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An Approach to Discuss Preconception Care to Childbearing Women in Primary Care Practice

A Scholarly Project Presented to the Faculty of

Nicole Wertheim College of Nursing and Health Science

Florida International University

In Partial Fulfillment of the Requirements

for the Degree of Doctor of Nursing Practice

By

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Abstract

Background: To examine the effects of implementing patient education on preconception care to all women including women of reproductive age. This quality improvement (QI) project was formed with evidence-based research that provides awareness to women on their fertility and conception, and to become their advocates to their reproductive health.

Purpose: The purpose of the study is to improve the quality of reproductive health for young women of childbearing age and to educate women on preconception care and fertility awareness. Methods: Recruitment were chosen at random until the goal of 20 participants were obtained. Participants were directed to use a tablet device or phone to complete the pretest and posttest via QR code or web link. Frequency counts were used to examine the distribution of categorical demographic variables to determine the appropriate statistical test to report knowledge about preconception care. Parametric statistics were determined to be most appropriate due to the nature of the data and distribution of scores. Specifically, the Wilcoxon Signed Rank test was used to examine whether the change in knowledge was statistically significant. Frequency distributions were also used to report the distribution of responses on additional items asked at the posttest. *Results:* At the pretest, scores ranged from 4 to 7 with a mean of 6.65 (SD = 0.75). At the posttest, scores ranged from 5 to 7 with a mean of 6.5 (SD = 0.71). 20 participants were recruited with 50% attrition rate as not all had completed the post-test individually from the same tablet or device. Analysis of the 10 cases with matched data from pre- and post- revealed that knowledge did not change significantly from pre- to post- (p = 1.00). Despite the fact that the P value was not statistically significant change in knowledge, when asked whether they believed they learned more about preconception health after viewing the PowerPoint, 100% of the women said yes.

Conclusions: Preconception care is important for all women including women of childbearing age but results reveal it may not be discussed to each woman in primary care practice. It is important for women to become more empowered to talk about their reproductive and pregnancy plans with their PCP. For providers, cultural and familial influences should be considered and taken into account for each individual.

Keywords: Preconception care, fertility, delayed childbirth, pregnancy, primary care practice, education, women, reproductive health

Introduction

There is a lack of initiating education on preconception care within primary care. Due to workforces allowing women to step into positions they were not able to before, society has focused more on success through job positions or advancing their careers (Armijo et al., 2021). Stress levels due to societal demands can be greater when working in certain professional settings, which could effect their hormones and in result can lead to issues when trying to conceive (Armijo et al., 2021). Multi-factors such as stress, environmental factors, nutrition, health, genetic factors are some of the many components that could cause potential barriers or delays to pregnancy in women. Therefore, health care professionals should educate on fertility issues to increase more awareness on the risks for women of childbearing age.

Background

This project emphasizes the importance to access preconception care and education on a healthy pregnancy, due to the recent decision made by the Supreme Court to overturn the Roe vs. Wade law, now limiting abortion access (Gerstein & Ward, 2022). As such, some states are currently banning abortion rights after 6 weeks to 15 weeks of pregnancy (Gerstein & Ward, 2022). This change is important as it can cause detrimental outcomes to the patient and the child as fetal diagnoses may not be discovered until later in pregnancy (Gerstein & Ward, 2022). Thus, the lack of implementing preconception care in healthcare can lead to a potential increase risk for fetal issues.

One study found there were certain barriers such as working extensive hours and the high demands of training that has led to issues with fertility, family planning, and reproductive health in women physicians (Armijo et al., 2021). Other problems consisted of fertility issues in the past, having to take off a month of clinical rotation after they gave birth, some jobs prevented from

prolonged breastfeeding, and the demands of training and long hours of work had been the most common factor in delayed childbearing for these professionals (Armijo et al., 2021). Providers who are assessing and evaluating women of childbearing age who have professional roles should have the discussion on the preventative measures of planning for parenthood. Women of childbearing age that expresses their desire of having children should discuss the options of preconception care, fertility preservation, or ovarian reserve testing (Birch Petersen et al., 2015).

Problem Statement/Significance

There is a lack of teaching strategies or available resources that educates young women and women of childbearing age on preconception care. The deficiency in discussing with the provider before conception occurs or the lack of expertise in women's health from providers, can cause a deficiency in understanding the risks of delayed childbearing. The issue may result in more women of childbearing age problems with conception. Currently in today's society, health care system, and educational system, they have used the terms of abstinence, protected sex, condoms and birth control pills for young women. In addition, there seems to never be a right time to discuss about conception and pregnancy when the topic does arrive. Therefore, young teens should be educated on learning about taking care of their health at an earlier stage in order to have a higher chance of having a successful pregnancy when the time arrives. In addition, women should be willing to bring up the subject on preconception care. To be able to create a better generation, preconception is important because it allows for the female population the ability to feel open to discuss about planned parenthood and the possibility that fertility treatments are needed for certain health conditions.

In general, women have the ground or root knowledge that they can receive more information about fertility testing, however, the problem is the lack of education on the

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importance of getting tested sooner (Birch Petersen et al., 2015). Due to this lack of discussion to consider tests such as the anti-Mullerian hormone or introducing preconception care, it can result in lower chances of childbirth and an increase in complications when conceiving at a later age. Prior studies in western societies has noted that for the past four decades, women are postponing their first pregnancy and have an increase in maternal age with their first birth (Birch Petersen et al., 2015). In addition, delayed childbirth infers a higher possibility of "involuntary childlessness, smaller families, and declining fertility rates" (Birch Petersen et al., 2015).

Another study conducted by Williamson & Lawson (2015) showed that the attitudes, subjective norms, and perceived control were accounted for 61% in the intent to delay childbearing for women over the age of 30. However, perceived control was the most significant factor, accounting for 24%. The primary reason women want to delay childbearing is because they are confident that their fertility would be able to withstand a longer length of duration (Williamson & Lawson, 2015). In addition, perceived control is when women choose to delay childbearing due to their personal health, fertility, and the view that one would eventually be in a "stable relationship in the future" (Williamson & Lawson, 2015). Therefore, this concludes that there is a deficiency in knowledge related to fertility issues with the overall population, and that majority of people overestimate the longevity of female fertility (Williamson & Lawson, 2015).

In one study, amongst the women who dealt with infertility, 29.3% admitted to having decreased ovarian reserve (Stentz et al., 2016). When questioned on how they would have done it differently, 56.8% would not have changed anything in regards to fertility, conception, or childbearing, while 28.6% would have tried conception sooner, 17.1% would have chosen a different specialty, and 7% would have utilized cryopreservation (Stentz et al., 2016).

The consequences to this problem if there were no interventions implemented — such as increasing education on age and fertility — the higher the risk of involuntary childlessness, conceiving issues, and health complications during or after pregnancy. There is even a lack of knowledge on the impact of age and fertility even in areas of higher education (Delbaere, Verbiest, & Tydén, 2020). Although delayed childbearing has given women more flexibility to explore their career options or to further their education, the risks can lead to unintended decrease in fertility, increase in rates of miscarriage and chromosomal abnormality, and the likelihood of not attaining the desired family size (Peterson et al., 2018).

Women are aware of the high risk for miscarriage or genetic abnormalities at later ages, but they are often less informed about the risks for age-related fertility decline (Peterson et al., 2018). Less than 25% of women had talked about reproduction with their provider and that many women typically wait to get information on fertility and conception until they are older in which their reproductive potential is reduced (Peterson et al., 2018). In addition, of those women who had used OC to preserve their fertility, 79% of them would have liked to have done it sooner, but they did not due to the fact that they were unfamiliar of the technology (Peterson et al., 2018).

Oocyte cryopreservation has the ability to change how women make decisions on their timing of education, work, partnership and parenthood (Stentz et al., 2016). Since patients typically reach out to their Obstetrics and Gynecology (OB-GYN) concerning their reproductive problems, it is important for primary care physicians to initiate discussions related to fertility preservation so they will have access to the full scope of reproductive options available (Stentz et al., 2016). For decades, health care providers have been following the recommendations from the Centers for Disease Control and Prevention on the discussion of reproductive life plan (RLP) (Delbaere, Verbiest, & Tydén, 2020). There are also interventions via websites and interactive

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tools to spread awareness on fertility by providing information for couples who wish to have children, when, and how many they desire to have (Delbaere, Verbiest, & Tydén, 2020). These interventions are crucial because research delineates that knowledge shapes the way people make their decisions (Delbaere, Verbiest, & Tydén, 2020). In fact, they found that with a later intended age for childbearing, it resulted in a twofold risk of childlessness at age 30 (García et al., 2015). There has been a lack of knowledge about reproduction, and health care professionals and educational systems do not educate sufficiently on global fertility knowledge (García et al., 2015).

Knowledge Gaps

The knowledge gaps for this rising issue is due to societal demands and how it may prohibit women to feel financially ready to start a family. On the other hand, one study showed that young and low-educated women with long-term or an increase in recurring unemployment appears to increase first childbearing (Miettinen & Jalovaara, 2020). This could be due to the male partner having a more sustainable income enough to support the family. They also found that unemployment however tended to delay parenthood in both men and women, but the correlation is stronger for men (Miettinen & Jalovaara, 2020). In addition, they found that the increase in unemployment periods has led to a lower rate of parenthood (Miettinen & Jalovaara, 2020).

The COVID-19 pandemic is another issue that may cause women to reconsider pregnancy due to the uncertainty of their children's future and how the virus or vaccine could affect them as well as their child (Kearney & Levine, 2021). Currently COVID-19 vaccines that were given during pregnancy has helped lower the risk of severe COVID-19 and other issues for the mother and her offspring (Brillo et al., 2021). However, more studies and statistics related to COVID-19 and its effects need to be explored (Brillo et al., 2021).

Another gap of information to this problem is the lack of evidence-based research pertaining to the implementation and the cost of OC and ovarian reserve testing. The anti-Mueller hormone test is becoming more available in the U.S. via online and direct-to-consumer (DTC) testing services (Kyweluk, 2020). DTC is a unique tool to investigate fertility that is also cost efficient and easily accessible (Kyweluk, 2020). Its ability to test in various backgrounds and identities to encourage women on considering assisted reproductive technology (ART) or egg freezing (Kyweluk, 2020). One study revealed the patients that tried this were not certain on the steps after reading the results, such as knowing the status of their fertility, how to conserve, and how to conceive (Kyweluk, 2020).

The proposed quality improvement project should allow providers the ability to offer women the available resources on aging and fertility that can serve as an aide to becoming proactive in their childbearing years. Childbearing women are not being restricted about the situation, but there is a current lack of emphasis, universal lack of knowledge, and providers have yet to expand their expertise in this area. For example, routine assessment and examination should screen younger women who are obese or overweight to discuss the importance of healthy eating habits. In addition, taking daily multivitamins prior to pregnancy is the initial step towards becoming pregnant (Masho, Bassyouni, & Cha, 2016). The U.S. Preventive Services Task Force made recommendations for women who plan on becoming pregnant interventions for behavioral counseling that would promote healthy weight gain and prevent excess in gestational weight during pregnancy (U.S. Preventive Services Task Force, 2021).

Summary of the Literature

In review of the literature, studies relative to infertility and delayed childbearing women were found through PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL) from Florida International University's databases, and Medline. Many of the studies were relative to the topic due to the study's title and abstract. There were a total of 16 studies that were considered to support the basis of the search out of a total of 315. The search included the following key terms: "fertility in women AND childbearing age," "elective ovarian reserve testing AND anti-Mullerian hormone," "professional childbearing women," "obesity AND pregnancy," "oocyte cyropreservation," and "delayed childbearing." The studies were not limited to race, as there were differing countries that are studying these topics.

In about every country in the world in the last half-century, there has been a sharp decline in fertility rates (Aitken, 2022). The severe decline in child births can lead to population decline specifically in industrialized regions (Skakkebæk et al, 2022). There are a variety of reasons, but the drive is due to the increase in social factors (Aitken, 2022). The most tremendous impact is women and their education and focusing on their life purpose while steering away from procreation (Aitken, 2022).

Other factors such as environmental and lifestyle factors have a great impact on reproductive health (Aitken, 2022). Adult male exposure to pesticides is associated with the alteration in semen quality, sterility, and prostate cancer (Obstetrics & Gynecology, 2013). There has been a noticeably high incidence of testicular cancer and decline in testosterone levels (Aitken, 2022). The two major health concerns is the increase in infertility leading to increase in assisted reproduction from poor semen quality and oocyte failure (Aitken, 2022). In addition, there is a decline in rates of legal abortion, showing the drop in total conception rates (Aitken, 2022).

Prenatal exposure to certain chemicals have increased the risk of cancer in childhood (Aitken, 2022). Even the exposure to pesticides can impede reproductive function in adult females

such as their puberty, menstruation, ovulation, fertility and menopause (Obstetrics & Gynecology, 2013). It is important for primary care providers to identify exposure to toxic environmental agents and to inform the consequences of such exposure. Reduction in the exposure of toxic environmental agents is an important goal for obstetricians and gynecologists that should provide the need of primary providers to understand the severity it causes in adult women and their reproductive health (Obstetrics & Gynecology, 2013). It is critical to identify the factors leading to this phenomenon and to implement the social, political, environmental and lifestyle changes required to reverse the direction it is heading (Aitken, 2022).

Limitations on the study pertained to the effectiveness of planned oocyte cryopreservation in younger versus older women. The inclusion criteria consisted of studies that were published in the last five years, were cross-sectional systematic reviews, meta-analyses, and randomized controlled trials. Exclusion criteria is that some used a qualitative methodology approach and a few were published more than five years ago.

Preconception Care

Preconception care is a multifaceted approach that involves the knowledge amongst the population in order to take the necessary actions to assist women of childbearing age and young women who will become mothers in the future. There should be an improved method to deliver preconception care at an individualized, organizational, and community level for preventative care and preventative spending (Goodfellow et al., 2017). From an individual level, the patient should take the necessary steps such as seeking assistance, receiving information, and taking initiative on maximizing their health before conception. The organizational level is for providers and companies to receive and provide education on preconception care. From a community level,

everyone in society should receive the same level of care and support through commercial and spreading awareness (Goodfellow et al., 2017).

Many women of childbearing age with professional roles have a lack of awareness on preconception health (Bortolus, et al., 2017). Strategies for the implementation of preconception care guidelines should be essential (Bortolus, et al., 2017). One study revealed that there are challenges when providing knowledge to middle and high school curriculum to prepare adolescents for future parenthood (Goodfellow et al., 2017). Most schools have incorporated information on teaching safe sex and preventing pregnancy without covering or addressing preconception care (Goodfellow et al., 2017). Other challenges were increasing awareness through communication and marketing, supporting professional knowledge on educating on preconception care, and ensuring that there are equitable services that would target those in need (Goodfellow et al., 2017).

Providers in primary care were unlikely to be preemptive about preconception care and addressed more on fertility concerns and contraceptive advice (Goodfellow et al., 2017). Before pregnancy, there are uncertain instructions pertaining to a woman's diet and physical activity, and providers are reluctant to raise issues about weight (Langley, Pearce, & Ellis, 2022). There is a correlation of obesity and lack of education on reproductive health and fertility disorders (Endocrine Society, 2022). Women with a pre-pregnancy body mass index (BMI) of more than 25 kilograms will have a higher chance of issues when conceiving a chid, higher risk of miscarriage, and stillbirth (Langley, Pearce, & Ellis, 2022). From a culture standpoint, one study revealed that only 56.8% of Puerto Rican women were aware about the correlation of obesity and its affects on fertility (González-Sepúlveda et al., 2020). Pregnancy complications occur more often when a woman is overweight, obese, or has uncontrolled gestational weight gain (Langley, Pearce, &

Ellis, 2022). In addition, women are having difficulty in correcting certain issues such as drug addictions or weight loss prior to conception (Goodfellow et al., 2017).

There are women that also lack the knowledge of knowing they can reach out for assistance on preconception care (Goodfellow et al., 2017). Many of them are having unplanned pregnancies instead of taking the preventative steps to improve their health prior to conception (Goodfellow et al., 2017). Being proactive by improving preconception care before and between pregnancies would result in better outcomes for women and their infants. Interventions that are individualized and culturally sensitive have shown a more favorable outcome on elaborating gestational weight gain and antenatal complications (Langley, Pearce, & Ellis, 2022).

Nutrition

Having a balance in nutritional intake with a healthy body weight will provide a higher chance of conception and a successful pregnancy. The importance of having a healthy diet plan with emphasis on balancing overall energy to maintain a healthy body mass index range of 20.0 to 24.9 is essential (Bold, 2017). A diet high in monounsaturated fats instead of trans fats, increase in vegetable instead of animal protein, and high-fat over low-fat dairy, decreased glycemic load, and increase in iron and multivitamins aids in reducing infertility (Bold, 2017). For women receiving IVF treatment, eating a diet that involves four slices of whole-wheat bread or cereals daily, monounsaturated or polyunsaturated fats, 200 grams of vegetables daily, two or more pieces of fruit, meat less than three times a week, and fish once a week will increase the chance of pregnancy (Bold, 2017).

Caffeine has been associated with miscarriage, stillbirth and a low birth weight (Bold, 2017). Consuming this stimulant has been correlated to reduce IVF success (Bold, 2017). The UK recommended that pregnant women should have a daily intake of 200 mg, which consists of two

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small cups of coffee daily (Bold, 2017). Professionals should encourage patients to keep in mind other sources of caffeine that is contributed to the daily intake of caffeine, which includes black or green tea, colas, other caffeinated soft drinks, chocolate, and hot chocolate (Bold, 2017).

Alcohol affects the reproductive health of men and women, and decreases the chances of a successful fertility treatment (Bold, 2017). There is evidence that it reduces follicle-stimulating hormone levels in women which decreases the production of follicles and ovulation (Bold, 2017). In ART, studies show fewer eggs at egg collection and lower pregnancy rates in women with alcohol intake (Bold, 2017). Consuming alcohol while trying to conceive should be minimized below the recommended 14 units per week for women (Bold, 2017).

Smoking cessation is encouraged in patients and should be referred to support services. Smoking reduces fertility for men and women, and causes delays in conception (Bold, 2017). Women who are smokers and receiving ART, it can cause adverse effects on ovarian function and reductions in live birth outcomes (Bold, 2017). Smoking can affect reproductive fertility in which it causes conception delay, ovarian follicular depletion, effects sperm parameters, and early pregnancy effects (Fertility & Sterility, 2018).

Oocyte Cryopreservation

Oocyte cryopreservation (OC) or egg freezing, is when a woman's eggs or oocytes are removed from her body, frozen, and stored as a preservation for women of reproductive age ("Egg freezing," n.d.). There has been an improved success in the survival of eggs during the freezing process, resulting in more potential fertilization and live birth rates, and giving women more autonomy in the last five years ("Egg freezing," n.d.). Oocyte cryopreservation can be used for various reasons such as women with cancer who received chemotherapy or radiation, surgery that has damaged the ovaries, chromosomal abnormalities, ovarian disease, and social or personal reasons in delayed childbearing ("Egg freezing," n.d.).

According to the American Society for Reproductive Medicine (ASRM), the most ideal time for a woman to freeze her eggs is in her 20's and early 30's due to higher ovarian reserve and healthier eggs (Dubofsky, 2021). Another study mentioned that even though there is a higher possibility for a future pregnancy in women that freeze their oocytes in their earlier years, recent data suggests that it is more appropriate for women between 35 to 37 to increase live birth rates including cost effectiveness (Gunnala & Schattman, 2017). Thus, it is important for women to have that discussion with their healthcare provider. Only 19% of primary health care providers (PHP) initiated the conversation about planned oocyte cryopreservation (POC), whereas 29% of patients did not discuss POC with their provider (Yee et al., 2022).

According to the National Conference of State Legislatures, 10% of U.S. women of childbearing age have received assistance for infertility after having the unsuccessful outcome of conception at least one year of regular or unprotected intercourse (NCSL, 2021). Assisted reproductive technology (ART) involves in vitro fertilization where the egg is fertilized outside the womb and then inserted into a woman's uterus (NCSL, 2021). There were more than 72,913 babies born in the U.S. in 2015 due to ART procedures (NCSL, 2021). In vitro fertilization can be expensive with costs ranging from \$12,000 to \$17,000 for each cycle and there is debate with insurance plans on its coverage (NCSL, 2021). There are 17 states that have passed laws requiring insurers to offer coverage for infertility diagnosis and treatment (NCSL, 2021).

One study involved checking the anti-Mueller hormone levels prior to receiving planned oocyte cryopreservation (POC) in women between the ages of 25 to 42 years of age, with a mean age of 36 years (Yee et al., 2022). The study revealed that half of the respondents who showed an

onset of fertility decline were more than 35 years of age (Yee et al., 2022). In addition, more than 50% of women received POC at the age when their fertility was starting to decline (Yee et al., 2022). This signifies the need for providers to also explore, distinguish, and converse about POC with women at high risk or older than 35 years of age with the appropriate referrals (Yee et al., 2022). There is not enough evidence to support the number of live birth rates after having planned OC ("Evidence-based outcomes," 2021). With the limitation of data, live birth rates were higher for women that had planned OC at a younger age compared to women of older age ("Evidence-based outcomes," 2021).

To explore the perspectives women have on OC, one study by Stevenson et al. (2021) reported that 93.9% of women have heard about OC and believe it should be an option for women. Only 7.2% would consider taking this route due to the social stigma and public opinions of OC (Stevenson et al., 2021). Half of the subjects felt as if OC was a "social stigma" and also believe that due to the media, they can prolong having a family even after 40 years old (Stevenson et al., 2021). Nonetheless, there is more awareness and acceptance on OC and more research that are evaluating these perceptions (Stevenson et al., 2021).

An increase in the cost of living is another reason for women to postpone childbirth in order to meet the promotions or demands in their workplace (Stevenson et al., 2021). In addition, women who can afford this procedure would prefer OC to create a family in the future (Stevenson et al., 2021). On the other hand, 85% of women would postpone having a family before their career or until they have a stable relationship (Stevenson et al., 2021). Even women with professional careers who received information on fertility from trusted sources, they lack the process to plan for their fertility (Stevenson et al., 2021).

When it comes to providing education on fertility in healthcare, providers may lack additional knowledge on new emerging technologies. Topics about fertility and its preservation does not happen until women are experiencing infertility issues due to their age (Stevenson et al., 2021). When receiving information about fertility, (37%) of women received it from formal or personal education, (46%) were from undergraduate students who learned it through school, and (5%) received it from a gynecologist (Stevenson et al., 2021). In addition, it was reported that the media such as Facebook and Instagram had been the most common source for participants to research information on OC (Hammarberg, Zosel et al., 2017).

Therefore, there needs to be a preconception care plan to offer support and testing for fertility in women of childbearing age. There is a lack of knowledge on the delivery of preconception care to women of childbearing age from providers and also a lack of awareness for women to receive this kind of care (Goodfellow et al., 2017). Of 238 American Gynecology residents, only 21% felt it was necessary to introduce the topic of OC to their patients (Stevenson et al., 2021). The subject about limits to fertility is not promoted or addressed by health care professionals. Many European countries are starting to take steps that discuss fertility topics in school-based sexual health education, which should initiate providers to follow as well (Stevenson et al., 2021). Women in their younger years often do not interact regularly with their gynecologist and when they do it is based on pregnancy prevention and not fertility planning (Stevenson et al., 2021).

Ovarian Reserve Testing

Ovarian reserve testing is method for patients to understand their reproductive lifespan and offers treatments such as reproductive technology (Tal & Seifer, 2017). Ovarian reserve testing is drawing certain hormone blood levels such as follicle-stimulating hormone (FSH) and estradiol in

the early stage of the menstrual cycle (American Society for Reproductive Medicine, 2014). The levels reveal the functioning between the ovaries and the pituitary gland (American Society for Reproductive Medicine, 2014). Women who have an elevated FSH and estradiol on cycle day-3 will have less chance of having a baby after ovulation induction or in vitro fertilization (IVF) compared with other women of the same age ("Ovarian reserve," 2014).

Women should receive the support and counseling on reproductive aging and options to maintain and optimize their fertility. There is another blood test that checks the levels of ovarian reserve, which is the anti-Mullerian hormone (AMH). According to the Department of Health and Human Services (n.d.), AMH is a hormone created by the ovaries in females and the testicles in males which form reproductive organs. Measuring this in the blood assists in diagnosing infertility, polycystic ovary syndrome (PCOS), and ovarian tumors (DHHS, n.d.). One study conducted by Hurley et al. (2018) had two tiers to the study with a sample of 337 women. Within this study, 92.1% are aware of OC, while 38.5% would consider OC in the future (Hurley et al., 2018). This percentage went up 60.3% if they had known their fertility was declining (Hurley et al., 2018). The second tier consisted of 42 residents and fellow physicians who were offered to take the AMH test. This study revealed that after finding out their AMH level, 12% would have changed their desired age to bear children, while 24% of them would consider cryopreservation after receiving their results (Hurley et al., 2018).

Female Infertility

Infertility is the inability to become pregnant after 12 months with regular sex without using birth control in women younger than 35 years of age or after six months of regular sex without birth control usage in women 35 years and older (Endocrine Society, 2022). Infertility can occur in many ways that could be due to female or male counterparts. Factors that may affect the production of luteinizing hormone or follicle-stimulating hormone can be due to damage of the hypothalamus, pituitary tumors, being too thin, too overweight, exercising, or excess stress (Endocrine Society, 2022).

Women of childbearing age should be aware of health promotion activities to prevent eating disorders that could affect their fertility (Mizgier et al., 2016). Implementing a culture that supports reducing the risk of pregnancy complications and offering fertility interventions can decrease involuntary childlessness (Rangel et al., 2021). It is important to mention that being diagnosed with infertility-related conditions places the woman at a higher risk of pregnancy hypertension, preeclampsia/eclampsia, gestational diabetes, ovulatory and placental problems, and low birthweight (Stern et al., 2022). Receiving ART treatment can also potentially increase the woman's risk of placental problems but is varied for the other conditions mentioned (Stern et al., 2022).

In health care, infertility or involuntary childlessness affects approximately 10% of the population world-wide, and 30% of women experience infertility between the ages of 25 to 44 years old (Bold, 2017). Women who experience infertility have reported that it led to negative effects on their quality of life and their relationships with their partner, such as having higher levels of grief, distress, guilt and frustration (Bold, 2017). Fertility treatment such as Assisted reproductive technology (ART) can be a positive outcome to women who get pregnant as a result. However, a negative result can leave women experiencing mental health issues such as depression (Bold, 2017).

Endometriosis

Endometriosis is one of the leading causes of female infertility (Bold, 2017). Some common symptoms include painful periods (dysmenorrhea), pain with intercourse, pain during

bowel movements or urinating, and excessive bleeding (Wasson, 2018). It is estimated that roughly half of women with infertility issues also have endometriosis (Martin, 2022). In addition, it is a progressive condition, causing more and more growth of endometriosis tissue within the pelvis and abdominal areas that can block the reproductive glands, making it more difficult for the sperm to reach the egg (Martin, 2022). There are four stages of the disease, and those who are in the early I and II stages have a higher chance to conceive without additional medical treatment, but they are likely to require medication, such as intrauterine insemination (IUI), or IVF in the later stages (Martin, 2022). Studies showed there were improved outcomes of eating a gluten-free diet for a year in women with endometriosis as they tend to have more gastrointestinal or painful symptoms (Bold, 2017).

Sexually Transmitted Disease

The CDC reports that sexually transmitted diseases (STD) had accounted for almost half of people from 15 to 24 years old in the U.S (CDC, 2021). In addition, the U.S. is one of the highest in pregnancy rates for young women between the ages of 12 to 16 years old (CDC, 2021). Untreated sexually transmitted disease can lead to tubal factor infertility, which is a major health concern worldwide and also pelvic inflammatory disease (Tsevat et al., 2017). Screening for chlamydia and gonorrhea annually can help reduce issues related to infertility in the United States for young women (Anyalechi et al., 2019).

Pelvic Inflammatory Disease

Pelvic inflammatory disease (PID) is an infection of the woman's reproductive organs that involves the uterus, fallopian tubes, ovaries, and cervix (OASH, 2021). If not treated, it can result in issues with becoming pregnant, problems during pregnancy, and long-term pelvic pain (OASH, 2021). The chances of becoming pregnant is even further reduced when a woman has a diagnosis of PID more than once, as the bacteria can cause inflammation in the fallopian tubes which can lead to scarred tissue (OASH, 2021). It is six times more likely for women with a history of PID to have an ectopic pregnancy (OASH, 2021). In addition, non-hispanic white women and nonhispanic black women had the highest infertility prevalences due to PID (Anyalechi et al., 2019).

Screening for Celiac Disease

Providers should keep in mind to also screen patients for celiac disease (CD). CD is known to cause damage in the lining of the small intestine, which results to malabsorption and nutritional issues such as zinc, vitamin B12, iron and folate deficiency (Bold, 2017). This disease is also linked to amenorrhea, premature ovarian failure and obstetric complications such as premature birth or low birth weight (Bold, 2017). There are also reports of women having successful pregnancies after adapting the gluten-free diet in women with a history of CD and miscarriage (Bold, 2017).

Polycystic Ovary Syndrome

Polycystic ovary syndrome (PCOS) is one of the main causes of anovulatory infertility and affects 5–10% of women of reproductive age (Bold, 2017). This normally occurs at the onset of menstruation, and is correlated with a higher chance of cardiovascular disease, hypertension and hormone associated cancers (Bold, 2017). Symptoms include irregular periods, excess in androgen, and polycystic ovaries (Mayo Clinic, 2022). Nutrition is important since approximately 50% of patients with PCOS are overweight (Bold, 2017). In addition, excess abdominal adipose tissue is linked with higher testosterone production that can result in hirsutism and acne (Bold, 2017). Dietary support strategies involves decreasing in sugar intake and increase fiber for appetite regulation, as well as increasing nutrient density (Bold, 2017). In addition, exercise can help with insulin sensitivity (Bold, 2017).

Cultural Awareness

The World Health Organization had made recommendations for maternity care that involves high quality, respective, and community involved care (Jones et al., 2017). These interventions should provide culturally-appropriate maternity care to help improve women's use of skilled maternity care (Jones et al., 2017). Such interventions involve overseeing the economic, geographical and social determinants that affects the ethnic minority groups access to these services and providing culturally-appropriate care (Jones et al., 2017). Another important factor is community participation that explores the issues with current services and the potential solutions from the community perspective in order to develop and implement these interventions (Jones et al., 2017). In addition, implementing a patient-centered care approach should become the centerpiece to the intervention (Jones et al., 2017).

Latin women have a higher risk for diabetes and reproductive health complications during pregnancy (Abujaradeh, 2021). Considering the patient's cultural and familial perspectives when providing care and preconception counseling is important to this population (Abujaradeh, 2021). American Indian and Alaska Native adolescents have a higher risk for gestational diabetes (GDM), type 2 diabetes, and pregnancy complications compared to the general population (Terry et al., 2020). In the UK, black and black British women have an increased risk of stillbirth (Esegbona-Adeigbe, & Olayiwola, 2020). Mortality rates still remain high despite there being a decrease in stillbirth rates for these groups (Esegbona-Adeigbe, & Olayiwola, 2020).

Anti-Mueller Hormone

Elevated AMH levels can also assist in detecting the severity of polycystic ovary syndrome (PCOS). Polycystic ovary syndrome is the most common endocrine and metabolic disorders in premenopausal women and consists of signs and symptoms of androgen excess and ovarian dysfunction (Escobar-Morreale, 2014). It is a complex disorder with environmental influences that also includes diet and lifestyle factors and may be linked to obesity and cardiovascular issues (Escobar-Morreale, 2014). The AMH test will be able to address the likelihood of hyperandrogegism and to be proactive on addressing PCOS symptoms (Escobar-Morreale, 2014). Elevated levels can be due to a poor response to weight loss, while low levels following a treatment shows its effectiveness and better management of PCOS (Tal & Seifer, 2017). Furthermore, PCOS is important as it accounts for more than 75% of cases of anovulatory infertility (Rath & Gautam, 2021).

Assessing AMH levels to check the level of fertility had shown that women would consider oocyte cryopreservation (OC) or change the age of bearing children if they knew their fertility was declining (Hurley et al., 2018). One study showed that women between the ages of 25 to 42 who checked their AMH hormone levels prior to receiving planned OC revealed half of the respondents older than 35 years old had an early onset of fertility decline (Yee et al., 2022). Through AMH, one is able to learn the likelihood of premature ovarian insufficiency, beginning of menopause, fertilization, blastulation, implantation, and clinical pregnancy rates (Kotlyar & Seifer, 2020). On the other hand, it does not predict live-birth rates or reveal the risk of fetal developmental abnormalities (Kotlyar & Seifer, 2020). Although serum AMH is currently the preferred ovarian reserve marker, there are limitations in the clinical setting. There are various endogenous and exogenous factors that effect serum AMH levels, which raises conflicts for its use as a routine blood test (Moolhuijsen & Visser, 2020).

Purpose/PICO Clinical Questions/Objectives

This quality improvement (QI) project's primary objective provides women optimized knowledge on reproductive health and preconception, proactive health management for

childbearing women, and understanding treatment options for those with a history of fertility issues. Providers should discuss preconception care to women of childbearing age in order for them to make decisions about when conception would be ideal for them. It also provides better health outcomes for the woman and her child through education on improved diet, exercise, managing stress, and lifestyle habits. Women can then become their own advocates on their reproductive health that will provide the most benefits for the themselves as well as their child.

PICO, which stands for Population, Intervention, Comparison, and Outcome, is a method adapted into research to assess and explore important points that responds to the clinical question (Polit & Beck, 2017). For the PICO clinical question, the population is all women including women of childbearing age. The intervention is education on pre-conception care, election of checking fertility levels early, and consideration of elective ovarian reserve testing and oocyte cryopreservation. There is no comparison in this study. The outcome is that women of childbearing age will receive more knowledge about their reproductive health, be more conscious in adapting healthy behaviors, and to promote the ability of advocating for their rights on preconception care.

This project and its terms are as follows:

Population - All females which include young females and women of reproductive age *Intervention*- Education on pre-conception care, fertility testing, elective ovarian reserve testing and oocyte cryopreservation (OC).

Comparison - None

Outcome - Increase in knowledge on preconception care, education on reproductive lifespan, and alternative choices on planning for conception and optimized health.

Definition of Terms

- Anti-Mueller hormone: A hormone made from the ovaries in females and the testicles in males. It forms the male and female reproductive organs. Measuring this in the blood helps diagnose infertility, PCOS, menopause, and ovarian tumors (National Cancer Institute, n.d.).
- Assisted reproductive technology (ART): All fertility treatments in which either eggs or embryos are dealt with (CDC, 2006). It involves removing eggs surgically from the ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman (CDC, 2006). They do not include treatments that involve only the male sperm or procedures which a woman ingests medicine to stimulate egg production (CDC, 2006).
- Celiac disease: A chronic digestive and immune disorder that damages the small intestine from foods that contain gluten. It can result in digestion problems and prevents the absorption of nutrients that are essential to the body (NIDDK, n.d.).
- Infertility: Not being able to become pregnant after one year or more of unprotected sex (CDC, 2022).
- In-vitro fertilization: Includes taking medications and surgical procedures that help the sperm fertilize then egg, and help the fertilized egg implant in the uterus (Planned Parenthood, 2022).
- Oocyte cryopreservation: Also known as egg freezing, is when a woman's eggs are extracted, frozen, and stored to preserve reproductive potential for women of reproductive age (UCLA, n.d.).
- Pelvic inflammatory disease (PID): An infection of the woman's reproductive organs that is often resulted from a sexually transmitted infection (OASH, 2021). If it is not treated, it can

result in issues with becoming pregnant, problems during pregnancy, and long-term pelvic pain (OASH, 2021).

- Polycystic ovary syndrome (PCOS): The most common endocrine and metabolic disorder in premenopausal women that consists of signs and symptoms of androgen excess and ovarian dysfunction (Escobar-Morreale, 2014).
- Preconception care: Related to the health of women and men in their reproductive years when they can have a child. It includes steps that are taken prior to protect the health of a baby they might have sometime in the future (CDC, 2006).
- Sexually transmitted disease: Infection that is contracted from sexual contact caused from bacteria, viruses, or parasites. Ex.) Chlamydia, Gonorrhea, HIV/AIDS

Conceptual Underpinning and Theoretical Framework

The model that coincides with preconception care is implementing the Health Belief Model (HBM). This declares that when a person has a belief about a threat of an illness including the belief in the effectiveness of the recommended health behavior, it will anticipate the chance the person will implement the behavior (LaMorte, 2019). Within this model, there are six constructs that is parallel to women and preconception care. The first construct to the HBM is the perceived susceptibility in women and their knowledge on preconception health, as well as their perception on the risk of infertility. There may be varying differences to a woman's attitude on her priorities in life and knowledge about fertility. The next construct is perceived severity, which is evaluating the amount of women who understand about their fertility, the severity of delayed childbearing, and its correlation to their age and physical health (LaMorte, 2019).

The third construct is perceived benefits, which is the woman's perceptions on how effective preconception care is, screening, health maintenance, monitoring, and treatment for conception and pregnancy (LaMorte, 2019). The fourth construct is perceived barriers, which is the high cost of fertility treatments that health insurance companies may not cover that could prevent patients from performing such tests (LaMorte, 2019). The fifth construct is cue to action, which is providing further information on the rise of fertility complications over the last few years, which in result should steer more women to become advocates and take action on their reproductive health (LaMorte, 2019). Lastly, the sixth construct is self-efficacy, after proper evaluation and receiving preconception care, the patient is able to carry out the action and receive fertility treatment (LaMorte, 2019). In conclusion, by implementing the Health Belief Model, it will be able to define the gaps in women's health on fertility and to provide better education on preconception care and preventative measures for a safe and healthy pregnancy.

Methodology

The QI project takes place in the clinical immersion site at Total Health Clinic and participants were female patients. Recruitment from were chosen at random until the goal of 20 participants were obtained. Within the clinical site, 26% of patients are women of childbearing age, 60% Caucasian, 30% black, 2% Asian, 8% mixed race or other races. According to the United States Census Bureau, over 20% of the City is under 18 years old and 17.8% of the population is over 65 years old (U.S. Census Bureau, 2022). The city has 55% Caucasian, 45% Hispanic or Latino, 22.3% were identified as Black or African American, and 4.9% were Asian (U.S. Census Bureau, 2022). The project consisted of a questionnaire that collected the demographics, current knowledge, beliefs, and their current practice or intentions on fertility.

Procedures for data collection consisted of contacting patients prior to appointment via telephone and explaining procedures and also in-person communication. Once participants arrived to their appointment, they were directed to use a tablet device or phone to complete the pretest

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and posttest via QR code or web link. The powerpoint on preconception care were also accessible on their tablets via web link. Presentation on preconception care addressed smoking cessation, exercise, nutrition, alcohol consumption, caffeine intake, screening for disease, and testing or treatment options. It should be noted that implementing this questionnaire in primary care practice will allow providers to further assist women of child bearing age, the opportunity to discuss about preconception care, and future pregnancy. The outcome measures would be able to reveal the amount of women who are aware about their fertility in order to fill in the gaps to provide an intervention for women to become advocates for their reproductive health. It will also allow providers to perform a health screening, discuss about preconception care, provide educational materials, order tests or referrals as necessary, and offer treatment options.

Data analysis of the study would measure the consistency and frequency in the amount of women who understand about fertility and learning about preconception care. The type of data management and analysis plan consisted of storing data onto Qualtrics software, an online survey tool that allows participants to answer anonymously. In result, the implications to the study to advance nursing practice would be the implementation of preconception health and screening in every visit within primary practice in order for women to become their own advocates to improve their knowledge on fertility and their overall health.

Data Analysis

Frequency counts were used to examine the distribution of categorical demographic variables. To determine the appropriate statistical test to report knowledge about preconception care. Upon examination of the distribution of pre and post scores, parametric statistics were determined to be most appropriate due to the nature of the data and distribution of scores. Specifically, the Wilcoxon Signed Rank test was used to examine whether the change in

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knowledge was statistically significant. In addition, frequency distributions were also used to report the distribution of responses on additional items asked at the posttest.

Results

Sample Characteristics

Participant demographic characteristics for the sample of 20 participants are provided in Table 1. Ten percent of the women surveyed were less than 24, 55% were between 25 and 34, 25% were between 35 and 44, and 10% were 45 or older. There was a fairly even distribution of race/ethnicity with 25% White, 30% Hispanic, 30% Black, and 20% Asian. They had varying levels of education with 15% having completed high school, 45% having earned an Associate's Degree, 30% having earned a Bachelor's degree, and 10% having earned a Master's Degree. While most were employed full-time (80%), 20% were working 25 hours a week or less. Most of the sample (80%) reported currently trying to conceive or thinking of conceiving and none of them reported being currently pregnant. Close to half of the sample (40%) indicated that they were a parent having 1 (15%), 2 (15%), or 3 (10%) living children. Of these deliveries, 3 (15%) were preterm. When asked about their medical history, 25% of women indicated that they had irregular menstrual cycles, one woman indicated that she had a previous miscarriage, and one woman indicated that she had a previous abortion.

Some of the women (15%) indicated that they were trying to conceive under the care of a fertility specialist (15%). In addition, 15% indicated that they had a medical history that affects their ability to conceive. Close to half (45%) of the women felt prepared for pregnancy and believed they received enough education and preconception care from their primary care provider (PCP). In addition, most of the women (75%) were aware that they could ask their PCP to talk

about fertility and check fertility and hormone levels to evaluate their ability to conceive. Lastly, 75% of the women felt confident talking to their provider about their fertility.

Knowledge

At the pretest, scores ranged from 4 to 7 with a mean of 6.65 (SD = 0.75). Figure 1 displays the distribution of pretest scores. At the posttest, scores ranged from 5 to 7 with a mean of 6.5 (SD = 0.71). Analysis of the 10 cases with matched data from pre- and post- revealed that knowledge did not change significantly from pre- to post- (p = 1.00). Despite the fact that the P value was not statistically significant with change in knowledge, when asked whether they believed they learned more about preconception health after viewing the PowerPoint, 100% of the women said yes.

Additional Questions

At the posttest, additional questions about fertility and preconception care were asked. The majority of women (75%) did not believe that education on female fertility, preconception care, and options for conceiving are addressed sufficiently in society. When asked whether learning more about preconception care resulted in an interest to engage in a discussion with their PCP, 80% said yes, 15% said no, and one person (5%) was unsure. When asked whether they believed their PCP should be the gatekeeper to addressing fertility testing or education on preconception health, 75% said yes, 15% said no, and 10% were unsure. When asked whether learning about fertility testing, planning for pregnancy, and treatment options, 60% indicated that they were more willing to consider these options for themselves while the rest were either unsure (20%) or unwilling (20%). Lastly, when asked whether they would personally wish to receive more information on fertility, preconception care, and options for conceiving, 60% said yes, 25% said no, and 15% were unsure.

Discussion

This QI project aimed at determining the effects of preconception care and fertility awareness towards women of childbearing age and all women who are currently pregnant, undecided, and women who are planning on having children. The HBM assisted in providing a valuable framework by using education on preconception health and fertility awareness to participants to advocate for their reproductive health and address fertility questions sooner. The Health Belief Model was able to define the gaps in women's health on fertility and to provide better education on preconception care and preventative measures for a safe and healthy pregnancy.

It has been concluded after evaluation of the two tests that many women who were working full time, that 80% of them a currently trying or thinking of conceiving. Most of the women were aware that they could ask their PCP to talk about fertility and check fertility and hormone levels to evaluate their ability to conceive. Lastly, 75% of the women felt confident talking to their provider about their fertility. Pertaining to knowledge, analysis revealed that knowledge did not change significantly from pre- to posttest. In addition, 100% of the participants agreed they learned more about preconception health after viewing the PowerPoint.

75% did not believe that education on female fertility, preconception care, and options for conceiving are addressed sufficiently in society. 80% said yes that preconception care resulted in an interest to engage in a discussion with their PCP. 75% said they believed their PCP should be the gatekeeper to addressing fertility testing or education on preconception health. When asked whether learning about fertility testing, planning for pregnancy, and treatment options, 60% indicated that they were more willing to consider these options for themselves.

Limitations

Some of the limitations included a small sample size, with a total of 20 participants recruited with 50% attrition rate. Another limitation is insufficient research articles on the efficiency of fertility testing options including lack of statistics. IVF can be an expensive cost

worth \$12,000 to \$17,000 for each cycle and there is debate with insurance plans on its coverage. Not many states will offer coverage for infertility diagnosis and treatment. There is also not enough evidence to support the number of live birth rates after having planned OC. With the limitation of data, live birth rates were higher for women that had planned OC at a younger age compared to women of older age. There is also social stigma and public opinions for women to consider OC for themselves. In addition, with Roe vs. Wade ruling being overturned, women have limitations depending on the state they live in. Lastly, the COVID-19 pandemic was another limitation as it created changes on women's decision to having children.

Implications for Advanced Nursing Practice

The findings for this QI project yields the implication to implement the discussion of preconception care within primary care practice. Proactive measures such as implementing a short questionnaire during routine visits would offer female patients recognition and consideration of their reproductive health for future planning. Such questionnaire could include similar questions that were used within the pre- and post-test. Health care professionals can implement more education pertaining to women's health even in primary care practice in order to better serve all women and women of reproductive age and the means to refer them to fertility specialists as indicated. Thus, this QI project would help women adhere and become more recognizant about their health when planning for pregnancy.

Conclusion

Preconception care and fertility awareness are important components in women's health for all women but most importantly women of childbearing age. Preconception care may not be fully addressed and discussed to all women within primary care practice, and it is important due to new laws on abortion. For providers, considering the cultural or familial influences will further provide assistance pertaining to that individual. Therefore, it is crucial for women to become aware and empowered to explore and discuss their reproductive options with their PCP.

Diagrams/Tables

Characteristic	N (%)
Age	
18-24	2 (10)
25-34	11 (55)
35-44	5 (25)
45-54	2 (10)
Race or Ethnicity	
White or Caucasian	5 (25)
Hispanic, Latino, of Spanish	6 (30)
Black or African American	6 (30)
Asian or Asian Indian	4 (20)
Highest Degree or Level of Education	
High school graduate, diploma or equivalent	3 (15)
Associate degree	9 (45)
Bachelor's Degree	6 (30)
Master's Degree	2 (10)
How many hours do you work in a week?	
15-25	1 (5)
25-35	3 (15)
35-45	14 (70)
45 hours or more	2 (10)
Currently trying to conceive or thinking of conceiving?	16 (80)
Currently pregnant	0 (0)
Currently a parent	8 (40)

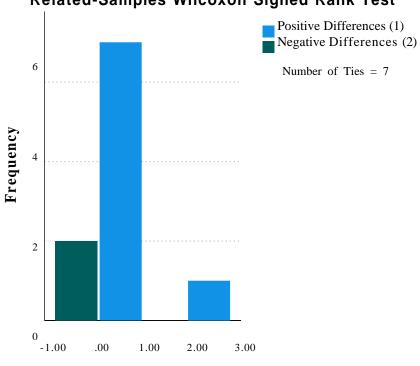
Table 1. Demographic Characteristics

Gravida

1	3 (15)
2	3 (15)
3	3 (15)
N/A	6 (30)
Term deliveries (37 weeks or more)	
0	1 (5)
1	1 (5)
2	4 (20)
3	1 (5)
N/A	6 (30)
Preterm deliveries (20 weeks to 36 weeks and 6 days)	
0	4 (20)
1	3 (15)
N/A	6 (30)
Abortions (both surgical abortions and miscarriages)	
0	7 (35)
1	1 (5)
2	1 (5)
N/A	6 (30)
Living Children	
1	3 (15)
2	3 (15)
3	2 (10)
Are you trying to conceive under the care of a fertility specialist?	3 (15)
Any medical history that affects your ability to conceive?	3 (15)
Medical History	

Irregular menstrual cycle	5 (25)
Miscarriage	1 (5)
Abortion	1 (5)
Other	2 (10)
Do you feel prepared for pregnancy and received enough education and preconception care from your primary care provider?	9 (45)
Are you aware that you can ask your PCP to talk about your fertility and check fertility and hormone levels to evaluate your ability to conceive?	15 (75)
Do you feel confident about talking to your provider about your fertility?	15 (75)

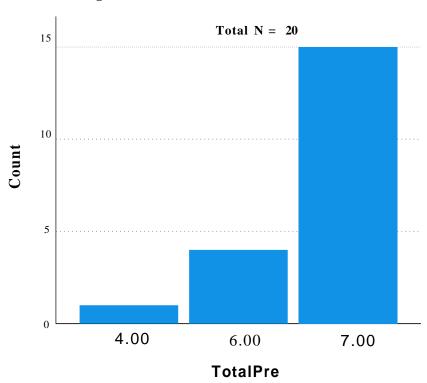
Figure 1.



Related-Samples Wilcoxon Signed Rank Test

totalpost – TotalPre

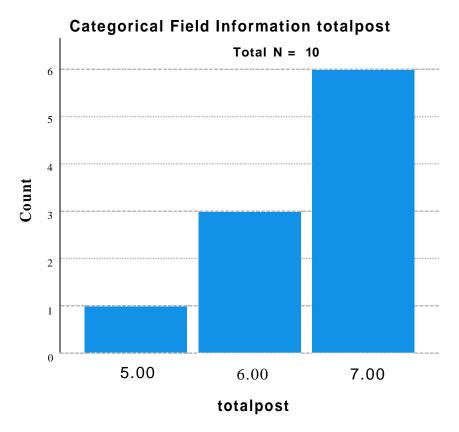




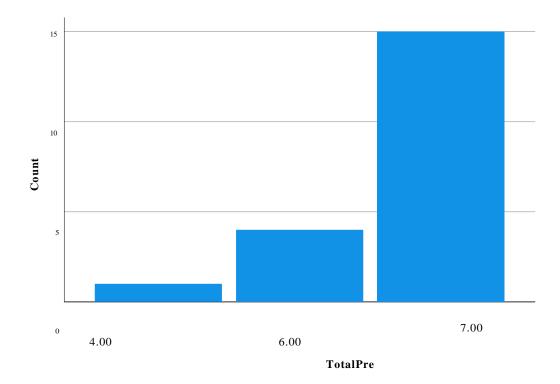
Categorical Field Information TotalPre

TotalPre field is ordinal but is treated as continuous in the test.



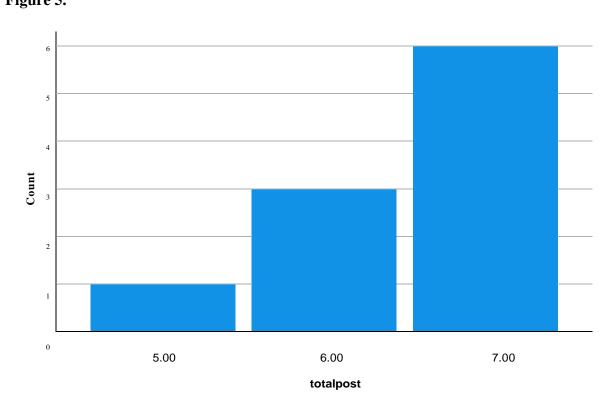


totalpost field is ordinal but is treated as continuous in the test.



Notes

Figure 4.



Notes Figure 5.

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Appendix A

Consent Form



ADULT ONLINE CONSENT TO PARTICIPATE IN A RESEARCH STUDY

An approach to discuss preconception in childbearing women: A quality improvement project

SUMMARY INFORMATION

Things you should know about this study:

- □ **<u>Purpose</u>**: The purpose of the study is to improve the quality of reproductive health for young women of childbearing age and to educate women on preconception care and fertility awareness.
- □ **Procedures**: If you choose to participate, you will be asked to complete a pre-test, watch an educational session on preconception care, and complete a post-test.
- Duration: This will take about 25 to 30 minutes.
- □ **<u>Risks</u>**: Participants are not expected to experience any risks, harms, or discomforts through participation in this project.
- □ **Benefits:** Potential benefits to participants include improved knowledge of preconception care in young female patients ages 18 years and older.
- □ <u>Alternatives</u>: There are no known alternatives available to you other than not taking part in this study.
- □ **<u>Participation</u>**: Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

The purpose of this study is to improve the quality of reproductive health for young women of childbearing age. The aim of this study is to educate women on preconception care and fertility awareness.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of 20 people in this research study.

DURATION OF THE STUDY

Your participation will involve 25 to 30 minutes.

PROCEDURES

If you agree to be in the study, we will ask you to do the following things:

- With their consent, participants will complete an anonymous pre-test survey to assess their knowledge, perceptions, and practices on preconception care. The survey is to be completed individually and is expected to take 5 minutes to complete. The results of the pre-test will be used to create a preconception care intervention based on the results of a related systematic review. Participants will then attend the preconception educational session, which is expected to last approximately 15-20 minutes. After completing the educational session, participants will be asked to complete the post-test, which will be identical to the pre-test. The post-test survey is expected to take up to 5 minutes to complete.
- 2. Data will be collected using the pre-test/post-test survey form attached. No identifiable private information is to be collected. Demographic data, including gender, age, ethnicity, and occupation will be obtained as part of the survey. Additionally, the pre-test/post-test survey will be used to collect data related to participants' knowledge, perceptions, and practices related to preconception care. Data analysis will be done by implementing a paired T test used with matched scores by using one group pre-test/post-test design.

RISKS AND/OR DISCOMFORTS

Participants are not expected to experience any risks, harms, or discomforts through participation in this project.

BENEFITS

Potential benefits to participants include improved knowledge of preconception care in female patients.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this study. Any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at anytime.

USE OF YOUR INFORMATION

□ Your information collected as part of the research will not be used or distributed for future research studies even if identifiers are removed.

COMPENSATION & COSTS

There are no costs to you for participating in this study.

MEDICAL TREATMENT

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Mary Nguyen at Pembroke Pines, FL by phone at 678-468-5316 or by email at mnguy035@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the "consent to participate" button below I am providing my informed consent.

• I consent to participate in this study.

Appendix B

Pre-test on Preconception Care

Demographics - Please answer the following questions:

- 1. What is your age: _____
- 2. What is your race or ethnicity? (Please circle):
 - White or Caucasian

Hispanic, Latino, or Spanish

Black or African American

Asian or Asian Indian

American Indian or Alaska Native

Pacific Islander or Hawaiian

Other

- 3. Highest level of education:
- 4. Current occupation: _____
- 5. Average hours of work per week: _____

Preconception care is related to the optimal health of women and men in their reproductive years when they can have a child. It includes steps that are taken prior to protect the health of a baby they might have sometime in the future (CDC, 2006).

Please select Yes or No:

- 6. Have you had a discussion with your provider about preconception care and fertility, or brought up the topic about when to plan conception? Yes/No
- 7. Do you wish that fertility and preconception care was mentioned and discussed more during your routine health visits? Yes/No

Are you currently:

- 8. Trying to conceive or thinking of conceiving? Yes/No
- 9. Pregnant? Yes/No
- 10. A parent (or were a parent)? Yes/No

If yes, please answer the following:

Gravida (number of total pregnancies) _____

Term deliveries (full births at 37 weeks or more) _____

Preterm (20 weeks to 36 weeks and 6 days) _____

Abortions (both surgical abortions and miscarriages) _____

Living children ____

11. Trying to conceive under the care of a fertility specialist? Yes/No

12. With any medical history that affects your ability to conceive? Yes/No

Do you have a past medical history of any of the following (Select all that apply):

13. Irregular menstrual cycle: _____ If yes, please describe: _____

14. Miscarriage (spontaneous abortion less than 20 weeks): _____

- 15. Abortion (Therapeutic/Induced): _____
- 16. Stillbirth: ____

17. Child with congenital disorder: _____ If yes, please describe: ______

18. Other (please describe): _____

Please answer the following questions:

18. Do you feel you are prepared for pregnancy and received enough education on preconception care from your primary care provider? Yes/No

19. Are you aware that you can ask your primary care provider to talk about your fertility or check fertility and hormone levels to evaluate your ability to conceive? Yes/No

20. Do you feel confident about talking to your provider about talking about your fertility? Yes/No

For women who have not had children, please answer the following

21. How old would you consider having children?

22. What are some factors that are delaying your plan to conceive?

True or False:

- 1. Diet and exercise play a role in the ability to conceive. (True/False)
- 2. Obesity can affect the ability for a woman to conceive. (True/False)
- 3. Smoking affects the ability for a woman to conceive. (True/False)
- 4. Environmental factors (toxic agents) and social factors (working extensive hours) can have an impact on reproductive health. (True/False)
- 5. Preconception care requires the knowledge and planning between a woman and her significant other for a healthy pregnancy. (True/False)
- 6. Physical challenges such as polycystic ovarian syndrome, sexually transmitted infections or endometriosis can affect the ability to conceive. (True/False)
- Culturally appropriate services takes account the preferences of individuals and the cultures of their communities is an important component when providing quality care on preconception to the population. (True/False)

Post-test on Preconception Care

True or False:

- 1. Diet and exercise play a role in the ability to conceive. (True/False)
- 2. Obesity can affect the ability for a woman to conceive. (True/False)
- 3. Smoking affects the ability for a woman to conceive. (True/False)
- 4. Environmental factors (toxic agents) and social factors (working extensive hours) can have an impact on reproductive health. (True/False)
- 5. Preconception care requires the knowledge and planning between a woman and her significant other for a healthy pregnancy. (True/False)
- 6. Physical challenges such as polycystic ovarian syndrome, sexually transmitted infections or endometriosis can affect the ability to conceive. (True/False)

7. Culturally appropriate services takes account the preferences of individuals and the cultures of their communities is an important component when providing quality care on preconception to the population. (True/False)

Please answer the following: (Yes/No)

1. Do you believe that education on female fertility, preconception care, and options for conceiving are addressed sufficiently in society? (Yes/No)

Comments: _____

2. Do you believe you learned more about preconception health after viewing the PowerPoint? (Yes/No)

Comments: _____

3. Are you more interested to discuss with your PCP after having learned more about preconception care? (Yes/No)

Comments: _____

4. Do you believe your PCP should be the gatekeeper in addressing fertility testing or education on preconception health prior to referring to a fertility specialist or OB-GYN? (Yes/No)

Comments: _____

5. After learning more about fertility testing, planning for pregnancy, and treatment options, are you more willing to consider these options for yourself? (Yes/No)

Comments: _____

- 6. Would you personally wish to receive more information on fertility, preconception care, and options for conceiving? (Yes/No)
- 7. Do you believe your PCP should be the gatekeeper in addressing fertility testing or education on preconception health prior to referring to a fertility specialist or OB-GYN? (Yes/No)

Comments: _____

8. After learning more about fertility testing, planning for pregnancy, and treatment options, are you more willing to consider these options for yourself? (Yes/No)

Comments: _____

9. Would you personally wish to receive more information on fertility, preconception care, and options for conceiving? (Yes/No)

Appendix C

IRB Approval Letter



MEMORANDUM

To:	Dr. Carmen V. Framil
CC:	Mary Nguyen
From:	Carrie Bassols, BA, IRB Coordinator
Date:	August 30, 2022
Proposal Title:	"An approach to discuss preconception in delayed childbearing women: A quality improvement project"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #:	IRB-22-0389	IRB Exemption Date:	08/30/22
TOPAZ Reference #:	112085		

As a requirement of IRB Exemption you are required to:

- 1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- 2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- 1) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

Appendix D

Preconception care Education session



PRECONCEPTION CARE

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PRECONCEPTION CARE

