prediabetes

c. Hypertension
d. All the Above

11. Mental health conditions are a co-morbidity of PCOS?
    a. True
    b. False

**The following is a case study regarding co-morbidities in PCOS**.

"Jane Doe," age 52 was recently released from the hospital with stage four uterine cancer after recently having both legs amputated from Insulin Dependent Diabetes Mellitus which is uncontrolled. She decided to not undergo any intervention for her cancer except for her Total Abdominal Hysterectomy. She tells the doctors and her family that she is just tired.

"I'm sorry family, friends, and health care providers. I have attempted to find someone since I was in high school to noticing my: missed periods, severe pelvic pain, weight gain, excessive hair, acne, insomnia, joint pain, edema, fatigue, episodes of rage, and low self-esteem. I ended up on lots of antidepressants and occasional in-patient psychiatric hospitalizations. But you know, they all said it was in my head. I was so confused because I literally ate like a bird but continued to gain weight. No one believed me. My parents took me to many specialists and they did say that I had Polycystic ovarian syndrome.

Years went by and I married and tried for years to have a baby. I even attempted infertility drugs and that didn't work. We did in-vitro fertilization and after $50,000.00 I did have a girl. I knew something was very wrong with me. This time in my life was hell. I was crazy most of the time. I kept gaining weight, feeling even more reclusive. I developed diabetes, hypertension, and fatty liver disease. I was prescribed so much medicine. And since I hated metformin, my health care provider started me on insulin. That is what fueled my downward slide.

I kept gaining weight. Over 300 pounds at that point, I had a heart attack. Quadruple Bi-pass. Next, a divorce. My husband was done and told me that my health care providers said if I would just eat right and exercise that I would have been o.k. I was on diets, ran 5ks, ate 500 calories, drank lemon/vinegar water, and even a gastric band. I felt so defeated.

My daughter was having the same problems and turned 18. She went to her local health care provider who sent her to someone who specializes in PCOS. She was 200 pounds, no periods, and excessive hair and acne. This provider started her on weight loss medicine, spironolactone for hyper-androgenism, liraglutide, and a low-glycemic food plan. In one year she lost 50 pounds, regained normal cycles, was sleeping, and developed a positive self- image.

Recently that health care provider sat down with me and cried with me after my decision to not undergo any treatment for my cancer. She told me if I would have been diagnosed and treated appropriately that I would probably have been a healthy and vibrant woman at this juncture instead of hospice."

12. When reading this case study, consistent symptoms and health problems being a co-morbidity of PCOS, what appears to be the underlying issues that caused this patient to fail?
    a. Self-Motivation
    b. Depression
    c. Inflammation
    d. Health Care Providers

**D. Will the Continuing Education presentation on the new PCOS Guideline increase the provider's knowledge of prescribing weight loss medications for the obese patient with PCOS?**

13. According to current 2013 Endocrine Society practice guidelines in PCOS_____ is recommended for weight loss in the PCOS patient who is overweight or obese?
    a. Metformin
    b. Calorie restricted diet
    c. Phentermine
    d. Orlistat

14. Which is not recommended in the treatment of obesity in PCOS according to the current 2013 Endocrine Society practice guidelines for PCOS?
    a. Liraglutide
    b. Exercise
    c. Diet control
    d. Reduced calories

15. "PR" is a 41-year-old female who comes to the clinic for a new patient consultation. At today's visit, she is 5 feet 3 inches tall and 140 pounds. Her body mass index is 25. She is not worried about her weight. She is more concerned with no menses and hair growth on her abdomen and back. She has severe acne that bothers her self-esteem. Only one pregnancy was induced by Clomid and weight loss. According to the 2016 AACE/ACE clinical practice guidelines for obesity and co-morbidity of PCOS, which in not a recommended treatment option?
    a. Liraglutide
    b. Metformin
    c. Bariatric Surgery
    d. Phentermine

16. You obtain “PR’s” family history. Her mother and grandmother are both obese and have been diagnosed with type 2 diabetes and hypertension. Both had a difficult time getting pregnant. They had severe issues with their cycles and losing weight. There was no family history of thyroid cancer or pancreatitis. Her previous history was free of those diagnoses as well. Her lab work showed elevated fasting insulin at 23, low B12 at 145, low Vitamin D at 17, HgbA1c of 5.9%. “PR” did not tolerate the Liraglutide, metformin, or orlistat. After six months, she gained 30 pounds. What is the next intervention after lifestyle and diet according to the 2016 AACE/ACE obesity guidelines?
    a. Phentermine
    b. Bontrix
    c. Roux-en-Y Gastric Bi-Pass
    d. Tradjenta

**Thank you for completing the pre/posttest!**

**Recommendations for future presentations:**