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**Integrating Health-Related Quality of Life and Evidence-Based Polycystic Ovarian
Syndrome Management: A Quality Improvement Initiative**

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Abstract

Polycystic Ovary Syndrome (PCOS) is a prevalent endocrine disorder affecting approximately 10% of women of reproductive age, characterized by symptoms such as irregular menstrual cycles, infertility, and metabolic issues (Fatemeh et al., 2021). Despite its prevalence, the management of PCOS remains challenging due to its manifestations and impact on quality of life. Current treatment paradigms often fail to adequately address the comprehensive needs of this patient population, highlighting a substantial gap in care.

Utilizing the Plan-Do-Study-Act (PDSA) methodology, this quality improvement (QI) project aimed to enhance the management of PCOS and improve the quality of life for patients in a primary care setting by integrating a digital health application, Calcium. This technology was introduced to patients diagnosed with PCOS and provided access to monthly HRQoL questionnaires, educational resources on PCOS management, and tools for personal health tracking. An advanced practice nurse then collaborated with each patient to create personalized care plans in response to monthly Health-Related Quality of Life (HRQoL) surveys. The intervention's impact was assessed by comparing the patient's baseline and monthly HRQoL scores. Preliminary findings from the six-month project period indicate a significant improvement in HRQoL scores among participants. Patients reported enhanced self-management of symptoms and expressed increased satisfaction with the personalized care approach facilitated by the app.

The project has demonstrated a reduction in participating patients' PCOS symptoms through digital technology. This technology supports the development of personalized care plans with an advanced practice nurse based on their monthly HRQoL surveys and their use of educational resources and PCOS management tools.

Integrating Health-Related Quality of Life and Evidence-Based Polycystic Ovarian Syndrome Management: A Quality Improvement Initiative

Screening one's health-related quality of life (HRQoL) has become essential to public health surveillance (Centers for Disease Control and Prevention [CDC], 2016). HRQoL is generally considered a valid indicator of both unmet needs and intervention outcomes related to health care (Saketkoo et al., 2021). Self-assessed health status is a more powerful predictor of mortality and morbidity than objective health measures (Saketkoo et al., 2021). HRQoL aims to understand physiologic, psychological, and social impairments resulting from chronic symptoms, patient-perceived disease severity, and side effects from interventions. Decreased HRQoL correlates to worsening disability and death. However, actions promoting HRQoL are linked to increased survival (Saketkoo et al., 2021). Polycystic ovarian syndrome (PCOS) is an endocrine disorder that impacts reproductive-aged patients with ovaries. The Centers for Disease Control and Prevention (2021) reports that PCOS affects 6% to 12% of said population, and its manifestations contribute to a diminished HRQoL (Fatemeh et al., 2021). If inadequately treated, PCOS can lead to obesity, infertility, pregnancy complications, dyslipidemia, type two diabetes, hypertension, cardiovascular disease, and psychological comorbidities (Kim, 2021).

Healthcare Problem

In 2006, the Androgen Excess Society (AES) underscored the importance of hyperandrogenism in the diagnosis of PCOS, concurrently acknowledging the diagnostic significance of ovarian morphology (Christ & Cedars, 2023). As per the AES guidelines, diagnosing PCOS involves identifying hirsutism, with or without biochemical hyperandrogenism, in conjunction with either oligo-anovulation or polycystic ovarian morphology. (Christ & Cedars, 2023).

PCOS is responsible for a wide range of symptoms, including infertility, dysmenorrhea, acne, obesity, hair loss of the scalp, and excess body hair growth (Fatemeh et al., 2021). Forslund et al. (2022) found that HRQoL is negatively impacted in perimenopausal patients with PCOS based on the individual's response to treatment. Early and effective management of PCOS has been correlated with improved HRQoL (Aryal et al., 2022). However, recent reports have shown that even though PCOS is one of the most common reproductive endocrine disorders, diagnostic challenges, delayed diagnoses, and less-than-optimal treatment protocols have left many patients with PCOS inadequately managed (Hoeger et al., 2020).

Consistent diagnosis, treatment, and follow-up are critical in managing PCOS, and medical providers must be provided with up-to-date research regarding its diagnosis and treatment. It is also crucial for providers to evaluate the quality of life of those affected by PCOS before initiating therapy to offer support and lifestyle changes to ease them through their plan of care. Angin et al. (2019) found that defining the patient's specific concerns regarding the quality of life can assist in choosing the proper treatment strategies and adequately evaluating a clinical response. If providers understand the impact of a PCOS diagnosis on quality of life correctly, enhanced care, including HRQoL assessment and patient support, can be provided. Therefore, the capability to improve self-care for this population, leading to a higher quality of life, can be provided (Rzońca et al., 2018).

The Abbreviated World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) measures one's quality of life regardless of health status. It consists of twenty-six items that examine responses connected to physical, psychological, social, and environmental domains. Scores are calculated by finding means in each area. The higher the score, the higher the quality of life (Rzońca et al., 2018). The Polycystic Ovarian Syndrome Questionnaire (PCOSQ) is a tool

that was developed to evaluate the quality of life of those with PCOS. The PCOSQ contains domains specific to the five common manifestations of PCOS, including emotional disturbances, hirsutism (excess hair growth), weight changes, infertility, and menstrual disorders. Each item is answered using Likert scale options from one (always) through seven (never). Higher scores are indicative of a better quality of life. Research has revealed that those suffering from PCOS display marked impairments pertinent to the measured domains (Behboodi Moghadam et al., 2018)—those with PCOS experience physical, mental, emotional, cognitive, and social barriers to PCOS management. Therefore, multidisciplinary services are necessary (Pirodda et al., 2021). To adequately support patients with PCOS, healthcare providers should provide up-to-date PCOS diagnosis and treatment protocols, as well as evidence-based lifestyle interventions, understanding, and support (Pirodda et al., 2021).

Literature Review

Within the Doctor of Nursing Practice (DNP) domain, a systematic approach to evidence collection is pivotal, transcending beyond academia to fundamentally inform and sculpt clinical praxis. Utilizing the esteemed Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model, the project meticulously classified fourteen scholarly articles into tiers of evidential credibility, thus assuring methodological rigor. Four articles were ascribed to the highest level of evidence, indicating a robust research design with minimal bias. At the same time, six were designated as Level II and another as Level III, reflecting a gradation of methodological strengths. These ranged from systematic reviews with and without meta-analyses to mixed methods studies, narrative literature reviews, and randomized control trials.

The synthesis of such a diversified body of literature underpins the generation of evidence-based recommendations, thereby marrying the theoretical underpinnings of nursing

science with the tangible exigencies of healthcare delivery. PCOS personalized healthcare, PCOS screening tools, and mobile health apps are reviewed in the following section.

PCOS Personalized Healthcare

In personalized healthcare, a pre-therapeutic assessment of a patient's quality of life is imperative, particularly for conditions such as Polycystic Ovary Syndrome (PCOS). Studies by Angin et al. (2019) and Rzońca et al. (2018) underscore the significance of these assessments in tailoring individual care. Furthermore, Aryal et al. (2022) posit that early and proactive PCOS interventions correlate with enhanced health-related quality of life (HRQoL). Optimal management of PCOS necessitates uniformity in diagnosis, treatment, and diligent follow-up. It is equally crucial that medical professionals are furnished with the latest knowledge and strategies for managing PCOS. To this end, instruments such as the WHOQOL-BREF, which evaluates the overall quality of life across four domains, and the PCOSQ, which precisely measures the quality of life impacts of PCOS, are valuable tools (Rzońca et al., 2018; Behboodi Moghadam et al., 2018). Effective care for PCOS should be comprehensive, incorporating multidisciplinary services to address the multifaceted physical, mental, and social hurdles associated with the syndrome (Pirota et al., 2021). This approach should be supported by updated clinical guidelines and lifestyle modifications conducive to the patient's well-being (Pirota et al., 2021).

Polycystic Ovarian Syndrome Measurement Tools

PCOS emerges within the literature as the preeminent endocrine disorder afflicting women of reproductive age, with profound implications for their health-related quality of life (HRQoL). The scholarship elucidates that PCOS transcends the reproductive and metabolic

spheres to encompass psychological dimensions that insidiously erode women's health and quality of life across their life continuum.

An array of factors frequently compromises the HRQoL for individuals with PCOS. Physical manifestations such as menstrual irregularities and infertility, coupled with concerns about physical appearance, precipitate psychological distress, thereby attenuating HRQoL. Additionally, metabolic attributes of PCOS, including insulin resistance and dyslipidemia, exacerbate anxiety and depression, either as direct symptomatic responses or because of the chronic disease diagnosis.

Notwithstanding PCOS's high prevalence, the patient's quality of life is often marginalized within clinical settings. The management of PCOS is characterized by fragmentation across medical disciplines, contributing to the need for more attention to HRQoL. The literature is bereft of ample evidence-based data that encapsulates the lived experiences of those with PCOS, spanning the diagnostic journey, health concerns, and disease management continuum.

Symptomatic expressions of PCOS can precipitate a profound decline in quality of life, engendering stress and adversely affecting psychological well-being, social integration, and sexual health. It is established within the corpus of literature that women with PCOS endure compromised emotional states, particularly concerning anxiety and depression, which lead to a substantive diminution in quality of life. However, the correlation between the phenotypic and biochemical characteristics of PCOS and the nature and intensity of psychological disorders remains an enigma.

Assessment instruments such as the PCOS Questionnaire (PCOSQ) measure the quality of life in women afflicted with PCOS, enabling a nuanced understanding of the syndrome's

varied impacts on HRQoL. The health risks associated with PCOS extend beyond reproductive challenges to include enduring concerns such as diabetes, metabolic syndrome, and endometrial cancer, thus highlighting the imperative for comprehensive assessment and intervention to facilitate HRQoL.

Sociotechnical Framework and Mobile Applications in Healthcare

In multidisciplinary healthcare, the Sociotechnical Framework and Actor-Network Theory (ANT) provide profound insights into integrating technology within care delivery systems. The ANT postulates that human and non-human actors, including technology, possess agency and significantly influence social processes (Cresswell et al., 2010; Booth et al., 2015). This theory illuminates the interplay between individuals and technological tools, underscoring how material artifacts shape and are shaped by human action, thus contributing to the complexity of healthcare practices (MacLeod et al., 2019).

The utilization of mobile applications in healthcare exemplifies the ANT's principles, where smartphones emerge not merely as devices but as active participants within the healthcare ecosystem, enhancing patient engagement and self-management, particularly for those with chronic conditions such as PCOS (Lin & Yang, 2021). These applications transform the approach to health monitoring, bringing forth a paradigm where the immediacy of digital documentation influences patient reflection, knowledge, and self-perception.

The Calcium app is a paragon within this realm, functioning as a cloud-based solution that marries patient-centric interfaces with robust data analytics. It fosters an environment conducive to personalized care plans and amplifies the user's autonomy over their PCOS management. Its features extend beyond mere tracking, offering educational content, interactive tools, and real-time communication, promoting adherence and enhancing the overall quality of

life. Furthermore, by seamlessly integrating validated questionnaires like the PCOSQ and WHOQOL-BREF, the app garners a comprehensive understanding of the patient's health status, informing and tailoring the care pathways to each patient's unique needs (Hamper, 2020).

The Calcium app exemplifies the ANT's notion of distributed agency by serving as an instrumental actor within the healthcare network. Its design and functionality represent a concerted response to the demands for a more nuanced, engaging, and practical patient care experience. Through its deployment, the project at hand has not only embraced the ANT's sociotechnical perspective but has capitalized on it to revolutionize PCOS care, thereby setting a benchmark for future health innovations.

IHI Model of Improvement and PDSA Cycle

The incorporation of the Institute for Healthcare Improvement (IHI) Model of Improvement and the Plan-Do-Study-Act (PDSA) cycle into a family practice initiative proffers a systematic and iterative methodology to advance Polycystic Ovary Syndrome (PCOS) management. This structured approach embarks with the "Plan" phase, formulating a comprehensive PCOS treatment regimen, aligning with extant clinical directives, quality-of-life indices, and fortified patient education paradigms. This phase is governed by delineating SMART objectives, ensuring each intervention is specific, measurable, achievable, relevant, and time-bound, and laying the groundwork for tangible improvements.

As the initiative transitions into the "Do" phase, it operationalizes the proposed strategies by instituting an evidence-based treatment framework, applying HRQoL assessments in initial consultations, and refining the diagnostic and therapeutic continuum. In parallel, the distribution of patient education resources commences.

The critical "Study" phase involves a rigorous evaluation of the efficacy of the implemented plan. This is characterized by an exacting analysis of the adherence to clinical protocols, the patient engagement with HRQoL tools like the PCOSQ and WHOQOL-BREF, and the effectiveness of the refined diagnostic and management protocols. This evaluative stage is critical for comparing actualized outcomes against benchmarks, thus identifying successful strategies and highlighting areas needing further development.

In the "Act" phase, the insights garnered from the "Study" phase inform the recalibration of the intervention strategies. These may include refinements to the treatment protocols, enhanced utilization of the PCOSQ, optimization of diagnostic processes, and revision of educational content to meet the patient's needs better.

The PDSA cycle promotes continuous quality improvement by necessitating a return to the "Plan" stage upon completing the "Act" stage. This perpetual cycle drives constant improvement in PCOS care, ensuring that the approach remains responsive to new insights and contributes to the evolving care standards for PCOS patients. The benefits of employing the IHI Model of Improvement extend beyond systematic enhancement; it engenders an ethos of evidence-based practice and perpetual learning within healthcare teams, essential for delivering superior, patient-focused care in complex chronic conditions such as PCOS.

Community Health Assessment

A community health assessment is a local health assessment that isolates fundamental health needs through data collection and analysis. Evaluating those that support shared ownership of community health, assessing and improving community engagement, identifying areas of targeted focus, and utilizing evidence-based interventions are significant components of evaluating a community. It is crucial to use the highest quality data and share it with public and

private sources to yield the best possible outcomes (Centers for Disease Control and Prevention [CDC], 2018).

Utilizing the descriptive epidemiology process to answer five specific questions related to PCOS helps to identify the pattern of occurrence in terms of place, time, and person. In addition, it defines the relationship of the disease to the population at risk—the person or “who” is any patient of reproductive age with ovaries. In addition, this question also looks at health behaviors such as diet and exercise, as well as family history, culture, environmental exposures, and occupation. The clinical problem or the “what” is defined as PCOS or those diagnosed with metabolic syndrome, cardiovascular disease, infertility, diabetes, hypertension, obesity, and or dyslipidemia. The “where” is Allegheny County, Pennsylvania. It is essential to compare the frequency of this syndrome, if possible, to that of surrounding counties to understand how disease frequency varies. According to the Centers for Disease Control and Prevention (2021), PCOS affects 6% to 12% of this population. Compared to neighboring counties, Allegheny County has 885,033 more residents than Westmoreland (U.S. Census Bureau, 2021d), 1,071,466 more residents than Beaver County (U.S. Census Bureau, 2021b), 1,028,620 more residents than Washington County and 1,043,817 more residents than Butler County (U.S. Census Bureau, 2021c). This results in a higher incidence of PCOS in Allegheny County due to a higher number of residents.

The “when” or time frame is a diagnosis within the last year, five years, and decade. This allows the opportunity to trend data and monitor the frequency of this health problem over time. The “why” or “how” relates to causes and risk factors, which include genetic and environmental factors as well as an unhealthy lifestyle (Ajmal et al., 2019). The specific potential causes of this geographic location and population are explained below. Understanding the epidemiology of

PCOS in Allegheny County helps to facilitate a quality improvement initiative. Knowing how many patients are potentially affected or at risk helps create a clinical priority in this location. Discerning risk factors aid in predicting the future prevalence of this syndrome and related comorbidities.

Allegheny County is ranked among the healthiest counties in Pennsylvania regarding health outcomes and health factors (County et al., 2022). The county has a lower incidence of those reported as smokers compared to state averages. Additionally, fewer residents have been told they have diabetes, are in fair or poor general health, and are obese or overweight compared to Pennsylvania overall (Pennsylvania Department of Health, 2019). Hospitalizations related to cerebrovascular disease, unintentional falls, influenza and pneumonia, and nephrotic diseases occur higher than PA totals. Allegheny County has elevated average hospital inpatient occupancies and admissions (Pennsylvania Department of Health, 2019).

The general fertility rate in Allegheny County from 15-44 years of age is lower than in Pennsylvania overall. Birth rates from ages 20 to 29 are also reported at lower rates (Pennsylvania Department of Health, 2019). The percentage of low birth weight is statistically similar in both the county and state (Pennsylvania Department of Health, 2019) and consistent with national averages, ranking 32nd overall (Centers for Disease Control and Prevention [CDC], 2021a). Infant mortality rates per 1,000 live births are higher in Pennsylvania than the national averages (CDC, 2021a).

As mentioned previously, the CDC (2021) reports that PCOS affects 6% to 12% of women of reproductive age. According to Allegheny County's population data, this results in 38,000 to 76,000 affected residents. Cardiovascular disease (CVD) and cerebrovascular events are common occurrences related to local deaths and hospitalizations. Multiple studies regarding

CVD and cerebrovascular disease were conducted comparing women with and without PCOS. Patients in the PCOS group yielded a significantly elevated risk of ischemic heart disease, CVD, myocardial infarction, and stroke (Zhang et al., 2020).

Regarding the prevalence of breast cancer within the county, several carcinogenic components are associated with PCOS. Limited studies have been conducted to correlate the risk of breast cancer to PCOS. To err on the side of caution, reproductive cancers should be added to the potential long-term health consequences of PCOS and warrant increased surveillance (Yin et al., 2019). Low fertility rates, like what is seen in Allegheny County, are repeated concerns among individuals diagnosed with PCOS. Infertility is projected to affect 12% of couples across the globe. The American Society of Reproductive Medicine estimates the rate of infertility among those with PCOS to be up to 80% (Lentscher et al., 2020). Infant mortality rates are a concern within Allegheny County. Those with PCOS have been shown to have a 50% increased risk of stillbirth compared to unaffected women, particularly at term (Valgeirsdottir et al., 2021).

Air quality in the Allegheny County region poses a considerable health concern. Patients exposed to a high concentration of air pollutants have been shown to have higher risks of PCOS (Lin et al., 2019). This is attributed to long-term pollutant exposure increasing inflammation. Exposure causes oxidative stress and cell damage, predisposing a patient to PCOS (Lin et al., 2019).

In conclusion, the community health assessment of Allegheny County highlights several critical health issues and disparities that warrant attention and intervention. The evaluation reveals higher rates of various health problems, including heart disease, accidents, sexually transmitted infections, and infant mortality, compared to state and national averages. Additionally, the assessment underscores the pressing need to address environmental factors

such as poor air quality, which may contribute to health issues like PCOS. Addressing these challenges and implementing evidence-based interventions will be crucial in improving the overall health and well-being of the residents of Allegheny County.

DNP Project's Purpose

The purpose of this project is to reduce physical and emotional symptoms impacting the quality of life of women with PCOS in a primary care setting through timely and accurate diagnosis and personalized evidence-based care.

This project aims to conduct a quality improvement initiative related to PCOS care. The first component will implement a PCOS treatment protocol with up-to-date clinical guidelines for disease management and optimized patient care. Additionally, HRQoL assessments will measure, improve the quality of life, and guide individualized care plans within a family practice setting. This allows for the integration of HRQoL and evidence-based PCOS management. Patient-reported data obtained from HRQoL assessments will be used to prioritize medical management.

Furthermore, this project will enhance clinical practice processes that include timely and accurate diagnoses, education of providers and patients, and treatment of manifestations that significantly impact quality of life. PCOS is a multifaceted and complex process that requires individualized, evidence-based, and supportive care. The outcomes of this quality improvement project will reduce the burdens impacting women with PCOS and improve their quality of life.

Project Aims and Objectives

Aim 1 (Plan): Complete a gap analysis of the current practice for treating patients with PCOS compared to the evidence-based protocols regarding the quality of life in these patients.

Objective 1.1: Complete a literature search on the quality of life in PCOS and present a synthesis of findings to stakeholders to determine elements to be implemented and evaluated in current practice

Objective 1.2: Identify gaps and inconsistencies in the current practice currently provided to patients diagnosed with or at risk for PCOS at the family practice.

Objective 1.3: Develop PCOS protocol including all provider and clinical staff stakeholders

Aim 2 (Plan): Develop clinical practice changes needed to support the implementation of a PCOS protocol.

Objective 2.1: Complete a new PCOS workflow for patients and providers/staff, including in-office visits, follow-up care, and referrals.

2.1.1: Establish the logistics of enrolling patients and scheduling interviews and education sessions with the support of the office staff.

Objective 2.2: Develop guidelines and documentation for PCOS patient assessment, quality of life surveys (PCOSQ and WHOQOL-BREF), and educational materials.

Objective 2.3.: Develop education sessions for providers and office staff to support the implementation of the PCOS protocol.

Aim 3 (Do): Implement a quality improvement initiative to support improvements in the quality of life of PCOS patients.

Objective 3.1: Conduct education sessions for providers and office staff to ensure proper screening, surveillance, documentation, and maintenance of patients at risk for or diagnosed with PCOS.

Objective 3.2: Enroll PCOS patients in interview sessions with the DNP student; the electronic health record will be utilized to identify patients diagnosed with PCOS. In collaboration with the DNP student, the office staff will send letters to PCOS patients with instructions on downloading and enrolling in the calcium application.

Objective 3.3: Schedule patient visits for enrolled patients, including patient interviews utilizing PCOSQ and WHOQOL-BREF screening tools to establish a baseline quality of life and repeat visits in 1 month.

Objective 3.4: Interview PCOS protocol patients regarding satisfaction with the program and their recommendations for change.

Objective 3.5: Interview clinicians and clinical staff regarding PCOS protocol implementation.

Objective 3.6: Monitor patient data collection process for reliability and provide project updates to stakeholders monthly.

Aim 4 (Study): Evaluate the impact of quality improvement initiatives in improving PCOS manifestations and quality of life of PCOS patients.

Objective 4.1: Analyze patient interviews collected during the first visit and the 1-month follow-ups.

Objective 4.2: Analyze quality of life measurements comparing the initial visit and 1-month follow-ups, utilizing the PCOSQ and WHOQOL-BREF.

Objective 4.3: Analyze patient satisfaction and patient recommendations for project improvement.

Objective 4.4: Analyze provider and staff interview data.

Aim 5 (Act): Share analysis of project data with stakeholders and identify strengths and weaknesses, needed modifications, and recommendations for changes to be made.

Objective 5.1: Present project data findings to the providers and staff

Objective 5.2: Identify project strengths and weaknesses and needed workflow modifications

Objective 5.3: Identify recommendations for the next steps regarding the PCOS protocol

Methodology

This initiative is dedicated to executing a quality improvement project within the scope of PCOS management. A central tenet of this project is establishing a PCOS treatment protocol grounded in contemporary clinical guidelines to streamline disease management and enhance patient care quality. Integral to this protocol is the systematic assessment of HRQoL, which both gauges and enriches the quality of life for patients, thereby informing the personalization of care plans within the context of a family practice environment. This approach embodies the harmonization of HRQoL evaluation with evidence-based management of PCOS, ensuring that patient-reported outcomes from HRQoL assessments are effectively harnessed to direct medical management priorities.

Moreover, the project intends to refine clinical practice procedures by ensuring prompt and precise diagnosis, bolstering the education of healthcare providers and patients alike, and addressing the most impactful PCOS symptoms on patients' quality of life. Recognizing PCOS's intricate and multifaceted nature, the project advocates for an evidence-based, personalized care paradigm that encapsulates supportive care measures. Anticipated to alleviate the burdens borne

by those with PCOS, the project's successful implementation is expected to yield significant improvements in their quality of life.

Sophisticated technologies, such as smartphone applications, can enhance healthcare delivery, extending its reach to an increasingly broad audience (Haleem et al., 2021). As a particularly advantageous technological advancement, this simplifies access to preventive care, significantly improving individuals' long-term health outcomes and quality of life (Haleem et al., 2021). Studies have shown that subjects with PCOS exhibited a pronounced reliance on the Internet for acquiring information, which appears to have contributed to an average postponement of three months before seeking medical intervention (Kaur et al., 2021). A prevalent catalyst for ultimately pursuing treatment was the distress associated with observable bodily and physiological alterations (Kaur et al., 2021). Despite eventually obtaining medical attention, notable dissatisfaction was expressed concerning the efficacy and outcomes of the treatments administered (Kaur et al., 2021).

The Calcium application represents an innovative, cloud-based solution designed to enhance healthcare delivery by integrating a patient-centric mobile application with a productivity-enhancing dashboard for healthcare providers. This platform facilitates superior care quality through the automation and digitization of healthcare processes, enabling medical and physician groups to extend a comprehensive suite of services to their patients. Key features of the Calcium app include around-the-clock guidance through daily reminders and directives, curated educational content such as videos and articles, and secure data-sharing capabilities that ensure seamless communication of Electronic Medical Records (EMR) among care providers. At the heart of Calcium's functionality are meticulously crafted patient pathways to guide individuals toward improved health outcomes. These pathways transform standard care

instructions into interactive reminders, alerts, and action plans, empowering patients to pursue their health objectives actively. By leveraging gamification and behavioral science principles, Calcium engages patients in their health management, fostering a sense of ownership and proactive involvement.

Moreover, the app's configurable pathways allow for the customization of patient feedback mechanisms and the collection of Remote Patient Monitoring (RPM) data. This dual approach keeps patients motivated and adherent to their care plans. It enables healthcare providers to monitor patient progress effectively, ensuring timely interventions and adjustments to treatment strategies.

Including the Calcium smartphone application is pivotal to this quality improvement initiative. This innovative application is set to act as a conduit for executing the newly established protocols and HRQoL assessments, enabling real-time communication and data exchange between patients and healthcare providers. Calcium's role is twofold: it not only facilitates the collection of patient-reported data, which is instrumental in tailoring individual care plans, but also serves as an educational and monitoring tool that reinforces the initiative's overarching goals. The app's design aligns seamlessly with the initiative's objectives by enhancing patient engagement, fostering adherence to treatment regimens, and supporting continuous health progress monitoring, thus representing a quintessential component of this quality improvement project.

Delineating the project timeline into distinct phases is essential in ensuring the systematic execution and success of research initiatives. The proposed six months of this project are strategically divided to optimize the team preparation and the data collection process. The initial month is dedicated to the preparation and education of the office staff, a critical phase that is

foundational to the project's overall success. This preparatory period is designed to ensure that all personnel involved are adequately equipped with the necessary knowledge and competencies required for the efficient execution of their roles within the project.

Investing time in the training and education of staff will strive to enhance the quality of data collected and foster a collaborative and informed work environment. This phase will involve a comprehensive training program encompassing the project's objectives, methodologies, and ethical considerations, ensuring all team members are aligned with the project's goals and understand their responsibilities.

Following the initial preparatory month, the subsequent five months are allocated for rigorous data collection. The extended duration acknowledges the intricacies of gathering high-quality, reliable data, which is pivotal for the validity and credibility of the research findings. This period will allow for the meticulous execution of the data collection plan, including deploying surveys, interviews, or experimental methodologies as the project's research design dictates.

Furthermore, segmenting the project timeline into preparation and data collection phases aligns with best practices in project management within academic research, facilitating a structured approach that enhances the project's efficiency and effectiveness. This structured timeline also allows for incorporating interim evaluations, ensuring necessary adjustments can be made to improve project outcomes.

In summary, the strategic allocation of six months for this project, with a distinct emphasis on preparation and data collection phases, indicates a systematic approach designed to optimize project outcomes. This approach ensures that office staff are well-prepared and

informed and facilitates data collection, which is crucial for achieving the project's research objectives.

Setting

This quality improvement initiative is situated within a family practice in a suburban locale outside of Pittsburgh, PA, catering to a diverse patient demographic of all ages. The primary objective is to elevate the standard of living for patients within the reproductive age bracket who are grappling with PCOS. The practice's multidisciplinary team is committed to this endeavor, comprising a physician, physician assistant, and ancillary staff. They contribute a confluence of their professional expertise, the informed consent of the participating patient population, pertinent patient data, and the requisite infrastructural facilities to realize the goal of enhancing life quality for these patients, ultimately leading to the meticulous management of PCOS.

The advanced practice nurse's role in this initiative is pivotal and includes providing educational resources, administering HRQoL questionnaires, and dedicating time and specialist knowledge to the project. To successfully meet the initiative's aims, it is crucial to recognize and address the myriad factors that influence the quality of life in patients afflicted with PCOS and to disseminate this knowledge among all stakeholders involved in the care delivery process.

The initiative's progress and effectiveness are quantifiable through the meticulous documentation and analysis of HRQoL assessment outcomes, EHR data, biometric parameters, and laboratory test results. The process is intended to be iterative and responsive, allowing for real-time adjustments and enhancements to the care strategy.

In the short term, the initiative is expected to bolster the knowledge base of healthcare providers and patients regarding PCOS, establish a foundational understanding of the quality-of-

life benchmarks for those affected by the condition, and formulate a comprehensive, patient-centric care framework. These initial steps are foundational for the development of the quality improvement process.

The intermediate goals are centered on broadening the scope and precision of PCOS diagnoses, increasing the frequency and coverage of PCOS screenings, and optimizing the scheduling and administration of HRQoL assessments for individuals recently diagnosed with PCOS. By refining these processes, the initiative aims to identify and address PCOS at earlier stages and tailor interventions more effectively to individual patient needs.

From a long-term perspective, the initiative envisions a transformation in the standards of PCOS care, fostering significant enhancements in the quality of life for individuals living with the syndrome. The overarching aspiration is to curtail the prevalence of associated comorbidities through sustained, high-quality care and ongoing patient engagement. Integrating the Calcium smartphone application within this framework amplifies the initiative's capacity to monitor patient health metrics, personalize care plans, and provide educational content, thus reinforcing the trajectory toward these long-term outcomes.

The initiative will begin in September 2023 and end in March 2024. The initial phase of the quality improvement project entails a structured educational session for the office staff. This session is designed to elucidate the initiative's objectives, outline the use of the Calcium smartphone application, and detail the process for conducting patient interviews. After this foundational training, the office personnel will initiate contact with patients diagnosed with PCOS to schedule the foundational interview. These interviews are a critical component of the project, gathering baseline data on patients' health status and experiences with PCOS management.

After each interview, the insights garnered will be systematically relayed to the healthcare providers. This step ensures that any necessary modifications to patient care plans can be made, thereby aligning the management approach more closely with the individual needs and circumstances of the patients. Follow-up interviews are scheduled monthly throughout the project, facilitating ongoing assessment and adaptation of care plans.

This manuscript delineates a quality improvement initiative predicated on the Plan-Do-Study-Act (PDSA) cycle to augment the quality of life for individuals with PCOS in a primary care environment. The implementation of the Calcium application is central to this endeavor. The app systematically collects patient-reported data by engaging patients to complete targeted questionnaires. This data is then leveraged to give patients personalized, evidence-based information, which is instrumental in managing their condition.

The nature of the PDSA cycle allows for continuous refinement of the care process. The application's functionalities enable the translation of clinical guidelines and patient responses into actionable health management plans. These plans are meticulously reviewed and, if warranted, revised in collaboration with the physician, thus ensuring that the management strategies are tailored to address the evolving needs of each patient. Therefore, the Calcium app is pivotal in this quality improvement project, bridging the gap between patient-reported outcomes and evidence-based clinical decision-making.

Implementation

The implementation of this quality improvement project commenced with the meticulous creation of an educational session by the DNP student. The student developed a comprehensive PowerPoint presentation grounded in evidence-based practice to equip the office staff with the necessary knowledge and skills to support the project's objectives. The presentation

encompassed the pathophysiology of PCOS, the critical role of HRQoL assessments, and the functionality of the Calcium smartphone application within the context of this initiative.

The presentation by Kami Beveridge Wast, MSN, CRNP, CMSRN, from Duquesne University's School of Nursing, discusses strategies for improving the quality of life in patients with Polycystic Ovary Syndrome (PCOS). PCOS is identified as an endocrine disorder affecting women of reproductive age, characterized by a variety of symptoms such as infertility, dysmenorrhea, acne, obesity, and excessive body hair growth. These manifestations contribute to a diminished health-related quality of life (HRQoL), affecting individuals' functional and emotional well-being (Fatemeh et al., 2021; Forslund et al., 2022).

The presentation outlines a timeline for a quality improvement project starting in November 2023 and concluding in February 2024. This project involves initial patient engagement through the Calcium application, where participants complete PCOS and WHOQOL questionnaires. The DNP student will further adjust treatment pathways based on these results and conduct interviews to tailor the care (Appendix slide).

Wast also provides criteria for suspecting PCOS in patients presenting with symptoms of hyperandrogenism like acne and hirsutism, often exacerbated by obesity. The necessity of evaluating these patients for PCOS is emphasized, considering the significant overlap of symptoms with other conditions and the potential underlying risks such as cardiovascular diseases and diabetes (Barbieri & Ehrmann, 2023).

The evidence-based practices (EBPs) for managing PCOS are detailed across various domains—emotions, body hair, weight, infertility, and menstrual problems. The approach includes psychological screenings using validated tools such as the PHQ-9 for depression and the GAD-7 for anxiety, highlighting the prevalence of mood disorders and eating disorders among

these patients (Masoudi et al., 2021; Barbieri & Ehrmann, 2023). For hirsutism and menstrual irregularities, the first-line treatments suggested are combined oral contraceptives or alternative androgenic medications. In cases of suboptimal response, options like bariatric surgery or pharmacotherapy are considered for weight management, with specific medications chosen based on their impact on fertility (Barbieri & Chang, 2023; Hazelhurst et al., 2022).

The section on infertility underscores the importance of cycle tracking and hormone assessments to ascertain ovulatory functions, with interventions timed according to cycle phases (Kuohung & Hornstein, 2023). For menstrual problems, the recommendation includes the use of progestin-releasing IUDs or continuous progestin therapy to protect against endometrial hyperplasia, a risk in PCOS patients (Slide on Menstrual Problems).

Lastly, the presentation highlights the role of nutritional supplements such as zinc, selenium, probiotics, and vitamin D in managing PCOS by modulating metabolic functions and reducing oxidative stress (Calcaterra et al., 2021; Guo et al., 2020). This comprehensive presentation effectively integrates current research with clinical practices, offering a multi-dimensional approach to managing PCOS and improving patient outcomes.

Following the development of the educational materials, the DNP student engaged in a series of collaborative meetings with the developers of the Calcium application. These sessions were dedicated to customizing the app specifically for the project, which involved the integration of the PCOSQ and the WHO-QOL instruments. Additionally, the app was enhanced to disseminate evidence-based guidance on nutrition, physical activity, relaxation techniques, and other relevant therapeutic interventions tailored to managing PCOS utilizing the best available evidence.

The next phase of implementation involved targeted communication with the patient cohort. The DNP student extracted a list of patients with a diagnosis code of PCOS from the EHR system. Each identified patient received a letter informing them of the project and inviting them to participate. The letter included comprehensive instructions and a QR code, facilitating the effortless download of the Calcium app from the Apple Store or Google Play, depending on the patient's device.

Once patients opted into the project, the DNP student enrolled each participant within the Calcium platform. Six patients consented to partake in the study. To preserve their anonymity within the context of this manuscript, they were each assigned a designation ranging from A to F, utilizing the initial segment of the Latin alphabet. The digital environment created by Calcium was the nexus for interactive patient engagement and individualized care management. The initial action within this virtual platform was the distribution of the PCOSQ and WHOQOL-BREF questionnaires through the Calcium application. Participants were notified via smartphone notifications, prompting them to complete the questionnaires. This process established a baseline for assessing each patient's quality of life and the severity of PCOS symptoms.

The patient's responses to the initial questionnaires were pivotal. They informed the subsequent customization of the care pathway within the app, ensuring that each patient's unique concerns and needs were addressed comprehensively. Through the Calcium application, the DNP student could then orchestrate a tailored approach to care for each participant. Individualization is critical, as PCOS manifests with a spectrum of symptoms and impacts each patient differently, necessitating a nuanced approach to management.

As the initiative progressed, monthly administrations of the designated questionnaires were conducted to assemble longitudinal data compared with the baseline metrics obtained at the

project's inception. This comparative analysis was instrumental in discerning patterns, trends, and deviations in patient-reported outcomes over time. Concurrently, iterative modifications were applied to the care plans as needed, informed by the responses provided by the clients. This reflective process ensured that the therapeutic pathways remained aligned with and responsive to the evolving needs and conditions of the clients. Under the guidance of the DNP student, a certified registered nurse practitioner (CRNP), recommendations were provided to the physician and physician assistant regarding adjustments to treatment plans. These recommendations encompassed, among other things, modifications to oral contraceptive regimens, referrals for cognitive behavioral therapy, consultations with endocrinology or gynecology specialists, the inclusion of insulin-sensitizing medications, and the incorporation of supplementary community support services based on the patient's questionnaire responses. Such a meticulous approach underscores the project's commitment to evidence-based, patient-centric care, allowing for a fluid and adaptable management strategy that mirrors the lived experiences and preferences of the patients.

In summary, implementing this quality improvement project was a carefully orchestrated process that combined educational preparation, technological innovation, personalized communication, and evidence-based practice. Through these concerted efforts, the DNP student facilitated a proactive and patient-centered approach to PCOS management, leveraging the capabilities of the Calcium application to provide a nuanced, responsive, and holistic healthcare experience for each participant.

Data Management Plan

Data collection methods encompassed digital tracking of app usage statistics, questionnaire responses, and qualitative feedback from users. Validation checks were integrated

into the app to ensure the completeness and accuracy of data, and periodic audits were conducted in collaboration with the app developers. Following the initial data acquisition phase, an issue emerged regarding the accurate reporting of patient data by the Calcium application. This challenge necessitated several collaborative sessions with the application developers and extensive troubleshooting efforts to restore accurate data retrieval effectively. Ongoing evaluations focused on individual-level measures, utilizing internal (app analytics, electronic health records) and external (patient-reported outcome measures) data sources. Data collection occurred twice monthly, with subsequent analyses to assess the intervention's impact over the five months of gathering data.

DNP Project Results

The results of this DNP Project indicate that the quality of life among project participants with individuals with PCOS has improved, and this was substantiated by validated PCOS-specific quality-of-life questionnaires. This was particularly pronounced within emotional well-being and physical health domains. The graphical representations, delineated in the appendices (see Appendix A), exhibit the trends observed throughout the study. The analysis of these variations illuminates the significance of individualized care plans and highlights the pivotal role that continuous engagement via the application plays in effectuating improved health outcomes.

An intriguing benefit surfaced was an augmented cognizance of PCOS and its associated comorbidities among the participants. Nevertheless, the investigation identified potential barriers, such as disparate levels of digital literacy among the user base. Within the cohort, a subset manifested a marked improvement in emotional well-being, as reflected in their PCOS Questionnaire (PCOSQ) scores (Appendix A). This finding corroborates the existing literature that individuals with PCOS frequently exhibit compromised mental health, which may impede

social interactions and communication, potentially leading to the development of depressive and anxiety disorders (Naumova et al., 2020). Thus, there is a compelling necessity for dependable information to be made accessible for those diagnosed with PCOS, underscoring the importance of digital platforms endorsed by healthcare professionals for disseminating pertinent information (Ismayilova & Yaya, 2022).

Furthermore, the data set unveiled improvements in menstrual regularities among participants, positing that those who experienced these improvements were also prescribed contraceptives suitable for PCOS management, specifically those with appropriate androgenicity (Appendix A-B). The preferred treatment modality, consisting of Combined Oral Contraceptives (COCs), aims to regulate menstrual cycles and address hyperandrogenism (Oguz & Yildiz, 2021). The study did not reveal a significant impact on the treatment of hirsutism, corroborating literature that posits COCs may reduce adrenal androgen production but may necessitate a prolonged period to affect hirsutism significantly (Shah et al., 2018).

The overall quality of life was also assessed using the WHOQOL-BREF instrument, validated across various cultural contexts, and affirms its capacity to detect significant changes in life quality pertinent to well-being targets (Skevington & Epton, 2018). Each participant displayed improvements to differing degrees, as documented in the appendices of this manuscript (Appendix A-B).

To effectively address Objective 3.4, a structured qualitative methodology was employed, wherein patients enrolled in the Polycystic Ovary Syndrome (PCOS) treatment protocol were interviewed to ascertain their satisfaction levels with the program and to solicit their recommendations for its enhancement. The interviews were conducted using semi-structured questionnaires that included open-ended and closed-ended questions. This approach allowed for

collecting in-depth responses while providing the flexibility to explore specific areas of interest as they arose during the interviews. The data gathered were subsequently analyzed using thematic analysis, which facilitated the identification of recurring themes and patterns relating to patient satisfaction and their perceived areas for improvement.

Similarly, Objective 3.5 was achieved through a series of structured interviews with clinicians and clinical staff involved in implementing the PCOS protocol. These interviews aimed to evaluate the practical aspects of protocol deployment and to identify any challenges or barriers encountered by the staff. The interview format was tailored to extract detailed insights into the workflow processes, the adequacy of training and resources, and the overall effectiveness of the protocol from the perspective of those administering it. Responses were meticulously recorded and analyzed to discern commonalities and divergences in staff experiences, which were critical in assessing the operational feasibility and efficacy of the PCOS treatment protocol.

Both interviews were instrumental in providing a holistic understanding of the PCOS program from the perspectives of the patient and healthcare provider. This dual approach ensured that the program's effectiveness and efficiency were thoroughly evaluated and highlighted areas for potential refinement, aligning with the overarching goals of enhancing patient outcomes and optimizing clinical practices within PCOS management.

Ethical Considerations

The ethical considerations for the quality improvement project involving the Calcium smartphone application for patients with PCOS in a primary care setting were paramount to ensure respect, safety, and privacy for all participants.

The project rigorously maintained confidentiality standards to safeguard participants' personal health information. It employed advanced data encryption techniques for the app and ensured that all patient data transmitted and stored were protected against unauthorized access. Access to sensitive information was meticulously controlled, limited to authorized personnel trained in handling confidential data, and adhered to a strict code of conduct emphasizing patient privacy.

Informed consent was a critical component, ensuring that participants were fully aware of the nature of the project, the extent of their involvement, and the potential risks and benefits associated with their participation. The process entailed providing detailed information about the study in understandable language, ensuring participants understood how their data would be used, their right to withdraw without penalty, and the measures in place to protect their privacy. Consent was granted by the patient, who was provided the option to enroll in the initiative upon receiving the letter. This consent process was structured to enable participants to pose questions and obtain comprehensive responses before they agreed to participate.

Transparent communication regarding using and storing personal health information was maintained throughout the project. Participants were informed about the specific types of data collected, the purposes for which it was collected, how long it would be stored, and the protocols for its eventual disposal. Such transparency helped build trust between the researcher and participants, ensuring they felt secure in contributing to the project.

Before the project's commencement, ethical approval was sought and obtained from the institutional review board (IRB) at Duquesne University. This process involved submitting a detailed proposal outlining the project's aims, methodologies, data handling practices, and the measures in place to protect participants' rights and well-being. The IRB's approval confirmed

that the project met the required ethical standards for research involving human subjects, including adherence to beneficence, non-maleficence, autonomy, and justice principles.

One significant ethical concern in the management of PCOS arises from the presumption that every patient diagnosed with the condition identifies as a woman. This conjecture not only overlooks the complexity of gender identity but also risks marginalizing transgender men and non-binary individuals who may suffer from PCOS. Ethically, healthcare providers must adopt a more inclusive approach that recognizes the diverse identities of their patients. The conflation of PCOS solely with women disregards the experiences of those who do not align with this identity, potentially leading to feelings of alienation and discomfort, which can deter individuals from seeking necessary medical care. Moreover, it underscores the importance of healthcare practices evolving to ensure that discussions, literature, and support systems are designed in a manner that is welcoming and affirming to all, regardless of gender identity. According to findings disseminated by the Cleveland Clinic, the prevalence of PCOS within the transgender population alone was documented at 23.8% (Rangi et al., 2024). Addressing this ethical concern requires a shift towards more inclusive healthcare practices that acknowledge and cater to the needs of all individuals with PCOS, fostering an environment where everyone can receive care that is both respectful and affirming of their identity.

These careful ethical considerations and practices underscored the project's commitment to respecting participants' rights and safety, ensuring that the research was conducted with the utmost integrity and aligned with the core principles of medical ethics. The project successfully demonstrated the efficacy of a digital health intervention in improving the quality of life for patients with PCOS in a primary care setting. The Calcium app facilitated a novel approach to personalized care, enabling patients to engage actively in their health management process.

Interpretation

The interpretation of the results from the quality improvement project, which introduced the Calcium smartphone application for managing PCOS, highlights the significant impact of digital health solutions on chronic condition management. This scholarly examination delved into the intricate relationship between digital health intervention and its outcomes, compared findings with existing literature, evaluated the broader impact on stakeholders, elucidated discrepancies between expected and actual results, and discussed the economic implications and strategic considerations inherent in the project's execution.

The application's introduction was correlated with notable enhancements in the quality of life among PCOS patients, marked by improved self-management practices and increased engagement in health-related behaviors. The direct association between the intervention and outcomes can be attributed to the application's ability to provide personalized, evidence-based information and foster a collaborative care approach between patients and healthcare providers. This relationship underscores the potential of digital health tools to empower patients and facilitate a more proactive management of chronic conditions.

The observed benefits of the Calcium app are consistent with a growing body of research supporting the efficacy of digital health interventions in chronic disease management. Studies have shown the promising potential of digital solutions for providing healthcare services to patients with chronic diseases (Bitar & Alismail, 2021). Furthermore, several of these scholarly works advocate for the sustained application of these technological solutions, emphasizing their value in the future landscape of healthcare delivery (Bitar & Alismail, 2021).

Research suggests that such technologies can facilitate better disease understanding, improve adherence to treatment regimens, and enhance patient-provider communication (Haleem

et al., 2021). By providing personalized information and support, digital tools empower patients to take an active role in their health care, potentially leading to better clinical outcomes and quality of life (Haleem et al., 2021). The success of the Calcium app adds to this evidence, underscoring the utility of mobile health solutions in addressing complex conditions like PCOS.

The project also revealed essential insights into how individual patient contexts affect the effectiveness of digital health interventions. Variability in outcomes highlighted that while digital tools can significantly improve health management, their impact can be modulated by personal health literacy, technology access, usability, cultural attitudes toward health, and the nature of the managed condition. Variations emphasize the need for digital health solutions to be highly customizable and adaptable to meet diverse patient needs and preferences. It suggests that the one-size-fits-all approach is less practical in digital health interventions and that success depends on the ability to tailor content and functionalities to individual patient profiles.

The results of this project are consistent with an expanding amount of evidence supporting the effectiveness of digital health interventions in the management of chronic diseases, such as depression, chronic pain, diabetes, and others. Studies have similarly reported improvements in patient engagement, self-management, and overall health outcomes following the adoption of such interventions. However, this project contributes to the literature by focusing on a specific population, patients with PCOS, thereby filling a gap in the research on digital health applications tailored to this particular group.

The Calcium app has had a multifaceted impact on individuals and healthcare systems. For patients, it offered a novel avenue for managing their condition, leading to increased autonomy and potentially reducing the disease burden. It presented an innovative tool for healthcare providers to supplement traditional care models, enhancing patient-provider

communication and facilitating personalized care planning. The project highlighted the viability of integrating digital health solutions into primary care practices at a systemic level, suggesting a scalable model for improving chronic disease management across broader healthcare systems.

The project encountered variations between expected and observed outcomes, which can be primarily attributed to the dynamic nature of individual patient contexts. Digital literacy, health literacy, socioeconomic status, and personal preferences influenced how individuals engaged with and benefited from the app. These differences underscore the importance of considering the heterogeneous needs of the target population when designing and implementing digital health interventions.

Implementing the Calcium app without incurring additional costs was a significant achievement, made possible through collaboration with the app developers. This strategic decision minimized financial barriers to the project's execution, allowing resources to be allocated more effectively elsewhere. However, this approach also involved trade-offs, such as the reliance on external partners for technical support and updates, which could affect the app's long-term sustainability and adaptability. Moreover, allocating resources to this digital intervention may have entailed an opportunity cost, redirecting attention and resources from other potential interventions or aspects of patient care. Nonetheless, the cost savings linked with this initiative are significant, as the DNP student enabled real-time communication with participants, offering guidance for more thorough management to anticipate complications and potentially mitigating the physical and psychosocial burdens associated with potential comorbidities.

The Calcium app demonstrates the complex interplay between digital health interventions and patient outcomes within PCOS management. The positive association between the app's use

and improved patient outcomes contributes valuable insights to the field of digital health while also highlighting the necessity of tailoring interventions to meet the diverse needs of the target population. The project's impacts extend beyond individual improvements, suggesting broader implications for healthcare delivery and chronic disease management. However, executing such interventions involves carefully considering economic factors and strategic trade-offs, emphasizing the need for a balanced healthcare innovation approach.

Implications for Practice and Future Research

The observed positive correlation between the Calcium app and enhanced patient outcomes, while acknowledging individual differences, provides significant insights for both clinical application and future research endeavors. It advocates for integrating digital health solutions into standard care practices, particularly for chronic conditions like PCOS, where long-term engagement and personalized care are crucial. However, it also calls for further investigation into how digital tools can be optimized to address the unique needs of different patient populations, including exploring the barriers to effective use and strategies to enhance accessibility and usability.

Additionally, the differences between observed and anticipated outcomes invite a deeper exploration of the mechanisms through which digital interventions exert their effects and how these can be enhanced or modified to achieve the desired outcomes. It suggests a need for ongoing evaluation and adaptation of digital health solutions, incorporating patient feedback and emerging evidence to refine and improve their impact.

In summary, the project's findings contribute to the evidence base supporting the use of digital health interventions in chronic disease management while also highlighting the importance of considering individual patient contexts in the design and implementation of such

technologies. This dual focus on efficacy and personalization is critical for maximizing the potential of digital health solutions to improve patient outcomes. Future work should explore the scalability of the intervention and its long-term sustainability in diverse healthcare settings. Additionally, this initiative possesses the potential to serve as a paradigmatic model for the management of a diverse array of chronic illnesses, offering a replicable framework for patient-centered care and digital health integration.

Limitations

The scope of applicability of the findings from this study may be limited to primary care environments and patient demographics that resemble those involved in the research, particularly those with existing access to and a degree of proficiency with digital health technologies. This limitation arises from the study's setting's inherent characteristics and the intervention's technological nature, which may not be universally representative or accessible across different healthcare contexts or among populations with varying levels of digital literacy and technology access.

The study utilized various methodological strategies to strengthen the robustness and significance of its conclusions, acknowledging potential drawbacks. Firstly, data analysis techniques were used to ensure the integrity and reliability of the study findings, allowing for a nuanced understanding of the intervention's impact within the specified context. This analytical rigor helps identify and control variables that could bias the results, thereby enhancing the credibility of the findings.

Secondly, the study adopted an iterative approach to refine the digital health intervention, incorporating continuous participant feedback to make adjustments throughout the research. This dynamic method of intervention development is crucial for addressing real-time challenges and

barriers encountered by users, ensuring that the technological solution remains responsive to the needs and preferences of its intended audience. By actively engaging with participant feedback, the study not only enhanced the usability and effectiveness of the digital tool but also increased the potential for broader applicability and acceptance across similar settings and populations.

Despite these efforts, it is essential to acknowledge that the generalizability of the findings may still be restricted by factors such as geographical location, healthcare infrastructure, and socioeconomic variables that influence access to and engagement with digital health solutions. Future research could benefit from exploring the application of similar interventions across a broader range of settings and populations, including those with limited technology access or digital literacy, to expand the understanding of how digital health solutions can be adapted and scaled for diverse healthcare contexts.

While the study's findings offer valuable insights into the effectiveness of a digital health intervention in a specific primary care setting, the generalizability of these results requires careful consideration of the context and characteristics of the target population. Ongoing efforts to refine and adapt the intervention, informed by robust data analysis and participant feedback, are essential to enhance the relevance and applicability of digital health technologies in various healthcare environments.

Funding

The utilization of the Calcium application was facilitated at no additional cost, courtesy of the application developers. Consequently, the project did not accrue any supplementary expenses.

Conclusion

Integrating HRQoL assessments and evidence-based management for PCOS represents a significant stride forward in personalized healthcare. This quality improvement initiative underscores the pivotal role of HRQoL in shaping healthcare delivery and outcomes, particularly for those living with chronic conditions such as PCOS. By employing the WHOQOL-BREF and PCOSQ as tools for measuring the multifaceted impacts of PCOS on individuals, this project has laid the groundwork for more nuanced and effective patient-centered care strategies.

The initiative's findings reinforce the notion that HRQoL is a critical determinant of health outcomes, echoing the broader literature's emphasis on self-assessed health status as a robust predictor of mortality and morbidity. In the context of PCOS, a condition that significantly impairs physical, psychological, and social well-being, the project's focus on HRQoL assessments as a basis for tailored treatment plans represents an innovative approach to mitigating the adverse effects of the syndrome on individuals' lives.

This project's methodological rigor, embodied in the Plan-Do-Study-Act (PDSA) cycle, has enabled a systematic evaluation of the intervention's effectiveness. The intervention's iterative refinement, driven by continuous feedback and data analysis, has enhanced the precision of the study's findings and its applicability to similar primary care settings. However, it is essential to acknowledge that the specific demographic and technological contexts of the study population may need to be revised to allow the generalizability of these results.

The discrepancy between anticipated and observed outcomes highlights the complex interplay between individual patient contexts and the effectiveness of digital health interventions. This variation underscores the importance of adaptable and patient-centric approaches in designing and implementing health technologies. Furthermore, collaborating with app developers

to facilitate the Calcium app at no additional cost represents a strategic decision that underscores the potential for scalable and sustainable digital health solutions in managing chronic conditions.

This initiative's implications extend beyond the immediate context of PCOS management, offering valuable insights into the broader field of digital health. The positive association between using the Calcium app and improved patient outcomes contributes to the growing evidence base supporting digital interventions in chronic disease management. However, the project also highlights the need for ongoing research to explore such interventions' scalability and long-term sustainability across diverse healthcare settings.

In conclusion, this quality improvement initiative has demonstrated the efficacy of integrating HRQoL assessments with evidence-based PCOS management within a primary care setting. By focusing on the individualized needs of patients with PCOS, the project improves patients' quality of life and contributes to the evolving landscape of personalized healthcare. The lessons learned from this initiative offer a roadmap for future research and practice, emphasizing the critical role of patient-centered approaches in enhancing the effectiveness of chronic disease management strategies.

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Appendix A

Monthly PCOSQ Scores by Domain Using a Likert Scale

Table 1

Baseline PCOSQ Results from November 2023

Patient	Emotional Well-being	Body Hair (Hirsutism)	Weight	Infertility	Menstrual Problems
A	1	4	2	6	2
B	5	3	4	7	3
C	6	4	5	5	4
D	5	2	3	5	3
E	3	6	4	4	2
F	7	6	5	6	1

Table 2
PCOSQ Results from December 2023

Patient	Emotional Well-being	Body Hair (Hirsutism)	Weight	Infertility	Menstrual Problems
A	3	3	2	6	4
B	5	3	4	7	4
C	6	4	6	5	3
D	5	3	4	5	3
E	4	6	5	4	3
F	7	7	4	6	2

Table 3
PCOSQ Results from January 2024

Patient	Emotional Well-being	Body Hair (Hirsutism)	Weight	Infertility	Menstrual Problems
A	4	3	2	6	5
B	5	4	4	7	3
C	7	4	6	6	4
D	5	3	5	5	4
E	4	6	5	4	2
F	7	7	3	6	3

Table 4
PCOSQ Results from February 2024

Patient	Emotional Well-being	Body Hair (Hirsutism)	Weight	Infertility	Menstrual Problems
A	5	3	2	7	6
B	5	4	4	7	4
C	7	4	6	7	5
D	5	3	5	5	5
E	6	6	5	4	3
F	7	7	4	6	3

Table 5
PCOSQ Results from March 2024

Patient	Emotional Well-being	Body Hair (Hirsutism)	Weight	Infertility	Menstrual Problems
A	5	5	4	7	6
B	6	4	5	7	6
C	7	5	6	7	6
D	7	3	6	6	6
E	6	7	5	6	4
F	7	7	5	6	5

Appendix B**Trends in Monthly PCOSQ Domain Scores for Each Patient Using a Likert Scale****Figure B1**

Trends in PCOSQ Scores for Patient A Across Project Duration

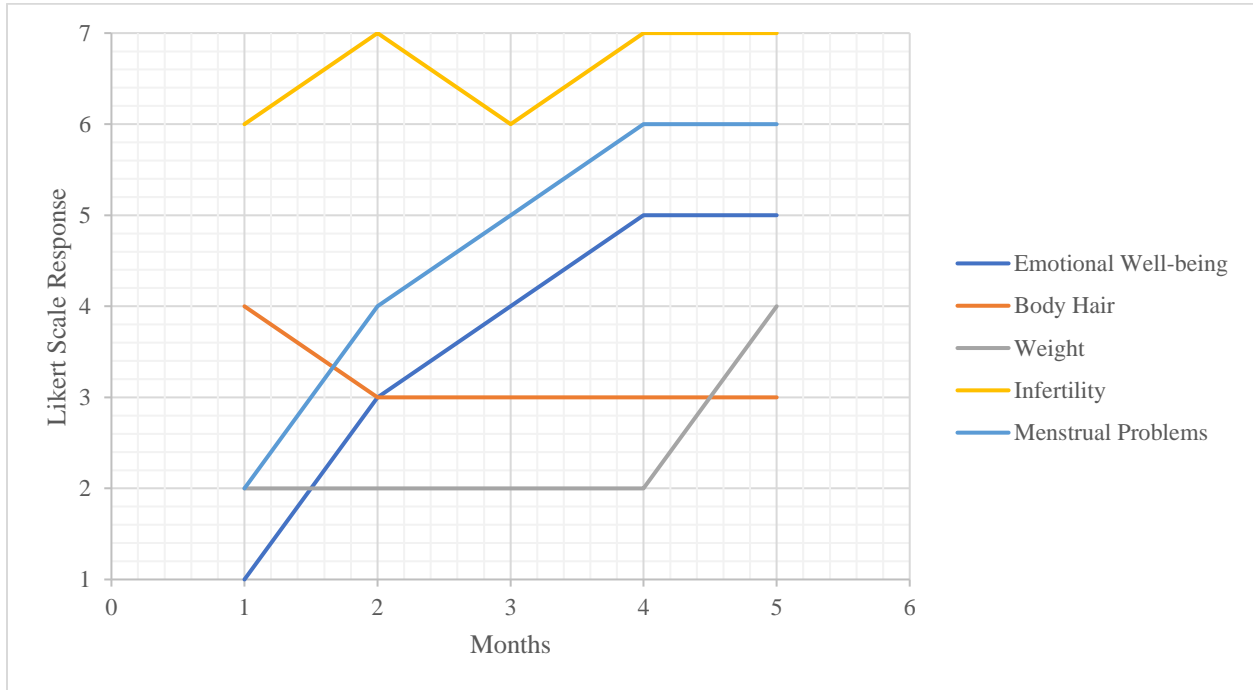


Figure B2
Trends in PCOSQ Scores for Patient B Across Project Duration

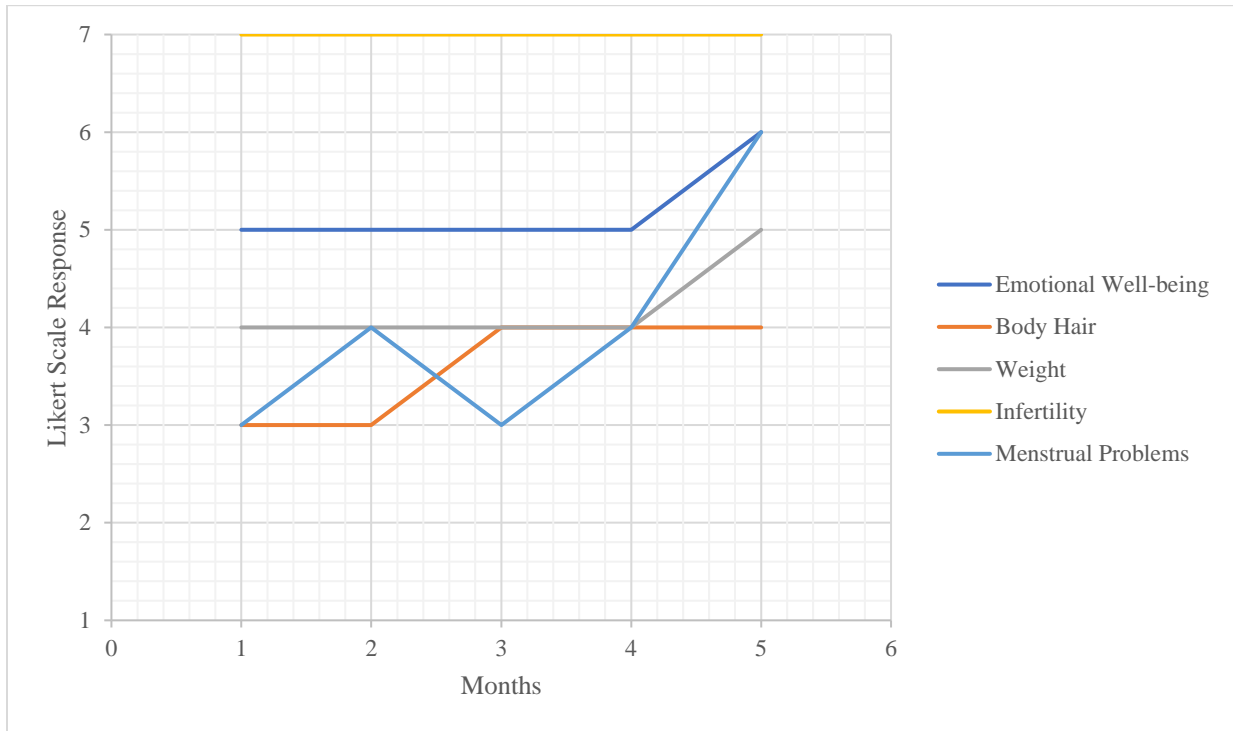


Figure B3
Trends in PCOSQ Scores for Patient C Across Project Duration

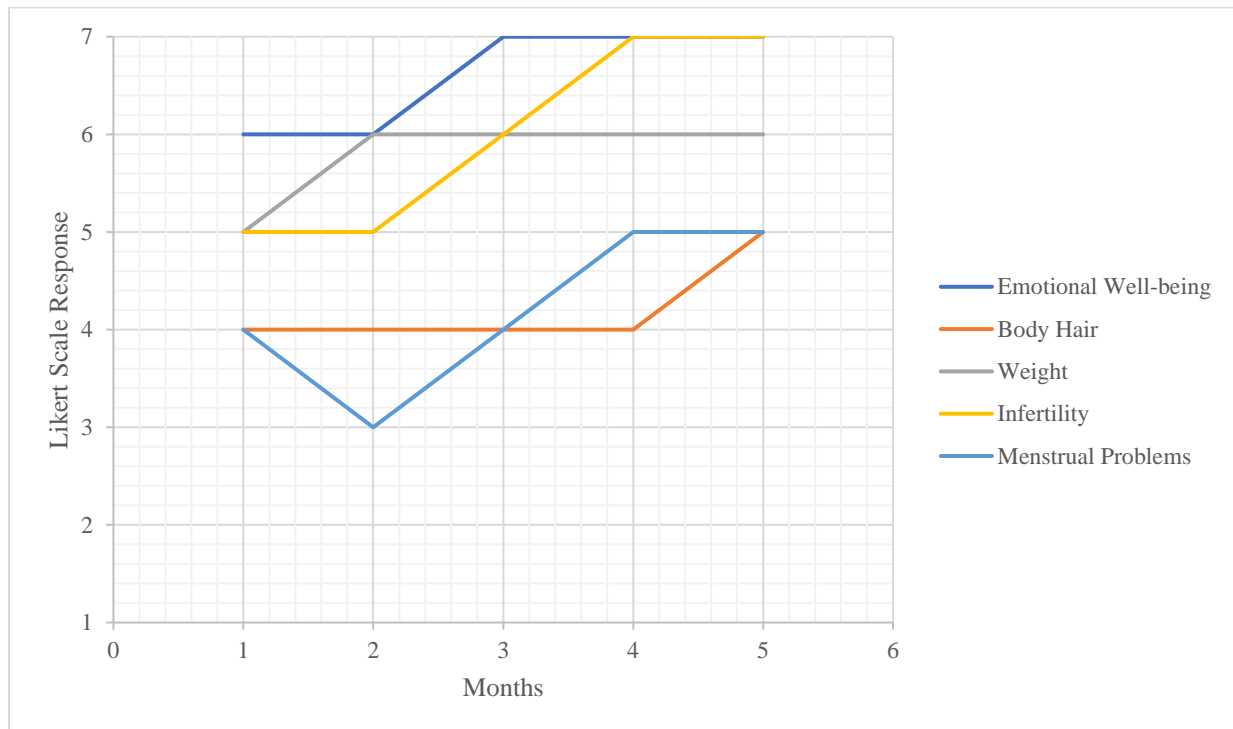


Figure B4
Trends in PCOSQ Scores for Patient D Across Project Duration

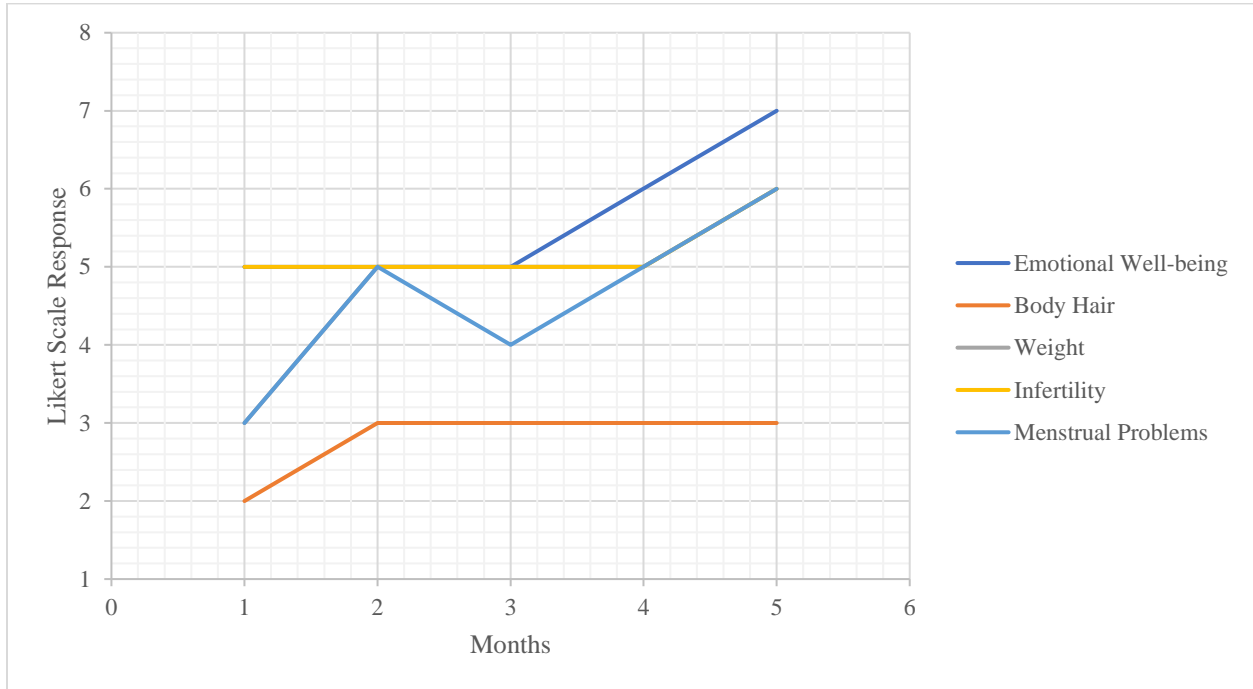


Figure B5
Trends in PCOSQ Scores for Patient E Across Project Duration

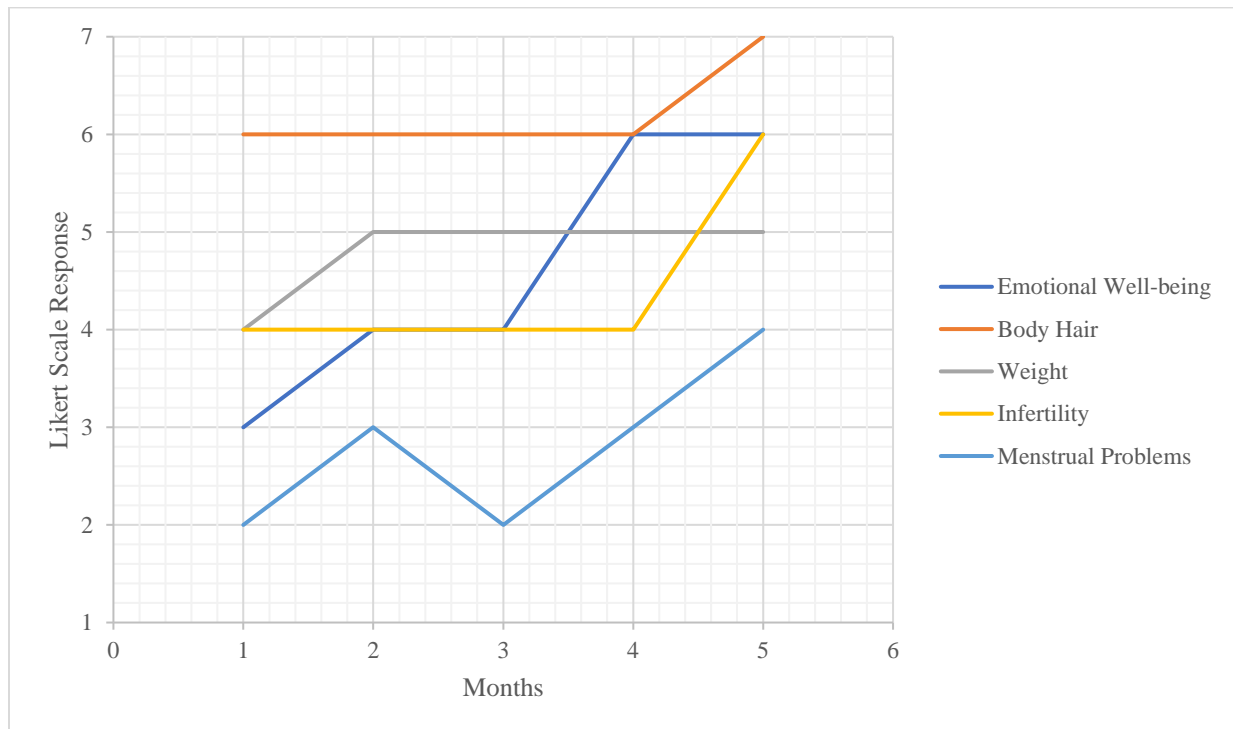
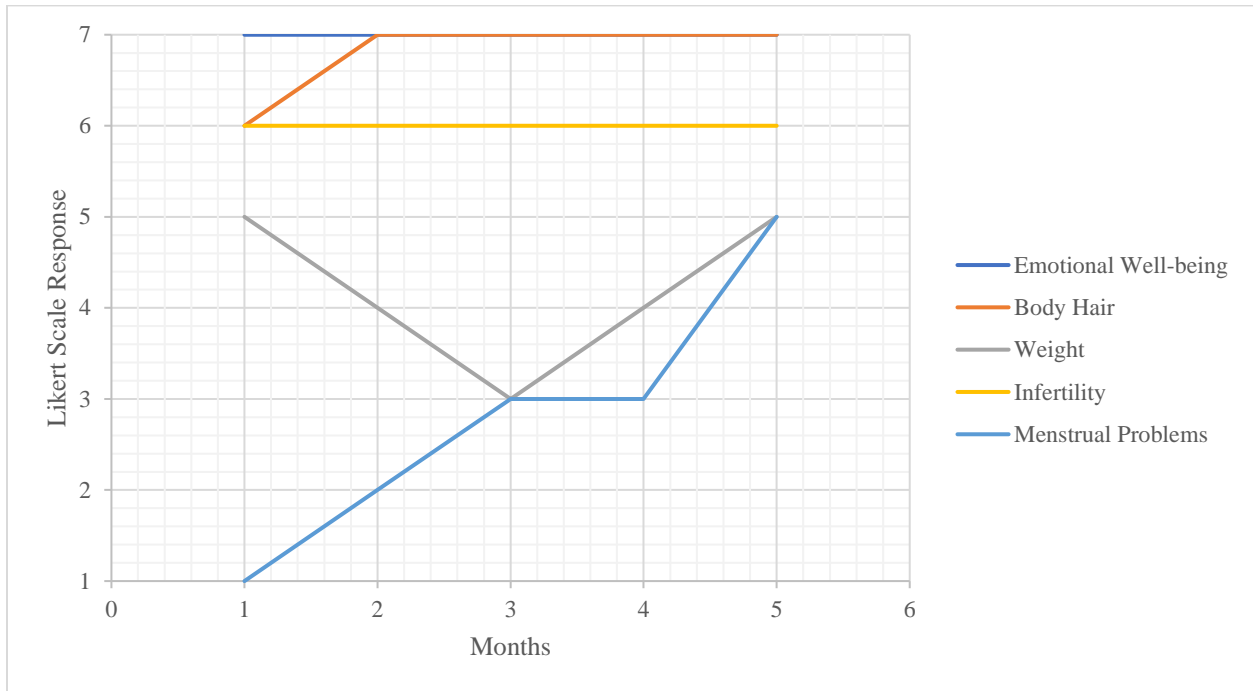


Figure B6
Trends in PCOSQ Scores for Patient F Across Project Duration



Appendix C
Monthly WHOQOL-BREF Scores by Domain

Table 1
 Baseline WHOQOL-BREF Results from November 2023

Patient	Physical Health	Psychological Health	Social Relationships	Environment	Overall QoL
A	68	66	72	82	72
B	78	72	78	80	77
C	74	76	80	75	76.25
D	86	84	89	85	86
E	89	83	90	89	87.75
F	83	86	84	90	85.75

Table 2
 WHOQOL-BREF Results from December 2023

Patient	Physical Health	Psychological Health	Social Relationships	Environment	Overall QoL
A	70	68	72	80	72.5
B	79	75	80	82	79
C	76	76	80	77	77.25
D	84	86	87	88	86.25
E	88	86	89	86	87.25
F	85	84	88	88	86.25

Table 2
WHOQOL-BREF Results from January 2024

Patient	Physical Health	Psychological Health	Social Relationships	Environment	Overall QoL
A	72	69	74	79	73.5
B	81	77	79	83	80
C	78	79	78	80	78.25
D	85	88	84	89	86.5
E	90	88	87	88	88.25
F	87	86	86	87	86.5

Table 3
WHOQOL-BREF Results from February 2024

Patient	Physical Health	Psychological Health	Social Relationships	Environment	Overall QoL
A	73	68	75	80	74
B	83	80	77	85	81.25
C	79	81	78	82	80
D	86	87	85	87	86.25
E	89	90	88	86	88.25
F	88	89	88	84	87.25

Table 4
WHOQOL-BREF Results from March 2024

Patient	Physical Health	Psychological Health	Social Relationships	Environment	Overall QoL
A	77	71	74	79	75.25
B	84	82	79	83	82
C	81	82	82	81	81.5
D	88	86	86	89	87.25
E	90	89	89	86	88.5
F	89	89	89	86	88.25

Appendix D

Trends in Monthly WHOQOL-BREF Domain Scores for Each Patient

Figure B1
Trends in PCOSQ Scores for Patient A Across Project Duration

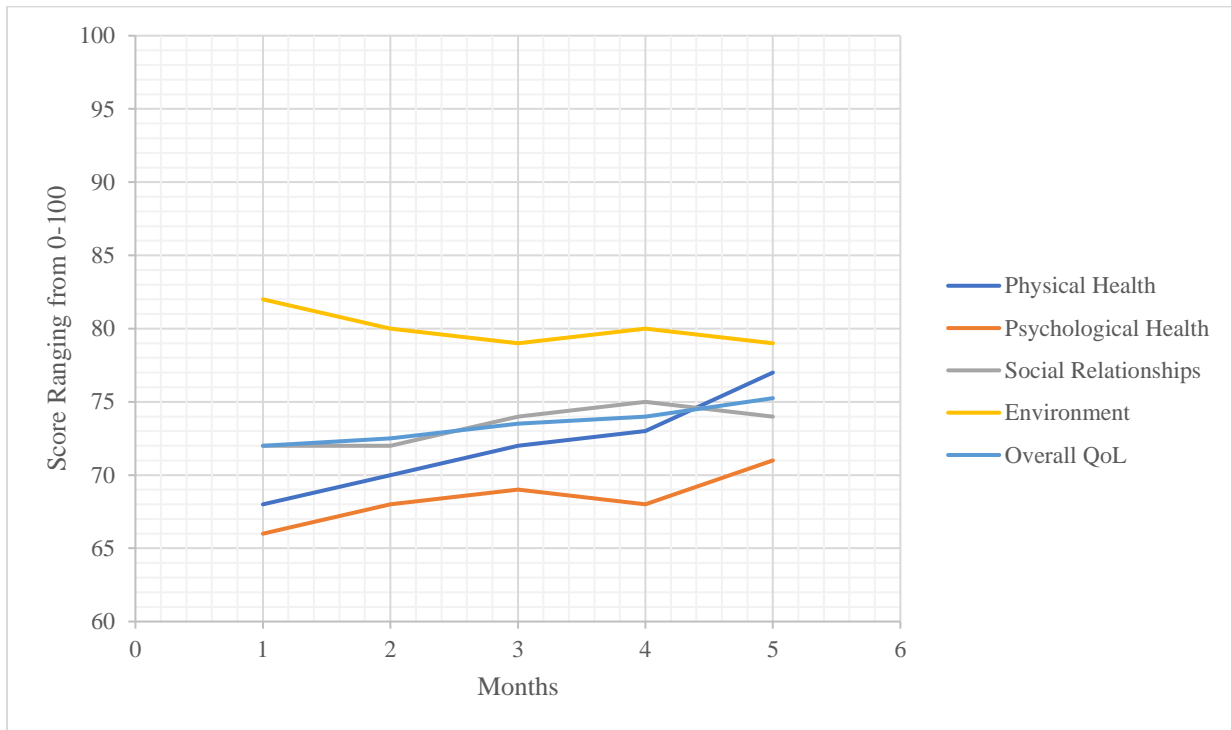


Figure B2
Trends in PCOSQ Scores for Patient B Across Project Duration

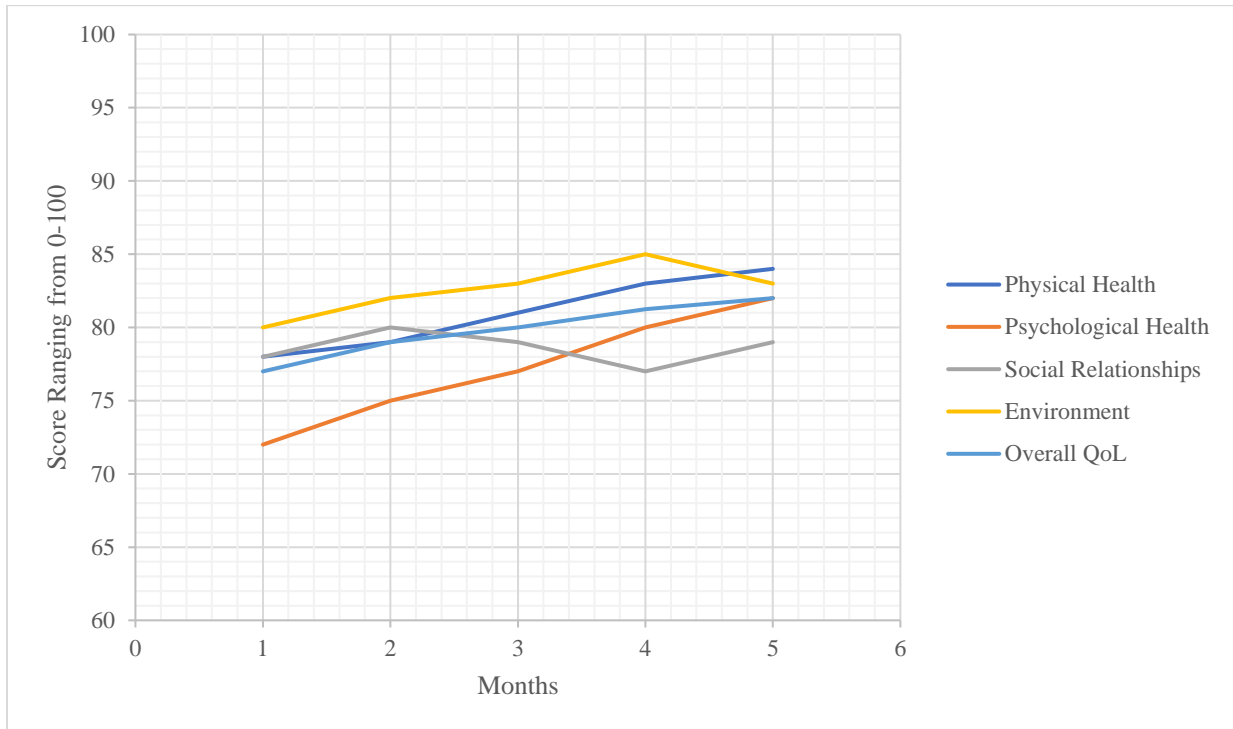


Figure B3
Trends in PCOSQ Scores for Patient C Across Project Duration

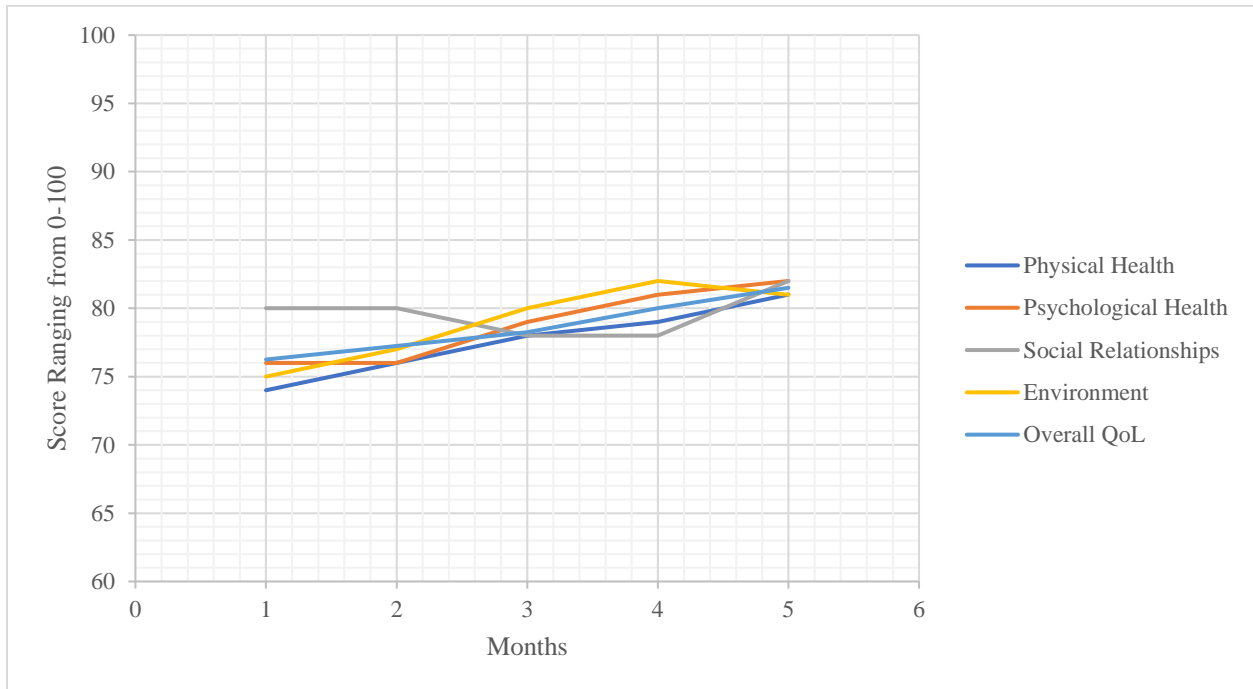


Figure B4

Trends in PCOSQ Scores for Patient D Across Project Duration

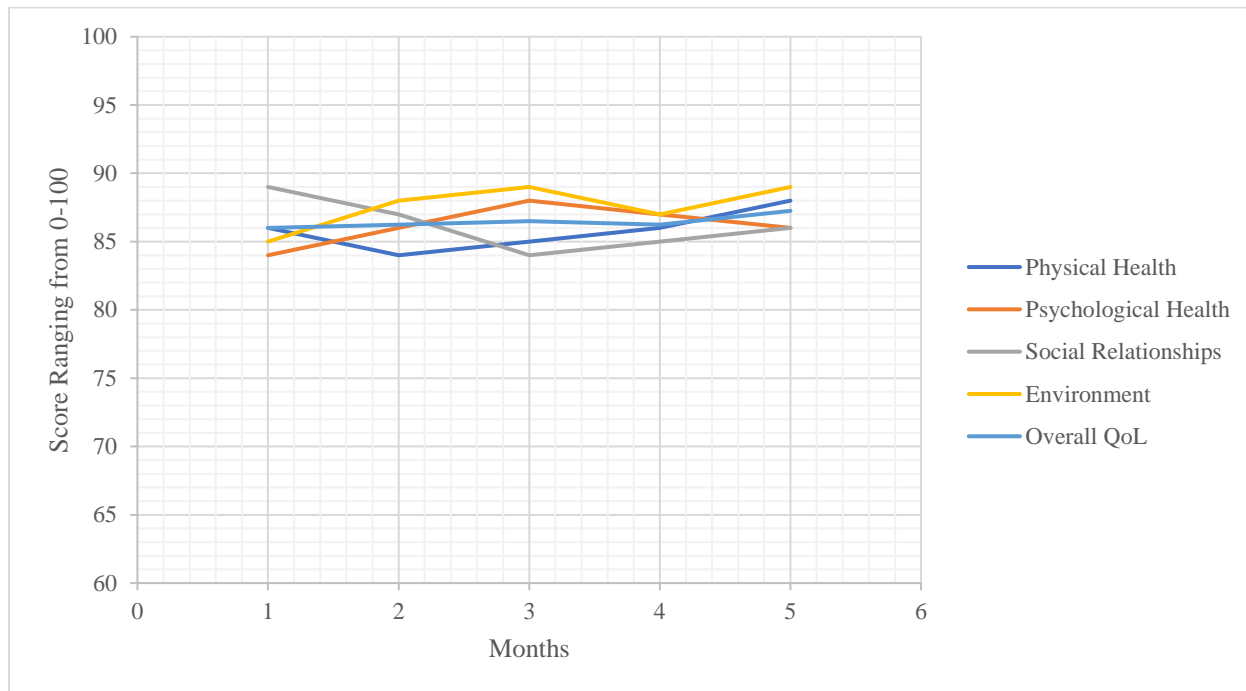


Figure B5
Trends in PCOSQ Scores for Patient E Across Project Duration

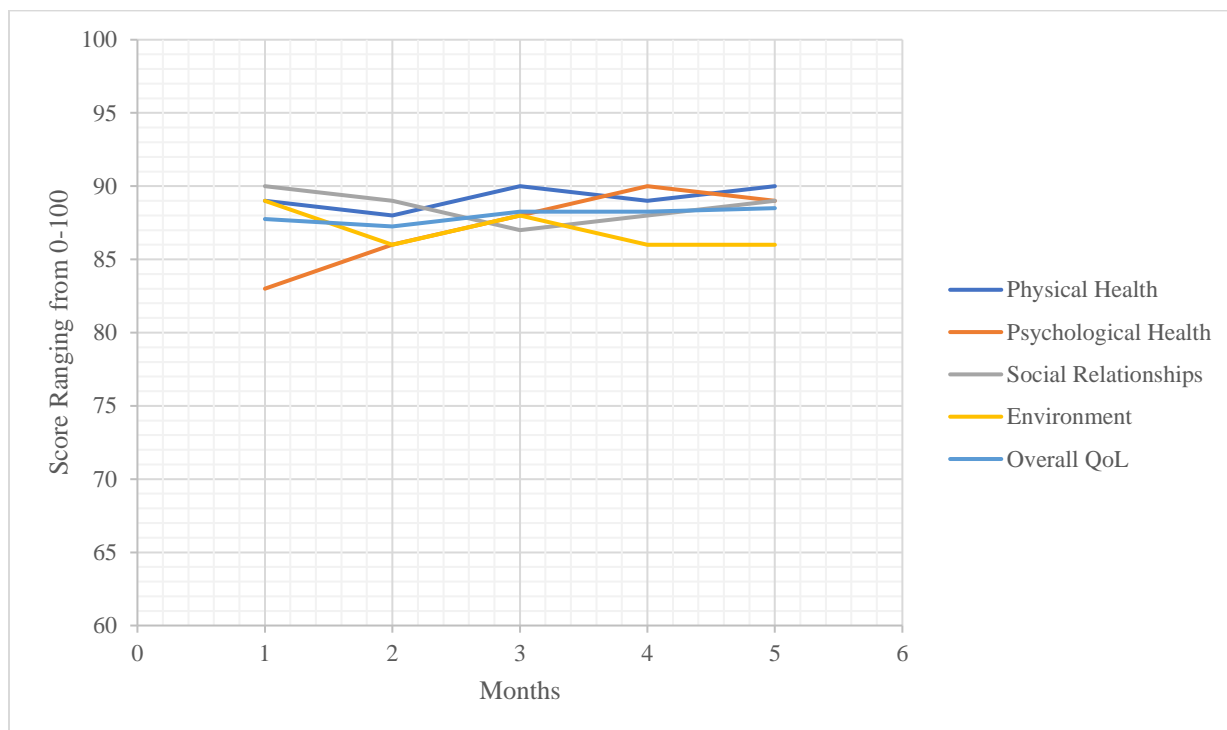
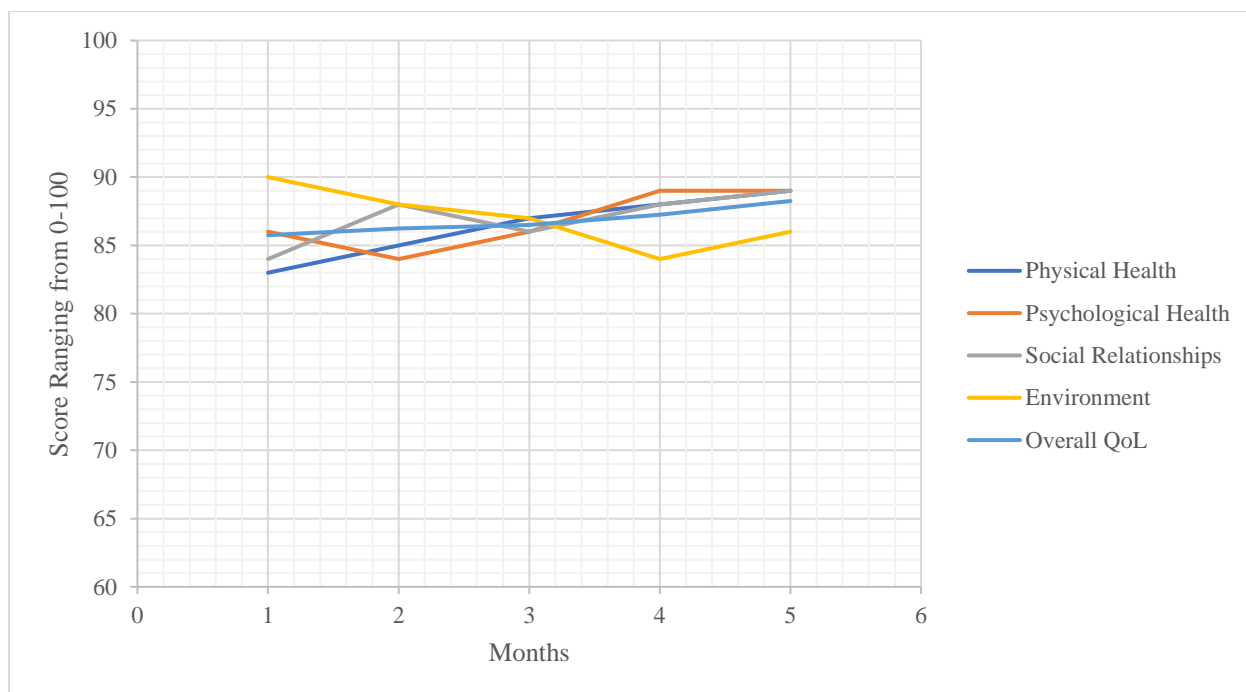


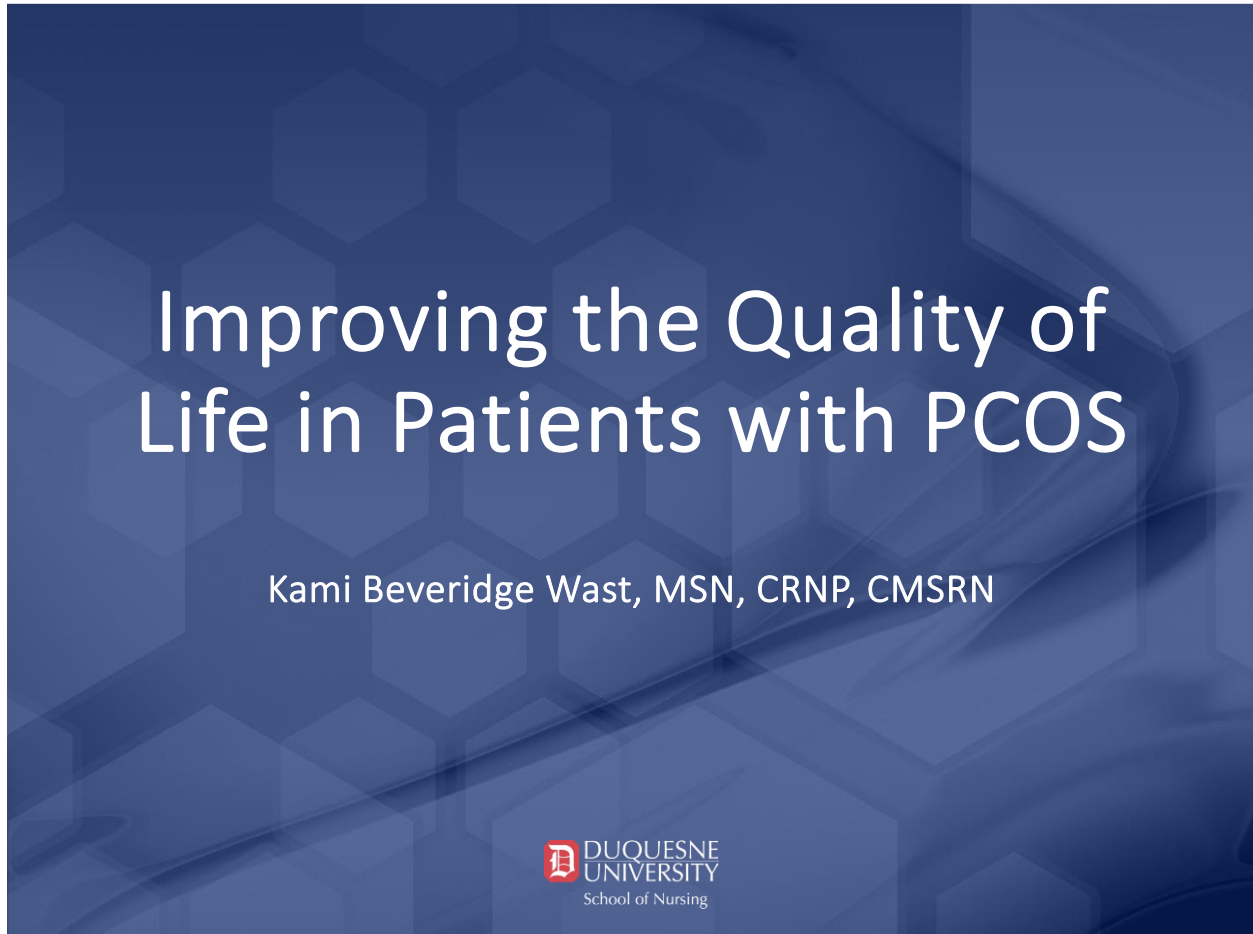
Figure B6
Trends in PCOSQ Scores for Patient F Across Project Duration



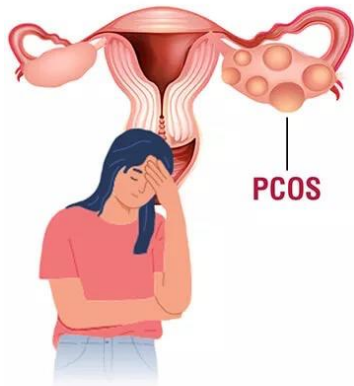
Appendix C
Education Session for Office Staff

Figures C1-C19

PowerPoint Slides Outlining PCOS Education and QI Initiative



Introduction




Polycystic ovarian syndrome (PCOS) is an endocrine disorder that impacts reproductive-aged patients with ovaries. PCOS is responsible for a wide range of symptoms including infertility, dysmenorrhea, acne, obesity, hair loss of the scalp, and excess body hair growth (Fatemeh et al., 2021).


PCOS and its manifestations have been identified as contributing factors to a diminished health-related quality of life (HRQoL) (Fatemeh et al., 2021). HRQoL means how the disease and its treatment influence a person's ability to function, as sensed by that individual (Forslund et al., 2022).

This presentation will provide an overview of the quality improvement project as well as current diagnosis guidelines and evidence-based treatment strategies for the manifestations of the syndrome.

Background

- Early and effective management of PCOS may improve HRQoL (Aryal et al., 2022)
 - It is crucial to evaluate the quality of life of those affected by PCOS before initiating treatment to offer support and lifestyle changes to ease them through their plan of care.
 - Defining the quality of life can be beneficial for choosing the proper treatment strategies and adequately evaluating a clinical response (Angin et al., 2019).
 - If the impact of a PCOS diagnosis on one's quality of life is understood correctly, the patient's condition and needs are prioritized appropriately.
 - Enhanced care and patient education can improve self-care in this population, leading to a higher quality of life (Rzońca et al., 2018).
- 

Measuring QOL

- The Abbreviated [World Health Organization Quality of Life Questionnaire \(WHOQOL-BREF\)](#) measures one's quality of life regardless of health status. It consists of twenty-six items that examine responses connected to physical, psychological, social, and environmental domains. Scores are calculated by finding means in each area. The higher the score, the higher the quality of life (Rzońca et al., 2018).
 - The [Polycystic Ovarian Syndrome Questionnaire \(PCOSQ\)](#) is a tool that was developed to evaluate the quality of life of those with PCOS. The PCOSQ contains domains regarding emotions, hirsutism (excess hair growth), weight, infertility, and menstrual disorders. Each item is answered using Likert scale options from one (always) through seven (never). Higher scores are indicative of a better quality of life. Research has revealed that those suffering from PCOS display marked impairments pertinent to the measured domains (Behboodi Moghadam et al., 2018). Women with PCOS experience physical, mental, emotional, cognitive, and social barriers to PCOS management. Therefore, multidisciplinary services, including psychological, dietetic, and exercise physiology, are necessary (Pirodda et al., 2021).
- 

Calcium Application

- Care management pathways are personalized for each patient's specific needs.
- Digital tools and resources for patients, including secure access to all health records



Apple Health integration

Pull in and merge data from your Apple Watch and Apple Health account.



Fitbit integration

Merge tracking data from your various Fitbit devices.



Health pathways

Clinically designed, personalized health improvement programs.



EHR integration

Gather electronic health records from all your healthcare providers.



Fitness tracker data

Add your fitness records from many leading fitness devices.



Medical device data

Collect and track data from top medical-grade devices.



Lifetime EHR storage

Back up all your health records to a secure cloud account.



Wearables tracking data

Integrate tracking records from leading wearable apps.



Vitals tracking

Record and track vitals data from various wireless devices.



Health Index

Handy snapshot metric of your current health status.



Health dashboard

Easily track key vital records and your pathway progress.



Secure privacy


Certified HIPAA compliant, multi-layered security.



Timeline

- November 2023
 - Invite participants and enroll in the Calcium application; the DNP student will set up the application with the PCOSQ and WHOQOL questionnaires
 - 11/8 = Day one; participants will receive a notification to complete questionnaires
 - DNP student will then develop evidence-based pathways for each individualized patient based on their quality-of-life questionnaire results and conduct patient interviews using Calcium
- December 2023
 - 12/6—repeat PCOSQ/WHOQOL and adjust the pathway based on the results
 - Update providers at Bartolomucci Family Practice with any changes/concerns
- January 2024
 - 1/17—repeat PCOSQ/WHOQOL and adjust the pathway based on the results
 - Midway point- conduct a patient interview with each participant
 - Update providers at Bartolomucci Family Practice with any changes/concerns
- February 2024
 - 2/28—final PCOSQ/WHOQOL and present findings to stakeholders
 - Update providers at Bartolomucci Family Practice with any changes/concerns






Diagnosing and Treating PCOS

Who to Suspect

- Any woman of reproductive age who presents with irregular menses and symptoms of hyperandrogenism (acne, hirsutism, male-pattern hair loss)
 - The presence of overweight or obesity should further raise suspicion.
- Some women present with either oligomenorrhea or hyperandrogenic symptoms alone should be evaluated for PCOS, particularly those with hyperandrogenism (as most women with hirsutism have PCOS).
- Women with polycystic ovaries on ultrasound and no other clinical features of PCOS (hyperandrogenism or menstrual dysfunction) do not have PCOS and need no further evaluation.
- These women may have associated risk factors for cardiovascular disease, including obesity, glucose intolerance, dyslipidemia, fatty liver, and obstructive sleep apnea that require evaluation and treatment.

(Barbieri & Ehrmann, 2023)



Rotterdam Criteria


Most expert groups use Rotterdam criteria to make the diagnosis of PCOS.

Two out of three of the following criteria are required to complete the diagnosis.

- Oligo- and/or anovulation
- Clinical and/or biochemical signs of hyperandrogenism
- Polycystic ovaries (by ultrasound)

Many women with irregular menses and hyperandrogenic symptoms can be diagnosed based on their history and physical exam alone. However, the diagnosis of PCOS is only confirmed when other conditions that mimic PCOS are excluded (e.g., disorders that cause oligo/anovulation and/or hyperandrogenism, such as thyroid disease, non-classic congenital adrenal hyperplasia [NCCAH], hyperprolactinemia, and androgen-secreting tumors).

(Barbieri & Ehrmann, 2023)



Four Phenotypes

	Phenotype A	Phenotype B	Phenotype C	Phenotype D
Hyperandrogenism and hirsutism	Present	Present	Present	Absent
Ovulatory dysfunction	Present	Present	Absent	Present
Polycystic ovarian morphology	Present	Absent	Present	Present



PCOSQ Domains


1. Emotions
2. Body hair
3. Weight
4. Infertility
5. Menstrual problems



EBP for Each Domain: Emotions

- Women with PCOS may be more likely to have mood disorders (depression and anxiety) than those with similar BMI without PCOS. They are also at risk for eating disorders (binge eating).
- Expert societies suggest screening all women with PCOS for depression and anxiety.
- The best approach is to use brief, validated screening tools such as the Patient Health Questionnaire (PHQ)-9 for depression and the Generalized Anxiety Disorder 7 (GAD-7) anxiety scale for anxiety disorders.
- There is also a questionnaire for [binge eating disorders](#)
- Evidence also suggests the preferred use of sertraline when medication is indicated.

(Barbieri & Ehrmann, 2023) (Masoudi et al., 2021)



EBP for Each Domain: Body hair

Women with hirsutism and irregular menstrual cycles have an underlying endocrine disorder (Barbieri & Ehrmann, 2022).

Measure:

- Serum total testosterone
- Human chorionic gonadotropin [hCG]
- Prolactin
- Follicle-stimulating hormone [FSH]
- Thyroid-stimulating hormone [TSH]
- Early morning 17-hydroxyprogesterone (around 8 AM)


For most females, COCs are the first-line drug; an anti-androgen can be added if the clinical response is suboptimal after six months of therapy (Barbieri & Chang, 2023).

- Choose a progestin with low or neutral androgenicity, such as norethindrone or norgestimate
- 

EBP for Each Domain: Weight

- Lifestyle behavioral interventions are the first line in weight management.
 - Consider referral to nutritionist
- Bariatric surgery is the most effective obesity treatment, resulting in sustained weight loss with a significant impact on obesity complications.
 - It may be an option for women with PCOS and severe obesity (BMI ≥ 40 or ≥ 35 with a high-risk obesity complication)
- The half-life of pharmacotherapy is to be considered when choosing the anti-obesity medication in women with obesity to PCOS seeking fertility.
 - GLP-1 vs Metformin

(Hazlehurst et al., 2022)



EBP for Each Domain: Infertility

- Encourage close cycle tracking.
- Examining ovulatory function is critical to evaluating the female partner since ovulatory dysfunction is a common cause of infertility.
- Women who have regular menses approximately every 28 days with minimal symptoms before menses (breast tenderness, bloating, fatigue, etc.) are most likely ovulatory.
- In women who do not describe their cycles as such, laboratory assessment of ovulation should be performed.
- Ovulation is most easily documented by a mid-luteal phase serum progesterone level, which should be obtained approximately one week before the expected menses.
 - For a typical 28-day cycle, the test would be obtained on day 21.
 - A progesterone level >3 ng/mL is evidence of recent ovulation.

(Kuohung & Hornstein, 2023)



EBP for Each Domain: Menstrual Problems

- Treatment of other endocrine abnormalities also helps decrease the risk of endometrial hyperplasia or carcinoma.
- Combined estrogen-progestin oral contraceptives (COCs) are first-line therapy for menstrual dysfunction and endometrial protection.
- COCs affect insulin sensitivity, carbohydrate metabolism, and lipid metabolism; the effects depend upon the estrogen dose and androgenicity of the progestin.
- **Absence of pregnancy should be documented before COCs are begun.**
- Alternative treatments for endometrial protection:
 - Intermittent or continuous progestin therapy
 - Progestin-releasing intrauterine device (IUD)
 - Recommend medroxyprogesterone acetate (5 to 10 mg) for 10 to 14 days every one to two months.



Androgenicity of COCs

Progestogen	AE	Est	And	AA	Glu	AM
Progesterone	++	-	-	(+)	+	+
Chlormadinone acetate	+	-	-	+	+	-
Cyproterone acetate	+	-	-	+	+	-
Medroxyprogesterone	+	-	(+)	-	+	-
Medrogestona	+	-	-	-	?	-
Dydrogesterone	+	-	-	-	?	(+)
Norethisterone	+	+	+	-	-	-
Levonorgestrel	+	-	+	-	-	-
Gestodene	+	-	+	-	(+)	+
Etonogestrel	+	-	+	-	(+)	-
Norgestimate	+	-	+	-	?	?
Dienogest	+	-	-	+	-	-
Tibolone	+	+	++	-	-	-
Drospirenone	+	-	-	+	?	+
Trimegestone	+	-	-	(+)	-	(+)
Promegestone	+	-	-	-	+	-
Nomegestrol	+	-	-	+	-	-

Abbreviations: AE = antiestrogenic, Est = estrogenic, Androgenic = androgenic, AA = antiandrogenic, Glu = glucocorticoid, AM = antimineralocorticoid. ++ = strongly effective, + = effective, (+) = weakly effective, - = ineffective, ? = unknown. Adapted from Wiegartz et al. [33].

(García-Sáenz et al., 2023)

Supplementation

- Both zinc and selenium are essential micronutrients for metabolism, acting as antioxidants counteracting the oxidative stress involved in PCOS (Calcaterra et al., 2021)
- Probiotics and prebiotics have also shown positive effects by modifying the gut microbiota, modulating the absorption of specific nutrients, and improving metabolic outcomes (Calcaterra et al., 2021)
- Curcumin is effective in metabolic syndrome (Calcaterra et al., 2021)
- Evidence suggests that vitamin D deficiency correlated with metabolic disorders in women with PCOS (Guo et al., 2020)



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