Application of a polycystic ovarian syndrome (PCOS) diagnostic questionnaire in clinical practice

Minnetta Williams FNP-BC

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APPLICATION OF A POLYCYSTIC OVARIAN SYNDROME (PCOS) DIAGNOSTIC QUESTIONNAIRE IN CLINICAL PRACTICE

by

MINNETTA WILLIAMS, FNP-BC

A SCHOLARLY PROJECT

Submitted in partial fulfillment of the requirements for the Degree of Doctor of Nursing Practice

to

The School of Graduate Studies

of

The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA
2017
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Submitted by Minnetta Williams in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the scholarly project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this scholarly project. We further certify that we have reviewed the scholarly project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

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(Date)

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Committee Chair

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Program Director

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College of Nursing Dean

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Graduate Dean
ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice  College: Nursing
Name of Candidate: Minnetta Williams
Title: Application of a Polycystic Ovarian Syndrome (PCOS) Diagnostic Questionnaire in Clinical Practice

Introduction: Polycystic Ovarian Syndrome (PCOS) is the most common cause of menstrual dysfunction and hyperandrogenism. PCOS is recognized as a heterogeneous disorder that results in overproduction of androgens, primarily from the ovaries and leads to anovulation, hirsutism, and insulin resistance. PCOS diagnosis is challenging for providers because of the varying diagnostic criteria and inconsistency of the patients’ complaints. A validated diagnostic screening questionnaire would be very helpful in assisting providers in making a clinical diagnosis of PCOS. The purpose is to have an effective diagnostic screening questionnaire that can be used in any provider’s office to assist in diagnosing probable PCOS. Objectives: The objectives were to determine how many Health Care professionals (HCP’s) used the PCOS screening questionnaire to identify probable PCOS, determine if questionnaire was helpful in diagnosing PCOS patients, identify feasibility of the utilization of PCOS Screening questionnaire in clinical practice, and to identify barriers in the use of the PCOS diagnostic screening questionnaire. Implementation Plan: Health care professionals (Nurse Practitioners and Physicians) that worked in Obstetrics/Gynecology and Family Practice/Adult Medicine participated in the study. A pre-test was given to each provider before they started using the PCOS screening questionnaire. The health care professional used the PCOS screening questionnaire in
their office for 3 months with patients that had complaints of menstrual dysfunction, hirsutism, obesity, or acne. At the conclusion of the 3 months, the health care provider was given a post-test. All participation was voluntary. **Results:** Before participation in the project, none of the providers had used a diagnostic PCOS screening questionnaire. 62.5% of the health care providers diagnosed 1-5 patients with PCOS; 12.5% diagnosed 5-10 patients with PCOS; and 25% diagnosed >10 patients with PCOS. **Conclusion:** All the health care providers found the PCOS screening questionnaire to be helpful and effective in diagnosing PCOS patients and would continue to use in their practice. In addition, the providers would recommend the questionnaire to their colleagues.
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Most of all, I would like to thank my family and friends for all their love, support, and encouragement during the journey. I would like to thank my parents for always encouraging me to push forward to be the best that I can be. I also would like to thank my loving and very supportive husband, Jonathan, for always encouraging me and pushing me to work a little bit harder to reach my goals. I want to thank my three wonderful children, Joshua, Jeremiah, and Gabrielle for providing much love and unending inspiration. I love you all!
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Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder and cause of anovulatory infertility in childbearing age women (Tang et al., 2006). This disease is complex and the exact physiology is unclear (Garad, Teede, & Moran, 2011). What is known about this condition is that hormone imbalance is the underlying problem. Hyperandrogenism and insulin resistance contributes to the etiology process of PCOS (Garad, Teede, & Moran, 2011). Women with PCOS can present with polycystic ovaries, but it is not necessary for this diagnosis (Boyle & Teede, 2012).

This population of women may have a plethora of symptoms and findings related to their condition. According to Madnani, Khan, Chauhan, Parmar (2013), the following signs and symptoms are common for women of reproductive age with PCOS: metrorrhrea or amenorrhea, acne, irregular menses, hirsutism, alopecia. Additional symptoms included metabolic syndrome, obesity, insulin resistance, acanthosis nigricans, Type 2 diabetes, dyslipidemias, hypertension, non-alcoholic liver disease, and obstructive sleep apnea (Madnani et al., 2013).

Moran et al. (2009) reported PCOS affects 5-10% of women who are in the reproductive age group. Occurring as young as 11, this condition has affected as many as 5 million women of childbearing age in the US alone (Eisenburg, 2014).

According to Sirmans & Pate (2014) 30% of the PCOS population will experience normal menses. Several studies have suggested that hypertension is more prevalent in the PCOS population compared to the general population (Bentley-Lewis, Seely, & Dunaif, 2011). According to Apridonidze, Essah, Iuorno, & Nestler (2005),
hypertension represented 45% of the PCOS population. A common factor in PCOS is obesity. Obesity seems to pose a higher risk for hypertension in the PCOS population. Women with PCOS may lack a healthy vasculature secondary to a decrease in nocturnal blood pressure (Bentley-Lewis, et al., 2011) and experience elevations in their mean arterial and ambulatory systolic pressures (Carmina, 2009). Often times PCOS is undiagnosed in women. This means that this population of women is uneducated regarding their condition, possible co-morbidities, and treatment options. It is imperative for health care providers to diagnose PCOS early to decrease risks for comorbidities. Understanding some of the PCOS related comorbidities such as obesity, hypertension, dyslipidemia, cancer, and Type 2 diabetes, will help this population live a balanced and healthier life.

Apridonidze et al. (2005) reported obesity in 67% of women with PCOS. Obesity seems to have increased over the years, which has had a big impact on the development of chronic conditions such as metabolic syndrome, coronary heart disease and type 2 diabetes (Apridonidze, et al., 2005). Reproductive health is significantly impacted by obesity due to increased body weight that contributes to ovulatory infertility. Overweight and obesity are commonly seen in PCOS women (Apridonidze, et al., 2005). Having excess body weight can exacerbate symptoms of PCOS such as hyperandrogenism, menstrual problems, infertility, insulin resistance, dyslipidemia, increased risk of metabolic syndrome, impaired glucose tolerance, and type 2 diabetes (Lim, Norman, Davies, & Moran, 2012).

Cardiovascular risk factors are significant among the PCOS population (Lim, et al, 2012). The risk varies according to the levels of LDL, HDL, triglycerides, and total cholesterol. Atherosclerosis has been reported to occur at higher rates in women with PCOS (Lim, et al, 2012). It has been noted that early coronary and other vascular
Diseases has been documented in the PCOS population by different techniques (Lim, et al, 2012). Some of the markers of vascular disease in the PCOS client are vessel intima-media thickness, coronary artery calcification, echocardiography with anatomic and functional differences, and impaired endothelial function (Apridonidze et al., 2005).

Dyslipidemia is strongly associated with the PCOS population (Apridonidze et al., 2005). According to data collected in a study by Apridonidze et al. (2005), 35% of the PCOS population had elevated lipid levels. Triglycerides and the low-density lipoproteins (LDL) were elevated above the normal limits and the high-density lipoproteins (HDL) were decreased (Apridonidze et al., 2005). According to Diamanti-Kandarakis, Papavassiliou, Kandarakis, and Chrousos, (2007), the National Cholesterol Education Program (NCEP) guidelines stated that approximately 70% of PCOS patients exhibit abnormal serum lipid levels. An unfavorable lipid profile that consists of increased LDL, decreased HDL and increased total cholesterol and triglyceride levels are associated with the elevated androgen and insulin levels found in women with PCOS (Hart & Norman, 2006). Among the lifestyle and genetic factors of PCOS, ethnicity has been shown to play a part in abnormal lipid profiles (Diamanti-Kandarakis et al., 2007). A recent study showed that 36% of Mediterranean patients with PCOS had abnormal lipid panels, which is significantly lower than US PCOS patients (Diamanti-Kandarakis et al., 2007). Most PCOS patients have a family history of PCOS. It is estimated that PCOS patients that have family members with a metabolic disorder, have approximately a 2.7 higher chance of having dyslipidemia than non PCOS patients. In this group, the development of dyslipidemia is approximately 1.8 in family members with PCOS (Diamanti-Kandarakis, et al., 2007).
Research has shown that the risk of endometrium, breast, and ovarian cancer is associated with women with PCOS (Hoyt & Schmidt, 2004). Endometrial cancer seems to be the greatest risk; it has been identified as being significant in PCOS patients (Hoyt & Schmidt, 2004). Long periods of exposure to estrogen that is unopposed could place someone to a risk of endometrial hyperplasia or cancer and possibly breast cancer. Though the exact linkage of PCOS and breast cancer is still unknown, some studies have suggested that chronic anovulation in the reproductive years may increase the risk of breast cancer in the menopausal years (Hoyt & Schmidt, 2004). The Cancer and Steroid Hormone study reported that patients with ovarian cancer were likely to report a history of PCOS (Hoyt & Schmidt, 2004). There is not enough research to support the theory and more studies are needed to clarify the association.

Type 2 Diabetes and Impaired glucose tolerance is also prevalent in the PCOS population. These patients have a 5 to 10-fold increased risk of developing Type 2 diabetes (Hoyt & Schmidt, 2004). It has been noted that there was a high prevalence of first degree relatives with type 2 diabetes, which confirms family history as an important risk factor (Hoyt & Schmidt, 2004). The overall presence of glucose intolerance in the PCOS population is 30-35% and 3-10% with Type 2 diabetes (Hoyt & Schmidt, 2004).

In order for this population to live a balanced life with PCOS, early detection is necessary. This task is the responsibility of the health care provider. The PCOS diagnosis can be challenging for health care providers because of the varying diagnostic criteria and variance in patients’ complaints. Over the years, different diagnostic criteria have been developed (Figure 1): a) National Institutes of Health (NIH) 1990 which includes the following elements and both criteria needed for
diagnosis: 1. chronic anovulation and 2. Clinical and/or biochemical signs of hyperandrogenism (with exclusion of other etiologies) (National institutes of health, 2012); b) Rotterdam 2003 which includes the following criteria and two of three criteria needed for diagnosis: 1. Oligo and/or anovulation 2. Clinical and/or biochemical signs of hyperandrogenism 3. Polycystic ovaries (National institutes of health, 2012); c) Androgen Excess & PCOS Society (AE-PCOS) 2006, which includes the following criteria and (both criteria needed for diagnosis: 1. Clinical and/or biochemical signs of hyperandrogenism 2. Ovarian dysfunction (oligo-anovulation and/or polycystic ovarian amorphology) (National institutes of health, 2012). Rotterdam is used the most often and recommended by Legro et al. (2013) for diagnosing PCOS. This criterion is most accepted because it is the most up-to-date and it has a wider scope; this criterion includes both the NIH and AE-PCOS criteria (National Institute of Health, 2012).

Figure 1. Diagnostic criteria for PCOS

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>• Chronic anovulation</td>
<td>• Oligo- and/or anovulation</td>
<td>• Clinical and/or biochemical signs of</td>
</tr>
<tr>
<td>• Clinical and/or</td>
<td>• Clinical and/or</td>
<td>hyperandrogenism</td>
</tr>
<tr>
<td>biochemical signs of hyperandrogenism</td>
<td>biochemical signs of hyperandrogenism</td>
<td></td>
</tr>
<tr>
<td>(with exclusion of other etiologies, e.g.,</td>
<td>• Polycystic ovaries</td>
<td>• Ovarian dysfunction (Oligo-anovulation</td>
</tr>
<tr>
<td>congenital adrenal hyperplasia)</td>
<td></td>
<td>and/or polycystic ovarian amorphology)</td>
</tr>
<tr>
<td>(Both criteria needed)</td>
<td>(Two of three criteria needed)</td>
<td>(Both criteria needed)</td>
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</tbody>
</table>

According to Boyle and Teed (2012), individual components of the diagnostic criteria for PCOS are difficult to measure. The Rotterdam criteria is used for PCOS diagnosis include the following: androgen excess, ovulatory dysfunction, and polycystic ovarian morphology (Boyle & Teede, 2012). Two of these are included as a major component in all major classifications. Each one of the criteria has strengths and limitations.
There are strengths and limitations with using androgen excess as diagnostic criteria (Figure 2). The strengths include the fact that androgen excess is a component in all major classifications, it is a major concern for patients, and there are animal models available for research (Boyle & Teede, 2012). The limitations include the fact that androgen excess is only measurable through blood; concentrations of blood vary from age to age and time to time; the assays are not standardized; and clinical hyperandrogenism quantification is difficult and may vary dependent upon ethnicity (Boyle & Teede, 2012). Ovulatory dysfunction also is a component in all classifications (Boyle & Teede, 2012). Another strength of ovulatory dysfunction, according to Boyle and Teede (2012), is that it is a common concern for patients and infertility is common. Given ovulation is not totally understood, this is a limitation for ovulatory dysfunction. Other limitations for ovulatory dysfunction is the fact that this criterion is difficult to objectively measure and normal ovulation varies. Lastly, the strength of polycystic ovarian morphology lie in the fact that this criterion, historically, has been associated with PCOS and may be associated with hypersensitivity to ovarian syndrome (Boyle & Teede, 2012). There are limitations which can affect this criterion. The limitations include the lack of standardized and normative measurements, imaging possibly inappropriate in certain circumstances, and technology not universally available to accurately image (Boyle & Teede, 2012).
Figure 2. Strengths and limitations of diagnostic criteria

<table>
<thead>
<tr>
<th>Diagnostic Criteria</th>
<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgen Excess</td>
<td>• Included as a component in all major classifications</td>
<td>• Measurement is performed only in blood.</td>
</tr>
<tr>
<td>(&quot;National institutes of health,&quot; 2012)</td>
<td>• A major clinical concern for patients</td>
<td>• Concentrations differ during time of day.</td>
</tr>
<tr>
<td></td>
<td>• Animal models employing</td>
<td>• Concentrations differ with age.</td>
</tr>
<tr>
<td></td>
<td>• Androgen excess resemble but do not fully mimic human disease</td>
<td>• Normative data are not clearly defined.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Assays are not standardized across laboratories.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Clinical hyperandrogenism is difficult to quantify and may vary by ethnic group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Tissue sensitivity is not assessed.</td>
</tr>
<tr>
<td>Ovulatory Dysfunction</td>
<td>• Included as a component in all major classifications</td>
<td>• Normal ovulation is incompletely understood.</td>
</tr>
<tr>
<td>(&quot;National institutes of health,&quot; 2012)</td>
<td>• A major clinical concern for patients</td>
<td>• Normal ovulation varies over a woman’s lifetime.</td>
</tr>
<tr>
<td></td>
<td>• Infertility a common clinical complaint</td>
<td>• Ovulatory dysfunction is difficult to measure objectively.</td>
</tr>
<tr>
<td>Polycystic Ovarian Morphology</td>
<td>• Historically associated with syndrome</td>
<td>• Technique dependent</td>
</tr>
<tr>
<td>(&quot;National institutes of health,&quot; 2012)</td>
<td>• May be associated with hypersensitivity to ovarian stimulation</td>
<td>• Difficult to obtain standardized measurement.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of normative standards across the menstrual cycle and lifespan (notably in adolescence) as ovarian morphology varies with age</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Technology required to accurately image not universally available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Imaging possibly inappropriate in certain circumstances (e.g., adolescence)</td>
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</table>

The strengths and limitations of the PCOS diagnostic criteria can cause confusion among health care professionals, which could delay the progress in understanding PCOS and the ability to collaborate with women to address and manage their PCOS health related issues. (National institutes of health, 2012). Once a patient has been identified as someone with probable PCOS, the appropriate lab studies need to be ordered and the diagnostic criteria (NIH 1990, Rotterdam 2003, or AE-PCOS Society 2006) can be applied to diagnose the patient. Also, the PCOS diagnostic screening questionnaire would be very helpful to providers in making a clinical diagnosis of probable PCOS and utilization of the PCOS evidence based PCOS guidelines could
be used for information on how to treat the patient. Using the screening diagnostic questionnaire for probable PCOS would help providers be more aware of patients that have PCOS, possibly decrease the cost of ordering various lab studies that may not be needed, and most of all, start early intervention to decrease PCOS related comorbidities.

**Purpose**

The purpose of this project is to incorporate the PCOS diagnostic screening questionnaire as a routine part of clinical care to diagnose probable PCOS patients.

**Objectives**

1. To assess the number of Health Care Professionals (HCP’S) that used the PCOS screening questionnaire to identify probable PCOS patients.
2. To determine if the PCOS screening questionnaire was helpful in diagnosing probable PCOS patients.
3. To identify the feasibility of utilization of PCOS Screening questionnaire
4. To identify barriers in the use of the PCOS diagnostic screening questionnaire.

**PICOT question**

Can the PCOS diagnostic screening questionnaire (Intervention) be effective in assisting health care providers (population) to diagnose probable PCOS (outcome)?

Benefits: Ability to diagnose PCOS early and decrease comorbidities; ability to educate patients early on preventive measures and lifestyle changes that will benefit them.
Review of Literature

The Methodology used was CINAHL, Ebsco, PubMed, and MEDLINE databases were used. The key words were Polycystic Ovarian Syndrome, PCOS, PCOS guidelines, PCOS diagnostic criteria, and PCOS diagnostic tools.

In 2007, Pederson, Brar, Faris, and Corenblum did a study in Calgary to validate a simple questionnaire to use in screening women for the possible presence of PCOS (2007). At that time there were not any validated tools available in the literature to assist in making the clinical diagnosis of PCOS (Pederson, Brar, Faris, and Corenblum, 2007). They constructed a 4-item questionnaire for the use of diagnosing PCOS. The participants completed a questionnaire that asked questions designed to assist in the diagnosis of PCOS before their appointment with an endocrinologist. Participants were adult women, age 18 years old or older, who were referred to a reproductive endocrinologist for menstrual irregularity, fertility concerns, and hirsutism. The questionnaire was administered in 2 parts: The first part requested demographic information and a medical history including specific questions regarding known diagnoses of diabetes, hypertension, and dyslipidemia. The second part requested menstrual and fertility history; questions were asked relating to frequency of menses, history of failed attempts of pregnancy, history, sites, and treatment of coarse midline hair growth and acne, history of breast discharge, obesity, and variability of symptoms with weight change (Pederson, Brar, Faris & Corenblum, 2007). The endocrinologist completed their assessment with the standard diagnostic criteria (NIH criteria) without knowing the answers to the 4-item questionnaire. The endocrinologists made a diagnosis of PCOS using clinical criteria and biochemical data. The history of infrequent menses, hirsutism, obesity, and acne were strong predictors of a diagnosis of PCOS. The questionnaire yielded a sensitivity of 85% and
a specificity of 85% on multivariate logistic regression and a sensitivity of 77% and a specificity of 94% using the 4-item questionnaire (Pederson, Brar, Faris & Corenblum, 2007). Findings from the study included a validated tool that providers can use to help diagnose PCOS and can guide them in treating menstrual irregularity, infertility, and cosmetic concerns (Pederson, Brar, Faris & Corenblum, 2007). The tool can be used to alert providers to screen for associated and potentially devastating comorbid conditions (Pederson, Brar, Faris & Corenblum, 2007). A positive result from the questionnaire should prompt a careful clinical assessment for metabolic and neoplastic complications of PCOS; a negative result does not rule out PCOS with certainty and must be referred to the appropriate specialist (Pederson, Brar, Faris & Corenblum, 2007). Another conclusion of the study was that the questionnaire could be incorporated into family physician's busy practices (Pederson, Brar, Faris & Corenblum, 2007). The researchers recommend further utilization and analysis of this tool to further assess its validity.

In Australia, it was noted that there were limited clinical guidelines and no evidence-based guidelines internationally for the assessment or management of women with PCOS (Teede et al., 2011). The PCOS Australian Alliance in conjunction with the Jean Hailes Foundation for Women’s Health developed an Evidence-based guideline for the assessment and management of PCOS to help providers make timely diagnosis, accurate assessments, and optimal management of women with PCOS (“Evidence-based guideline,” 2011). This guideline was developed by drawing from clinicians' judgement, patient preference and research evidence, and was intended to aid in clinical judgement and patient preference, not to replace it (Teede et al., 2011). Although there are many types of guidelines, this evidence-based guideline followed a rigorous, systematic process of development and
promoted consistency of care across all settings (Teede et al., 2011). The guideline is meant to be relevant to the assessment and management of reproductive-age adolescents and women with PCOS, including those experiencing infertility (Teede et al., 2011). These guidelines are applicable to all health care settings and various health care professionals. The Australian evidence-based PCOS guidelines provides 38 recommendations that address four key areas: Challenges of assessment and diagnosis, assessment of emotional wellbeing, lifestyle management, and therapy for infertility.

Tomlinson et al., 2017, performed a study on women with PCOS to identify how they were diagnosed and how their experience was with living a life with PCOS. It was thought that women with PCOS remain undiagnosed and are never referred for further investigation and treatment (Tomlinson et al., 2017). Therefore, significant health benefits could be achieved by improving recognition and detection of PCOS (Tomlinson et al., 2017). The study was used to identify possible strategies to improve PCOS detection and treatment. Women with PCOS were recruited from primary care, gynecology, endocrinology, and weight management clinics. The PCOS diagnosis was confirmed by using the Rotterdam criteria prior to the study. The study included women with a wide range of body mass index (BMI), who were between 18-45 years (Tomlinson et al., 2017). The results of the study revealed perceived delays and barriers to PCOS diagnosis: most women felt that they were diagnosed in their mid-twenties but had had signs and symptoms of PCOS for several years before; lack of empathy from the doctors; and received limited information about PCOS from their doctors (Tomlinson et al., 2017). The study also suggested significant concerns surrounding diagnosis, treatment and relationships with healthcare professionals (Tomlinson et al., 2017). According to Tomlinson et al., the concerns were associated
with considerable uncertainty, perceived delays and barriers, inadequate advice and a lack of accurate information (2017). Overall, the study suggested the need for increased education for healthcare professionals both in relation to the physical and emotional consequences of PCOS and in terms of patient/health professional interaction (Tomlinson et al., 2017).

A study was performed to assess PCOS diagnostic criteria and antimullerian hormone (AMH). The prevalence of PCOS can vary according to diagnostic consensus used, with estimates ranging from 9% according to National Institutes of Health consensus, up to 18% with the Rotterdam consensus (Mohammad & Seghinsara, 2017). In another study, the utility of AMH in combination with PCOS features for diagnosis of PCO was assessed (Sahmay et al., 2014). When the AMH was evaluated among the patients diagnosed with PCOS according to all three diagnostic criteria (the Rotterdam, Androgen Excess Society and National Institute of Health) as a single screening tool, it had relatively low sensitivity and specificity for diagnosis of PCOS (Mohammad & Seghinsara, 2017). It was suggested that satisfactory diagnostic potential could be achieved by combining the AMH level with other clinical symptoms (Mohammad & Seghinsara, 2017). The Rotterdam Criteria considers the antral follicle count (AFC) on ultrasound as one of the diagnostic criteria. Today’s technology of ultrasounds has improved and accuracy has increased, but the number of follicles seen in ultrasound increase too, depending on the specific equipment (Mohammad & Seghinsara, 2017). Serum AMH is synthesized by small antral follicles, which are precisely seen in ultrasound. However, even with the most advanced ultrasounds devices, the evaluation of polycystic ovarian morphology for diagnosis of PCOS has high variability and can be difficult to count antral follicles trans-abdominally in patients that have never been sexually active or patients that are
obese (Mohammad & Seghinsara, 2017). There is an absence of a worldwide standard for serum AMH assay, which makes the application of serum AMH level difficult (Mohammad & Seghinsara, 2017). The study concluded although there is a lack of well-defined population, stability and heterogeneity of circulating AMH, wide range of values, inter-laboratory variability and different immunoassay used worldwide, AMH could still be introduced as a criterion for PCOS diagnosis (Mohammad & Seghinsara, 2017).

**Theoretical Framework**

Rosswurm and Larrabee proposed a model for guiding nurses and healthcare professionals through a systematic process for the change to evidence-based practice (1999). This model recognized that translation of research into practice requires a solid grounding in change theory, principles of research utilization, and use of standardized nomenclature (Rosswurm & Larrabee, 1999). This model is based on theoretical and research literature related to evidence-based practice, research utilization, standardized language, and change theory (Figure 3). With many changes in the healthcare field, providers can no longer rely solely on clinical experience, pathophysiologic rationale, and opinion based processes (Rosswurm & Larrabee, 1999). It is imperative that providers learn to search for literature, critically appraise the findings, and synthesize the relevant evidence. The model has the following six phases (Rosswurm & Larrabee, 1999):

Figure 3. Rosswurm & Larabee Model for change to Evidence-Based Practice
1. Assess need for change in practice – Need to include stakeholders that may consist of discipline-specific or multidisciplinary practitioners, administrators, and patients who have a stake in the practice. Practitioners need to collect internal data and compare it with external data to identify the problem within practice.

Figure 4. Conceptual Framework

2. Link problem with interventions and outcomes - Define the problem by using language of standardized classifications and link the problem with classifications of interventions and outcomes. This will facilitate communications among practitioners;
provide standards for determining the effectiveness and cost of care, and identify the needed resources. Potential interventions and activities can be identified and outcome indicators can be selected.

3. Synthesize best evidence – The problem, potential interventions, and desired outcomes are critical in reviewing research literature. Research synthesis helps to determine the strength of the evidence to support the need for a change in practice.

4. Design a change in practice – A protocol, procedure, or standard is needed to help facilitate a change in practice to describe the process variables or sequence of activities in the change in practice. Relevant resources need to be identified and outcomes defined.

5. Implementing and evaluating change in practice – Pilot trial should be initiated with follow-up reinforcement of the practice change. Processes and outcomes need to be evaluated. In this phase, a decision should be made to adapt, adopt, or reject the practice change.

6. Integrate and maintain change in practice – Communicate recommended change to all stakeholders. If pilot trial results are positive, change strategies need to be identified. Monitor process and outcomes.

Many providers are treating symptoms of PCOS and not testing for or diagnosing PCOS. This is the reason that many patients that have PCOS are undiagnosed and are never educated on the comorbidities related to PCOS. It would be very helpful and important utilize a screening diagnostic PCOS questionnaire into practice. This would help with early PCOS diagnosis, and treatment and patient education.
SECTION II: SCHOLARY PROJECT PRODUCT
JNP - The Journal for Nurse Practitioners

A. Aims and Scope

JNP, the Journal for Nurse Practitioners, offers high-quality, peer-reviewed clinical articles, original research, continuing education, and departments that help practitioners excel as providers of primary and acute care across the lifespan. Each issue meets their practice needs and encourages discussion and feedback with thought-provoking articles on controversial issues and topics. JNP supports advocacy by demonstrating the role that policy plays in shaping practice and delivering outcomes.

The journal is published 10 times per year, distributed to approximately 100,000 readers in print form, and can be found online at www.npjournal.org. The journal is included in Scopus, CINAHL, and the Journal Citation Report published by Thomson Reuters.
Application of a Polycystic Ovarian Syndrome (PCOS) Diagnostic Questionnaire in Clinical Practice

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Highlights:
Early diagnosis of PCOS can decrease comorbidities in PCOS women
The feasibility of the diagnostic PCOS screening questionnaire in clinical practice
Barriers in using the diagnostic PCOS screening questionnaire in clinical practice
Application of a Polycystic Ovarian Syndrome (PCOS) Diagnostic Questionnaire in Clinical Practice

Polycystic ovarian syndrome (PCOS) is the most common endocrine disorder and cause of anovulatory infertility in childbearing age women (Tang et al., 2006). This disease is complex and the exact physiology is unclear (Garad, Teede, & Moran, 2011). What is known about this condition is that hormone imbalance is the underlying problem. Hyperandrogenism and insulin resistance contributes to the etiology process of PCOS (Garad, Teede, & Moran, 2011). Women with PCOS can present with polycystic ovaries, but it is not necessary for this diagnosis (Boyle & Teede, 2012).

This population of women may have a plethora of symptoms and findings related to their condition. According to Madnani, Khan, Chauhan, Parmar (2013), the following signs and symptoms are common for women of reproductive age with PCOS: metrorrhea or amenorrhea, acne, irregular menses, hirsutism, alopecia. Additional symptoms included metabolic syndrome, obesity, insulin resistance, acanthosis nigricans, Type 2 diabetes, dyslipidemias, hypertension, non-alcoholic liver disease, and obstructive sleep apnea (Madnani et al., 2013).

Apridonidze et al. (2005) reported obesity in 67% of women with PCOS. Obesity seems to have increased over the years, which has had a big impact on the development of chronic conditions such as metabolic syndrome, coronary heart disease and type 2 diabetes (Apridonidze, et al., 2005). Reproductive health is significantly impacted by obesity due to increased body weight that contributes to ovulatory infertility. Overweight and obesity are commonly seen in PCOS women (Apridonidze, et al., 2005). Having excess body weight can exacerbate symptoms of PCOS such as hyperandrogenism, menstrual problems, infertility, insulin resistance,
dyslipidemia, increased risk of metabolic syndrome, impaired glucose tolerance, and type 2 diabetes (Lim, Norman, Davies, & Moran, 2012).

Cardiovascular risk factors are significant among the PCOS population (Lim, et al, 2012). The risk varies according to the levels of LDL, HDL, triglycerides, and total cholesterol. Atherosclerosis has been reported to occur at higher rates in women with PCOS (Lim, et al, 2012). It has been noted that early coronary and other vascular diseases has been documented in the PCOS population by different techniques (Lim, et al, 2012).

Dyslipidemia is strongly associated with the PCOS population (Apridonidze et al., 2005). According to data collected in a study by Apridonidze et al. (2005), 35% of the PCOS population had elevated lipid levels. Triglycerides and the low-density lipoproteins (LDL) were elevated above the normal limits and the high-density lipoproteins (HDL) were decreased (Apridonidze et al., 2005). According to Diamanti-Kandarakis, Papavassiliou, Kandarakis, and Chrousos, (2007), the National Cholesterol Education Program (NCEP) guidelines stated that approximately 70% of PCOS patients exhibit abnormal serum lipid levels. An unfavorable lipid profile that consists of increased LDL, decreased HDL and increased total cholesterol and triglyceride levels are associated with the elevated androgen and insulin levels found in women with PCOS (Hart & Norman, 2006). Among the lifestyle and genetic factors of PCOS, ethnicity has been shown to play a part in abnormal lipid profiles (Diamanti-Kandarakis et al., 2007). A recent study showed that 36% of Mediterranean PCOS patients had abnormal lipid panels; this is significantly lower than the abnormal lipid panel of PCOS patients in the US (Diamanti-Kandarakis et al., 2007). Most PCOS patients have a family history of PCOS. It is estimated that PCOS patients that have family members with a metabolic disorder, have approximately a 2.7 higher
chance of having dyslipidemia than non-PCOS patients. In this group, the development of dyslipidemia is approximately 1.8 in family members with PCOS (Diamanti-Kandarakis, et al., 2007).

Research has shown that the risk of endometrium, breast, and ovarian cancer is associated with women with PCOS (Hoyt & Schmidt, 2004). Endometrial cancer seems to be the greatest risk; it has been identified as being significant in PCOS patients (Hoyt & Schmidt, 2004). It is thought that long periods of exposure to estrogen that is unopposed could place someone to a risk of endometrial hyperplasia or cancer and possibly breast cancer.

Type 2 Diabetes and Impaired glucose tolerance is also prevalent in the PCOS population. These patients have a 5 to 10-fold increased risk of developing Type 2 diabetes (Hoyt & Schmidt, 2004). It has been noted that there was a high prevalence of first-degree relatives with type 2 diabetes, which confirms family history as an important risk factor (Hoyt & Schmidt, 2004). The overall presence of glucose intolerance in the PCOS population is 30-35% and 3-10% with Type 2 diabetes (Hoyt & Schmidt, 2004).

In order for this population to live a balanced life with PCOS, early detection is necessary. This task is the responsibility of the health care provider. The PCOS diagnosis can be challenging for health care providers because of the varying diagnostic criteria and variance in patients’ complaints. Over the years, different diagnostic criteria have been developed (Figure 1): a) National Institutes of Health (NIH) 1990, which includes the following elements and both criteria needed for diagnosis: 1. chronic anovulation and 2. Clinical and/or biochemical signs of hyperandrogenism (with exclusion of other etiologies) (National institutes of health, 2012); b) Rotterdam 2003 which includes the following criteria and two of three
criteria needed for diagnosis: 1. Oligo and/or anovulation 2. Clinical and/or biochemical signs of hyperandrogenism 3. Polycystic ovaries (National institutes of health, 2012); c) Androgen Excess & PCOS Society (AE-PCOS) 2006, which includes the following criteria, and (both criteria needed for diagnosis: 1. Clinical and/or biochemical signs of hyperandrogenism 2. Ovarian dysfunction (oligo-anovulation and/or polycystic ovarian amorphology) (National institutes of health, 2012). Rotterdam is used more often and is recommended by Legro et al. (2013) for PCOS diagnosis. This criterion is commonly used because it is the most up-to-date and it has a wider scope; this criterion includes both the NIH and AE-PCOS criteria (National Institute of Health, 2012).

According to Boyle and Teed (2012), individual components of the diagnostic criteria for PCOS are difficult to measure. The Rotterdam criteria is used for PCOS diagnosis include the following: androgen excess, ovulatory dysfunction, and polycystic ovarian morphology (Boyle & Teede, 2012). Two of these are included as a major component in all major classifications. Each one of the criteria has strengths and limitations.

There are strengths and limitations with using androgen excess as diagnostic criteria (Table 2). The strengths include the fact that androgen excess is a component in all major classifications, it is a major concern for patients, and there are animal models available for research (Boyle & Teede, 2012). The limitations include the fact that androgen excess is only measurable through blood; concentrations of blood vary from age to age and time to time; the assays are not standardized; and clinical hyperandrogenism quantification is difficult and may vary dependent upon ethnicity (Boyle & Teede, 2012). Ovulatory dysfunction also is a component in all classifications (Boyle & Teede, 2012). Another strength of ovulatory dysfunction,
according to Boyle and Teede (2012), is that it is a common concern for patients and infertility is common. Given ovulation is not totally understood, this is a limitation for ovulatory dysfunction. Other limitations for ovulatory dysfunction is the fact that this criterion is difficult to objectively measure and normal ovulation varies. Lastly, the strength of polycystic ovarian morphology lie in the fact that this criterion, historically, has been associated with PCOS and may be associated with hypersensitivity to ovarian syndrome (Boyle & Teede, 2012). There are limitations, which can affect this criterion. The limitations include the lack of standardized and normative measurements, imaging possibly inappropriate in certain circumstances, and technology not universally available to accurately image (Boyle & Teede, 2012).

The strengths and limitations of the PCOS diagnostic criteria can cause confusion among health care professionals, which could delay the progress in understanding PCOS and the ability to collaborate with women to address and manage their PCOS health related issues. (National institutes of health, 2012). Once a patient has been identified as someone with probable PCOS, the appropriate lab studies need to be ordered and the diagnostic criteria (NIH 1990, Rotterdam 2003, or AE-PCOS Society 2006) can be applied to diagnose the patient. In addition, the PCOS diagnostic screening questionnaire would be very helpful to providers in making a clinical diagnosis of probable PCOS and utilization of the PCOS evidence based PCOS guidelines could be used for information on how to treat the patient. Using the screening diagnostic questionnaire for probable PCOS would help providers be more aware of patients that have PCOS, possibly decrease the cost of ordering various lab studies that may not be needed, and most of all, start early intervention to decrease PCOS related comorbidities. Therefore, the purpose of this project is to incorporate the PCOS diagnostic screening questionnaire as a routine part of clinical
care to diagnose probable PCOS patients. This project was designed to answer the following PICOT question: Can the PCOS diagnostic screening questionnaire be effective in assisting providers to diagnose PCOS?

**Review of Literature**

The Methodology used was CINAHL, Ebsco, PubMed, and MEDLINE databases were used. The key words were Polycystic Ovarian Syndrome, PCOS, PCOS guidelines, PCOS diagnostic criteria, and PCOS diagnostic tools.

In 2007, Pederson, Brar, Faris, and Corenblum did a study in Calgary to validate a simple questionnaire to use in screening women for the possible presence of PCOS (2007). At that time, there were not any validated tools available in the literature to assist in making the clinical diagnosis of PCOS (Pederson, Brar, Faris, and Corenblum, 2007). They constructed a 4-item questionnaire for the use of diagnosing PCOS. The participants completed a questionnaire that asked questions designed to assist in the diagnosis of PCOS before their appointment with an endocrinologist. Participants were adult women, age 18 years old or older, who were referred to a reproductive endocrinologist for menstrual irregularity, fertility concerns, and hirsutism. The questionnaire was administered in 2 parts: The first part requested demographic information and a medical history including specific questions regarding known diagnoses of diabetes, hypertension, and dyslipidemia. The second part requested menstrual and fertility history; questions were asked relating to frequency of menses, history of failed attempts of pregnancy, history, sites, and treatment of coarse midline hair growth and acne, history of breast discharge, obesity, and variability of symptoms with weight change (Pederson, Brar, Faris & Corenblum, 2007). The endocrinologist completed their assessment with the standard diagnostic
criteria (NIH criteria) without knowing the answers to the 4-item questionnaire. The endocrinologists made a diagnosis of PCOS using clinical criteria and biochemical data. The history of infrequent menses, hirsutism, obesity, and acne were strong predictors of a diagnosis of PCOS. The questionnaire yielded a sensitivity of 85% and a specificity of 85% on multivariate logistic regression and a sensitivity of 77% and a specificity of 94% using the 4-item questionnaire (Pederson, Brar, Faris & Corenblum, 2007). Findings from the study included a validated tool that providers can use to help diagnose PCOS and can guide them in treating menstrual irregularity, infertility, and cosmetic concerns (Pederson, Brar, Faris & Corenblum, 2007). The tool can be used to alert providers to screen for associated and potentially devastating comorbid conditions (Pederson, Brar, Faris & Corenblum, 2007). A positive result from the questionnaire should prompt a careful clinical assessment for metabolic and neoplastic complications of PCOS; a negative result does not rule out PCOS with certainty and should be referred to the appropriate specialist (Pederson, Brar, Faris & Corenblum, 2007). Another conclusion of the study was that the questionnaire could be incorporated into family physician's busy practices (Pederson, Brar, Faris & Corenblum, 2007). The researchers recommend further utilization and analysis of this tool to further assess its validity.

In Australia, it was noted that there were limited clinical guidelines and no evidence-based guidelines internationally for the assessment or management of women with PCOS (Teede et al., 2011). The PCOS Australian Alliance in conjunction with the Jean Hailes Foundation for Women’s Health developed an Evidence-based guideline for the assessment and management of PCOS to help providers make timely diagnosis, accurate assessments, and optimal management of women with PCOS (“Evidence-based guideline,” 2011). This guideline was
developed by drawing from clinicians’ judgement, patient preference and research evidence, and was intended to aid in clinical judgement and patient preference, not to replace it (Teede et al., 2011). Although there are many types of guidelines, this evidence-based guideline followed a rigorous, systematic process of development and promoted consistency of care across all settings (Teede et al., 2011). The guideline is meant to be relevant to the assessment and management of reproductive-age adolescents and women with PCOS, including those experiencing infertility (Teede et al., 2011). These guidelines are applicable to all health care settings and various health care professionals. The Australian evidence-based PCOS guidelines provides 38 recommendations that address four key areas: Challenges of assessment and diagnosis, assessment of emotional wellbeing, lifestyle management, and therapy for infertility.

Tomlinson et al., 2017, performed a study on women with PCOS to identify how they were diagnosed and how their experience was with living a life with PCOS. It was thought that women with PCOS remain undiagnosed and are never referred for further investigation and treatment (Tomlinson et al., 2017). Therefore, significant health benefits could be achieved by improving recognition and detection of PCOS (Tomlinson et al., 2017). The study was used to identify possible strategies to improve PCOS detection and treatment. Women with PCOS were recruited from primary care, gynecology, endocrinology, and weight management clinics. The PCOS diagnosis was confirmed by using the Rotterdam criteria prior to the study. The study included women with a wide range of body mass index (BMI), who were between 18-45 years (Tomlinson et al., 2017). The results of the study revealed perceived delays and barriers to PCOS diagnosis: most women felt that they were diagnosed in their mid-twenties but had had signs and symptoms of PCOS for several years before; lack of
empathy from the doctors; and received limited information about PCOS from their
doctors (Tomlinson et al., 2017). The study also suggested significant concerns
surrounding diagnosis, treatment and relationships with healthcare professionals
(Tomlinson et al., 2017). According to Tomlinson et al., the concerns were associated
with considerable uncertainty, perceived delays and barriers, inadequate advice and a
lack of accurate information (2017). Overall, the study suggested the need for
increased education for healthcare professionals both in relation to the physical and
emotional consequences of PCOS and in terms of patient/health professional
interaction (Tomlinson et al., 2017).

A study was performed to assess PCOS diagnostic criteria and antimullerian
hormone (AMH). The prevalence of PCOS can vary according to diagnostic
consensus used, with estimates ranging from 9% according to National Institutes of
Health consensus, up to 18% with the Rotterdam consensus (Mohammad &
Seghinsara, 2017). In another study, the utility of AMH in combination with PCOS
features for diagnosis of PCO was assessed (Sahmay et al., 2014). When the AMH
was evaluated among the patients diagnosed with PCOS according to all three
diagnostic criteria (the Rotterdam, Androgen Excess Society and National Institute of
Health) as a single screening tool, it had relatively low sensitivity and specificity for
diagnosis of PCOS (Mohammad & Seghinsara, 2017). It was suggested that
satisfactory diagnostic potential could be achieved by combining the AMH level with
other clinical symptoms (Mohammad & Seghinsara, 2017). The Rotterdam Criteria
considers the antral follicle count (AFC) on ultrasound as one of the diagnostic
criteria. Today’s technology of ultrasounds has improved and accuracy has increased,
but the number of follicles seen in ultrasound increase too, depending on the specific
equipment (Mohammad & Seghinsara, 2017). Serum AMH is synthesized by small
antral follicles, which are precisely seen in ultrasound. However, even with the most advanced ultrasounds devices, the evaluation of polycystic ovarian morphology for diagnosis of PCOS has high variability and can be difficult to count antral follicles trans-abdominally in patients that have never been sexually active or patients that are obese (Mohammad & Seghinsara, 2017). There is an absence of a worldwide standard for serum AMH assay, which makes the application of serum AMH level difficult (Mohammad & Seghinsara, 2017). The study concluded although there is a lack of well-defined population, stability and heterogeneity of circulating AMH, wide range of values, inter-laboratory variability and different immunoassay used worldwide, AMH could still be introduced as criteria for PCOS diagnosis (Mohammad & Seghinsara, 2017).

**Theoretical Framework**

Rosswurm and Larrabee proposed a model for guiding nurses and healthcare professionals through a systematic process for the change to evidence-based practice (1999). This model recognized that translation of research into practice requires a solid grounding in change theory, principles of research utilization, and use of standardized nomenclature (Rosswurm & Larrabee, 1999). This model is based on theoretical and research literature related to evidence-based practice, research utilization, standardized language, and change theory. With many changes in the healthcare field, providers can no longer rely solely on clinical experience, pathophysiologic rationale, and opinion based processes (Rosswurm & Larrabee, 1999). It is imperative that providers learn to search for literature, critically appraise the findings, and synthesize the relevant evidence (Figure 3).

The model has the following six phases (Rosswurm & Larrabee, 1999):
1. Assess need for change in practice – Need to include stakeholders that may consist of discipline-specific or multidisciplinary practitioners, administrators, and patients who have a stake in the practice. Practitioners need to collect internal data and compare it with external data to identify the problem within practice.

2. Link problem with interventions and outcomes - Define the problem by using language of standardized classifications and link the problem with classifications of interventions and outcomes. This will facilitate communications among practitioners; provide standards for determining the effectiveness and cost of care, and to identify the needed resources. Potential interventions and activities can be identified and outcome indicators can be selected.

3. Synthesize best evidence – The problem, potential interventions, and desired outcomes are critical in reviewing research literature. Research synthesis helps to determine the strength of the evidence to support the need for a change in practice.

4. Design a change in practice – A protocol, procedure, or standard is needed to help facilitate a change in practice to describe the process variables or sequence of activities in the change in practice. Relevant resources need to be identified and outcomes defined.

5. Implementing and evaluating change in practice – Pilot trial should be initiated with follow-up reinforcement of the practice change. Processes and outcomes need to be evaluated. In this phase, a decision should be made to adapt, adopt, or reject the practice change.

6. Integrate and maintain change in practice – Communicate recommended change to all stakeholders. If pilot trial results are positive, change strategies need to be identified. Monitor process and outcomes.
Many providers are treating symptoms of PCOS and not testing for or diagnosing PCOS. This is the reason that many patients that have PCOS are undiagnosed and are never educated on the comorbidities related to PCOS. It would be very helpful and important utilize a screening diagnostic PCOS questionnaire into practice. This would help with early PCOS diagnosis, and treatment and patient education.

**Methodology**

**Study settings**

In this scholarly project, a PCOS diagnostic screening questionnaire was introduced in Ob/Gyn clinics to improve early PCOS diagnosis by incorporating the questionnaire as a routine part of clinical screening. A convenience sampling method was used to select 8 health care professionals (Doctors and Nurse Practitioners) from selected clinics.

**Study Instruments**

The following instruments were used in the study:

1. A validated 4-item PCOS screening questionnaire (Pederson, Brar, Faris & Corenblum, 2007) was used in the clinic to help screen women, age > 19, for possible PCOS (Appendix A). The questionnaire was developed by Pederson, Brar, Faris, and Corenblum in a research study titled “Polycystic ovary syndrome validated questionnaire for use in diagnosis” that was published in Canadian Family Physician, volume 53, June 2007 (Pederson et al, 2007). Permission to use the questionnaire was obtained from Dr. Sue D. Pedersen via email. Each question was assigned a score value 1, -1, or 0 and if the total score is > or equal to 2, the diagnosis is consistent with PCOS and if the score is < 2, the diagnosis is not consistent with PCOS.
2. A PCOS pre-test that consisted of 8 questions was administered to the health care professional prior to the start of the study (Appendix B). The health care professionals were asked to use the screening questionnaire in their practice for all female patients and consider the helpfulness of the screening instrument in the diagnosis of PCOS.

3. A PCOS post-test that consisted of 8 questions was administered to the health care professional at the conclusion of the study (Appendix C).

4. A Ferriman Gallwey Index chart tool was used to help assess for hirsutism. Ferriman Gallwey Index is used for clinical assessment of hair growth in women and to score the degree of excess male pattern body hair (Appendix D). The chart represents hair growth in a male pattern on woman shown in four different degrees of severity in 11 different body parts. Everybody part assessed is given a score that ranges from 0 (no excessive terminal hair growth) to 4 (extensive terminal hair growth). The numbers are added up to a maximum count of 36. A final score of 6 or more is enough to indicate hirsutism.

5. A reference list of normal values was given for the laboratory investigation of PCOS and information regarding how the ovaries should look in PCOS (Appendix E).

Procedure

The IRB granted approval for the proposal on September 26, 2016. After receiving approval from the IRB to conduct the project, the PI started the study by recruiting health care professionals that see the PCOS population. The PI obtained consent from the health care professionals to participate in the study. Each health care professional was oriented prior to the start of the study regarding the PCOS screening questionnaire process and administration of the questionnaire. They were told that the questionnaire would only take approximately 3-5 minutes to complete because it only consisted of only 4 questions and most health care professionals usually ask these questions when they
see their patients. However, they usually do not score the findings. They were also given educational materials that included the Ferriman Gallwey chart and PCOS laboratory reference list. Before starting the project in their office, a pre-test was given to the health care professional. The purpose for this pre-test was to identify professional information and current PCOS diagnostic process. The health care professionals were asked to utilize the diagnostic screening questionnaire in their clinic for 3 months for patients that came to their clinic with complaints of menstrual dysfunction, hirsutism, obesity, reproductive issues, acne, or any symptoms related to PCOS for probable PCOS. Contact information for the PI was given to each health care professional so that if any questions or problems arose, they would be able to contact the PI. This study was considered a health care professional training activity, where there was no patient interaction and no patient identification collected by the PI. The questionnaire was a guide for the health care professionals and was not collected by the PI. The health care professionals were educated on how to interpret the results of the screening questionnaire. Educational materials were given that included clinical assessment techniques and recommended lab tests to order after identifying PCOS patients. Also, the health care professionals were given the Ferriman Gallwey Index chart tool. The Ferriman Gallwey Index chart was used to help assess for hirsutism. At the end of the 3-month period, the PI made contact with the health care professionals to give them the posttest. The post-test was administered to assess the feasibility of utilizing the questionnaire in practice, the number of patients diagnosed with PCOS, and the continued use of the questionnaire in practice.

**Evaluation**

Each health care professional calculated the results of the PCOS screening questionnaire upon completion of the 3-month study. If the response score was > or
equal to 2, the diagnosis was consistent with PCOS, which meant the patient would need further testing. If the questionnaire response was <2, the diagnosis was not consistent with PCOS and other etiologies needed to be explored by the health care professionals. Once all data had been collected, it was analyzed to determine the efficacy of the screening questionnaire. The PI was able to determine if the PCOS screening questionnaire was helpful in diagnosing probable PCOS patients.

Results

The PCOS scholarly project was conducted with eight health care professionals that consisted of four medical doctors and four Nurse Practitioners. The project took place in three family practice/adult medicine clinics and five obstetrics/gynecology clinics. The PCOS screening questionnaire was utilized in their clinics for three months and was used with patients that had symptoms related to PCOS. Each health care professional that utilized the PCOS screening questionnaire as a part of this scholarly project stated that it was helpful in identifying PCOS patients. All eight health care professionals in their pre-test said that they had never used a PCOS screening questionnaire prior to this study. They all said in their pre-test that they used different methods to identify PCOS patients in their clinic such as utilizing the Rotterdam criteria and clinical assessment. At the conclusion of this study, each health care professional said in their post-test that they would continue to utilize the PCOS screening questionnaire in their clinic. The PCOS screening questionnaire helped the health care professionals to identify several PCOS patients according to their post-test and it allowed them to devise a needed treatment plan for their patients. The health care professionals in their post-test stated that they would recommend the PCOS screening questionnaire to their colleagues.
**Discussion**

The PCOS screening questionnaire was helpful to health care professionals in identifying and diagnosing PCOS patients. The results indicated that 100% of the health care professionals would continue to utilize the PCOS screening questionnaire in their clinic. In addition, the results indicated that each provider would recommend the questionnaire to their colleagues. In the original study by Pederson, Brar, Faris & Corenblum, the 4-item questionnaire was validated as being useful in screening women with menstrual irregularities, hirsutism, and other related findings for the presence of PCOS (2007). Though, the questionnaire had not been validated in a family practice setting, it was concluded that the questionnaire could be easily incorporated into a busy family practice office (Pederson, Brar, Faris & Corenblum, 2007). In this scholarly project, 62.5% of the utilization of the screening tool took place in an OBGYN clinic and 37.5% of the utilization occurred in Family Practice/Adult primary care clinics. This tool was found to be effective in the identification of women with PCOS.

**Barriers**

In order for the diagnostic screening tool to be used in a provider's office, barriers need to be examined. A limitation of this scholarly project was participation of health care professionals. Several forms of communication were used to recruit health care professionals to participate in the project, which included electronic means, face-to-face, other colleagues, and phone. Though approximately 20 health care professionals were contacted, only 8 health care professionals were willing to participate. Some of the health care professionals thought that utilizing the questionnaire in their clinic for 3 months was too long and it would take too much time away from their clinical practice time to administer the questionnaire.
Sustainability Plan

In order to sustain this project in a clinical setting, the PCOS screening questionnaire needs to be effective in diagnosing PCOS patients. Now that it has been proven to be successful, it would be a great questionnaire to be used in assisting providers to screen for PCOS and to diagnose it early in order to decrease the comorbidities that accompany PCOS.

Benefits

This study was beneficial in providing a screening tool for HCPs to utilize in the early diagnosis of clients with PCOS. By identifying these patients early, health care professionals will be able to help decrease the comorbidities that come with PCOS. An early and accurate diagnosis of PCOS would allow health care professionals the ability to educate patients early on preventive measures and lifestyle changes that would benefit them.
REFERENCES


Table 1.
Demographical and professional information

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<tr>
<td>History, exam, sonogram</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab results, ultrasound, menstrual history, exam findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical findings, lab results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Menses, hair pattern, body shape, acne, fertility, facial features, transvaginal or external ultrasound, labs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultrasound, patient symptoms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3.

Feasibility of utilization of PCOS Screening questionnaire

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOS Screening questionnaire helpful in identifying PCOS patients:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of probable PCOS patients identified:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>5-10</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>&gt;10</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>Number of patients diagnosed with PCOS:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>5-10</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>&gt;10</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>Utilization of the Ferriman-Gallwey Index chart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>50</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>37.5</td>
</tr>
<tr>
<td>Have used previously</td>
<td>1</td>
<td>12.5</td>
</tr>
<tr>
<td>Utilization of the Laboratory Investigation of PCOS reference list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>75</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>25</td>
</tr>
</tbody>
</table>
Table 4.

Health Care Professional’s recommendation of PCOS screening questionnaire incorporation into clinical practice

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOS screening questionnaire is an effective tool to incorporate into clinic:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Recommendation of PCOS screening questionnaire to colleagues:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Educational materials were helpful in diagnosing and treating PCOS:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
Table 5.

Suggestions/Comments

<table>
<thead>
<tr>
<th>The lab values and materials will be a quick access for screening and diagnosis PCOS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do not recommend doing free testosterone. All the questions are appropriate. When the diagnosis of PCOS is made on clinical basis, I do several tests but not all tests (laboratory tests) on each patient. Depending on whether they are on period or long-term amenorrhea, order pregnancy test. I use my clinical judgment regarding pelvic ultrasound and endometrial biopsy regarding their age, habitus, and other symptoms.</td>
</tr>
</tbody>
</table>
## Diagnostic Criteria for PCOS

|----------|----------------|-----------------------|
| • Chronic anovulation  
  • Clinical and/or biochemical signs of hyperandrogenism (with exclusion of other etiologies, e.g., congenital adrenal hyperplasia)  
  (*Both criteria needed*) | • Oligo- and/or anovulation  
  • Clinical and/or biochemical signs of hyperandrogenism  
  • Polycystic ovaries  
  (*Two of three criteria needed*) | • Clinical and/or biochemical signs of hyperandrogenism  
  • Ovarian dysfunction (Oligo-anovulation and/or polycystic ovarian morphology)  
  (*Both criteria needed*) |
## Figure 2.

### Strengths and Limitations of diagnostic criteria

<table>
<thead>
<tr>
<th>Diagnostic Criteria</th>
<th>Strengths</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgen Excess (&quot;National institutes of health,&quot; 2012)</td>
<td>• Included as a component in all major classifications</td>
<td>• Measurement is performed only in blood.</td>
</tr>
<tr>
<td></td>
<td>• A major clinical concern for patients</td>
<td>• Concentrations differ during time of day.</td>
</tr>
<tr>
<td></td>
<td>• Animal models employing</td>
<td>• Concentrations differ with age.</td>
</tr>
<tr>
<td></td>
<td>• Androgen excess resemble but do not fully mimic human disease</td>
<td>• Normative data are not clearly defined.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Assays are not standardized across laboratories.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Clinical hyperandrogenism is difficult to quantify and may vary by ethnic group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Tissue sensitivity is not assessed.</td>
</tr>
<tr>
<td>Ovulatory Dysfunction (&quot;National institutes of health,&quot; 2012)</td>
<td>• Included as a component in all major classifications</td>
<td>• Normal ovulation is incompletely understood.</td>
</tr>
<tr>
<td></td>
<td>• A major clinical concern for patients</td>
<td>• Normal ovulation varies over a woman’s lifetime.</td>
</tr>
<tr>
<td></td>
<td>• Infertility a common clinical complaint</td>
<td>• Ovulatory dysfunction is difficult to measure objectively.</td>
</tr>
<tr>
<td>Polycystic Ovarian Morphology (&quot;National institutes of health,&quot; 2012)</td>
<td>• Historically associated with syndrome</td>
<td>• Technique dependent</td>
</tr>
<tr>
<td></td>
<td>• May be associated with hypersensitivity to ovarian stimulation</td>
<td>• Difficult to obtain standardized measurement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of normative standards across the menstrual cycle and lifespan (notably in adolescence) as ovarian morphology varies with age</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Technology required to accurately image not universally available Imaging possibly inappropriate in certain circumstances (e.g., adolescence)</td>
</tr>
</tbody>
</table>
Figure 3.
Rosswurm & Larabee Model for change to Evidence-Based Practice

1. Assess need for change in practice
   - Include stakeholders
   - Collect internal data about current practice
   - Compare internal data with external data
   - Identify problem

2. Link problem interventions and outcomes
   - Use standardized classification systems and language
   - Identify potential interventions and activities
   - Select outcomes indicators

3. Synthesize best evidence
   - Search research literature related to major variables
   - Critique and weigh evidence
   - Synthesize best evidence
   - Assess feasibility, benefits, and risk

4. Design practice change
   - Define proposed change
   - Identify needed resources
   - Plan implementation process
   - Define outcomes
   - Pilot study demonstration
   - Evaluate process and outcome
   - Decide to adopt, adopt, or reject practice change

5. Implement and evaluate change in practice
   - Communicate recommended change to stakeholders
   - Present staff in-service education on change in practice
   - Integrate into standards of practice
   - Monitor process and outcomes
**Figure 4.**

**Conceptual Framework**

1. Assess need for practice change
   - Involve Health care professionals (HP's) in OB/GYN, Family Practice, & other clinics that may see PCOS patients
   - PCOS pre-test
   - Current PCOS screening method vs. validated PCOS screening questionnaire
   - Identify the need to diagnose PCOS early to decrease PCOS related complications

2. Link problem interventions & outcomes
   - Utilize validated PCOS screening questionnaire
   - Select outcome measures such as number of HP's used the screening questionnaire, effectiveness of questionnaire, barriers to utilizing questionnaire, and percentage of HP's to continue utilizing the PCOS screening questionnaire

3. Synthesize best evidence
   - Synthesize "Polycystic ovary syndrome validated questionnaire for use in diagnosis". Canadian Family Medicine, vol. 55, June 2007
   - Validated screening questionnaire with sensitivity of 77% and specificity of 94% as a tool to support the diagnosis of PCOS
   - Positive result prompts clinical assessment for complications of PCOS

4. Design practice change
   - Incorporate validated PCOS screening questionnaire as a part of clinical care
   - HP's use questionnaire in clinic for 3 months for patients in clinic with complaints of menstrual dysfunction, hirsutism, obesity, reproductive issues, or acne
   - Define PCOS screening outcomes

5. Implement & Evaluate practice change
   - Pilot 4-item PCOS screening tool in practice for 3 months
   - Evaluate the use of questionnaire and outcomes via post-test
   - Make a decision to adopt, adapt, or reject practice change of utilizing the PCOS screening questionnaire from post-test results

6. Integrate & Maintain practice change
   - Within clinical practice, recommend the need for change in practice to all stakeholders
   - Present PCOS screening questionnaire to all staff involved in clinical care
   - Integrate questionnaire into daily clinical practice
   - Monitor the use of questionnaire and outcomes in clinical practice
APPENDICES
# APPENDIX A

## Screening Questionnaire for diagnosis of Polycystic Ovary Syndrome (PCOS)

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>CRITERIA TO ATTAIN SCORE VALUE</th>
<th>SCORE VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please answer this question, <strong>NOT INCLUDING</strong> any time spent pregnant, receiving birth control pills or injections, after menopause, or after having both ovaries or the uterus surgically removed: Between the ages of 16 and 40, about how long was your average menstrual cycle (time from first day of one period to the first day of the next period)? (select <strong>ONE</strong> only)</td>
<td>Patient indicates any one of: - 35-60 days - More than 60 days - Totally variable</td>
<td>1</td>
</tr>
<tr>
<td>• &lt;25 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 25-34 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 35-60 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• More than 60 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Totally variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>During your menstruating years (not including during pregnancy), did you have a tendency to grow dark, coarse hair on your (circle <strong>ALL</strong> that apply)</td>
<td>Patient indicates 3 or more sites</td>
<td>1</td>
</tr>
<tr>
<td>• Upper lip?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Chin?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Chest between the breasts?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Back?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Belly?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Upper arms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Upper thighs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been obese or overweight between the ages of 16 and 40? (circle <strong>ONE</strong>)</td>
<td>Patient indicates Yes</td>
<td>1</td>
</tr>
<tr>
<td>• Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between the ages of 16 and 40, have you ever noticed a milky discharge from your nipples (not including during pregnancy or recent childbirth)? (circle <strong>ONE</strong>)</td>
<td>Patient indicates Yes (Patient indicates No)</td>
<td>-1</td>
</tr>
<tr>
<td>• Yes</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>• No</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>If &gt; 2, consistent with diagnosis of PCOS If &lt; 2, not consistent with diagnosis of PCOS</td>
</tr>
</tbody>
</table>
Appendix B
PCOS Pre-test

Name: Contact number:

1. What is your health profession?
   a. Nurse Practitioner
   b. Physician Assistant
   c. Nurse Midwife
   d. Other

2. How many years of experience do you have in your health profession?
   a. 0-5 years
   b. 5-10 years
   c. 10-15 years
   d. > 15 years

3. How many years of experience in your current specialty area do you have?
   a. 0-5 years
   b. 5-10 years
   c. 10-15 years
   d. >15 years

4. Which specialty area is your clinic?
   a. OB/GYN
   b. Family Practice
   c. Other

5. How many patients do you currently see on a daily basis?
   a. 5-10
   b. 10-20
   c. 20-30
   d. > 30

6. How many patients do you diagnose with PCOS yearly in your clinic?
   a. 0-10
   b. 10-20
   c. 20-30
   d. >30

7. What diagnostic criteria do you use to diagnose PCOS?
8. Do you use a PCOS diagnostic screening questionnaire to identify probable PCOS patients based on symptoms?
Yes
No

If yes, what screening diagnostic questionnaire do you use?
Appendix C

PCOS Post-test

Name:                                                        Contact information:

1. Did you utilize the PCOS screening questionnaire with your patients to identify PCOS patients?
   Yes      No      I have used previously
   If no, please explain

2. Was the screening questionnaire helpful in identifying PCOS patients?
   Yes      No      I have used previously
   If no, please explain

   If yes, how many probable PCOS patients were identified?
   a . 0-5
   b . 5-10
   c . >10

   Of the above probable PCOS patients that were identified, how many of those patients were diagnosed with PCOS?
   a . 0-5
   b . 5-10
   c . >10

3. Did you utilize the Ferriman-Gallwey Index chart to help diagnose hirsutism?
   Yes      No      I have used previously
   If no, please explain

4. Did you utilize the Laboratory Investigation of PCOS reference list?
   Yes      No      I have used previously
   If no, please explain

5. Do you think that the PCOS screening questionnaire would be an effective tool to incorporate into your clinic?
   Yes      No

6. Would you recommend the PCOS screening questionnaire to other colleagues?
   Yes      No

7. Was the educational materials/information provided helpful in diagnosing and treating PCOS?
   Yes      No
8. Any suggestions or comments?
Appendix D

Ferriman Gallwey Index Chart

Modified Ferriman–Gallwey (F-G) hirsutism scoring system. Each of the nine body areas is rated from 0 (absence of terminal hairs) to 4 (extensive terminal hair growth), and the numbers in each area are added for a total score. A modified F-G score ≥6 generally defines hirsutism.
# Appendix E

## Laboratory Investigation of PCOS Reference list

<table>
<thead>
<tr>
<th>Test</th>
<th>Normal value</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-hCG</td>
<td>&lt; 5 mIU per mL (&lt; 5 IU per L)</td>
<td>Exclude pregnancy</td>
</tr>
<tr>
<td>TSH</td>
<td>0.5 to 4.5 μU per mL (0.5 to 4.5 mU per L)</td>
<td>Exclude thyroid dysfunction</td>
</tr>
<tr>
<td>Prolactin</td>
<td>&lt; 20 ng per mL (&lt; 20 μg per L)</td>
<td>Exclude hyperprolactinemia</td>
</tr>
<tr>
<td>Testosterone (total)</td>
<td>&lt; 20 ng per dL (&lt; 0.7 nmol per L)</td>
<td>Exclude androgen-secreting neoplasm</td>
</tr>
<tr>
<td>Testosterone (free)</td>
<td>20 to 30 years—0.06 to 2.57 pg per mL (0.20 to 8.90 pmol per L)</td>
<td>Establish diagnosis or monitor therapy</td>
</tr>
<tr>
<td></td>
<td>40 to 59 years—0.4 to 2.03 pg per mL (1.40 to 7.00 pmol per L)</td>
<td></td>
</tr>
<tr>
<td>DHEAS</td>
<td>600 to 3,400 ng per mL (1.6 to 9.2 μmol per L)</td>
<td>Exclude androgen-secreting neoplasm</td>
</tr>
<tr>
<td>Androstenedione</td>
<td>0.4 to 2.7 ng per mL (1.4 to 9.4 nmol per L)</td>
<td>Establish diagnosis</td>
</tr>
<tr>
<td>17 α-hydroxyprogesterone</td>
<td>Follicular phase &lt; 2 μg per L (6.1 nmol per L)</td>
<td>Exclude NCAH</td>
</tr>
<tr>
<td>Fasting insulin</td>
<td>&lt; 20 μU per mL (&lt; 144 pmol per L)</td>
<td>Exclude hyperinsulinemia</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>65 to 119 mg per dL (3.6 to 6.6 mmol per L)</td>
<td>Exclude type 2 diabetes or glucose intolerance</td>
</tr>
<tr>
<td>Fasting glucose: insulin ratio</td>
<td>@ 4.5</td>
<td>Exclude insulin resistance</td>
</tr>
<tr>
<td>Test</td>
<td>Normal value</td>
<td>Purpose</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Cholesterol (total)</td>
<td>150 to 200 mg per dL (1.5 to 2 g per L)</td>
<td>Monitor lifestyle changes</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>35 to 85 mg per dL (0.9 to 2.2 mmol per L)</td>
<td>Monitor lifestyle changes</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>80 to 130 mg per dL (2.1 to 3.4 mmol per L)</td>
<td>Monitor lifestyle changes</td>
</tr>
<tr>
<td>Pelvic ultrasonography</td>
<td></td>
<td>Monitor lifestyle changes</td>
</tr>
<tr>
<td>Endometrial biopsy</td>
<td>Negative for hyperplasia/malignancy</td>
<td>Exclude malignancy or hyperplasia</td>
</tr>
</tbody>
</table>

**Note:** Diagnosis of PCOS established by exclusion of other causes of oligomenorrhea or hyperandrogenism. Other tests may be of benefit in monitoring therapy.

*PCOS = polycystic ovary syndrome; β-hCG = beta subunit human chorionic gonadotropin; TSH = thyroid-stimulating hormone; DHEAS = dehydroepiandrosterone sulfate; NCAH = nonclassic adrenal hyperplasia; HDL = high-density lipoprotein; LDL = low-density lipoprotein.*

Pelvic ultrasound - ovarian volume greater than 10cm³ and/or 12 or more 2mm to 9 mm follicles.
December 18th 2016
Minnetta Williams
College of Nursing
The University of Alabama in Huntsville

Dear Ms. Williams,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome (PCOS)*, and found it meets the necessary criteria for continued approval. Your proposal seems to be in compliance with this institution’s Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB’s decision, please contact me.

Sincerely,

William Wilkerson
IRB Chair
Dean, Honors College
Appendix G

Krishna Kakani, MD
200 Franklin Street, Suite 102
Huntsville, AL 35801

Phone: 256-251-5121
Fax: 256-469-6061

Wednesday, September 07, 2016

Minnetta Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Tool in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

Krishna Kakani

Dr Krishna Kakani
Tuskegee Medical & Surgical Center

October 17, 2016

Minnette Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

[Signature]

Dearah D. Maxwell, M.D.
Appendix I

Leon W. Lewis, M.D., P.C.
Obstetrics & Gynecology
420 Lowell Drive • Suite 401 • Huntsville, Alabama 35801
Phone: 256-459-8845 • Fax: 256-459-8849
www.leonwlewismdgyn.com

Leon W. Lewis, M.D., F.A.C.O.G.
Board Certified
Obstetrics & Gynecology

Kristine L. Weaver, C.R.N.P.
Nurse Practitioner

October 01, 2016

Minnette Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

Leon W. Lewis MD
January 27, 2017

Miaorita Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

Name: Vivian Watson

Address: 1824 N Ridge Ave
Tifton Clinic

Business: Tifton Clinic

31794
February 25, 2017

Minnetta Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms. Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

Dr. Shannon L. Price OB GYN
Affinity Physicians for Women
39 Kent RD #1
Tifton, GA 31794
January 27, 2017

Minnette Williams, MSN, FNP-BC
College of Nursing
University of Alabama in Huntsville

Ms Williams,

I am pleased to support your research proposal entitled “Diagnostic Screening Questionnaire in Polycystic Ovarian Syndrome.” I give approval for you to recruit potential study participants from my clinical practice.

I look forward to collaborating with you on this work. Please keep me informed of your study planning.

Sincerely,

Name: Sheila Jones NP-C
Address: 1824 N. Ridge Avenue
Tifton, GA 31794
Business: Tifton VA Clinic
Appendix M

JNP Author Guideline

DESCRIPTION

*JNP: The Journal for Nurse Practitioners* offers high-quality, peer-reviewed clinical articles, original research, continuing education, and departments that help practitioners excel as providers of primary and acute care across the lifespan. Each issue meets their practice needs and encourages discussion and feedback with thought-provoking articles on controversial issues and topics. *JNP* supports advocacy by demonstrating the role that policy plays in shaping practice and delivering outcomes. The journal is an official publication of the American Association of Nurse Practitioners and also is affiliated with the Australian College of Nurse Practitioners.

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