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Brook M. Anderson
Bethel University

Anmol G. Clairmont
Bethel University

Lydia Lutz
Bethel University

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THE EFFECTS OF PATIENT EDUCATION ON ORAL CONTRACEPTIVE ADHERENCE RATES

A MASTER'S PROJECT

SUBMITTED TO THE GRADUATE FACULTY

GRADUATE SCHOOL

BETHEL UNIVERSITY

BROOK ANDERSON, PA-S

ANMOL CLAIRMONT, PA-S

LYDIA LUTZ, PA-S

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTERS OF SCIENCE IN PHYSICIAN ASSISTANT

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ABSTRACT

The purpose of this study was to evaluate the relationship between the quality of patient education regarding oral contraceptive (OC) use, and the resulting patient knowledge and adherence rates. Previous studies show a major disparity in patient knowledge of OC use as well as low adherence to their oral contraceptive regimen. This study attempted to evaluate the quality of the patient education provided to the participant. This study also evaluated the resources used in relation to the participants' basic knowledge of OCs and their adherence rate to their medication regimen.

A questionnaire was distributed to college-aged women at South Dakota State University. This inquired about basic demographic information, types of OC education resources utilized, and contained a pass/fail quiz, which assessed knowledge and adherence rates of OC regimens. The study results were found to be inconclusive, as the majority of participants assessed themselves as having adequate education; yet over half of the patients failed the survey. This indicates that participants do not have sufficient knowledge, and are, as a result, not adherent to their OC regimen. Further research must be done to assess more efficacious methods of patient education from both medical providers, as well as from the internet and print resources.

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Chapter One: Introduction

Introduction

Throughout the United States, oral contraceptives (OCs) are among the most commonly used form of birth control, despite many available methods of contraception (Sech, Segall-Gutierrez, Silverstein & Mishell, 2017). Even though OCs are among the most commonly used contraceptive, patient education is not well studied in women of childbearing age. Performing a research study in this area could help improve adherence and promote safe oral contraceptive use. Research regarding this topic could also help identify the gap in knowledge between the providers, OC administrators, and the patients. Throughout this chapter, a brief history of OCs, as well as current research regarding OC use, knowledge and adherence rates will be explored. This chapter will discuss the lack of patient knowledge prior to OC use, and how it affects the current population. The purpose of performing a research study on OCs will be addressed and the definitive research question will be defined. Definitions of commonly used terminology, limitations, and delimitations of the study will be discussed. This research study serves to evaluate the significance of contraceptive education prior to use of OCs and its relation to OC adherence rates.

Background

People have long been interested in birth control methods with records that date back to 1500 B.C. (Gibson, 2015). Examples include women in ancient Egypt using a crocodile dung pessary, women in ancient China drinking a mixture of lead and mercury, or a 15,000 year old cave painting depicting what could have been the first illustration of a man wearing something akin to a condom (Gibson, 2015). Birth control has since taken leaps and strides, allowing a woman a measure of control over her reproductive

outcomes. By the 1950's, the first oral contraceptive pill was synthesized from wild yams, which was effective at blocking ovulation (Gibson, 2015). The first FDA approved hormonal pill was released in 1956, approved only for menstrual disorders, as birth control was still illegal throughout the United States (Gibson, 2015). Time Magazine (2010) noted that the year 1956 saw a dramatic rise of menstrual irregularities among women nationwide. Shortly thereafter, on May 9, 1960, Enovoid was released as the first FDA approved oral contraceptive pill (Gibson, 2015). By 1965, almost 6.5 million women were on it, and by 1970, that number had doubled (Gibson, 2015). Discreetly referred to as "the pill," it became something of a national phenomenon, a symbol of control for women, and an invention that started a revolution (Eig.J, 2016).

Since the development of the first oral contraceptive pill, contraceptive practices have evolved and improved, allowing for various other methods besides oral contraception, such as intrauterine devices (IUD), transdermal patches, sponges, injections, cervical caps, etc. According to the 2012 National Health Statistics Reports, a majority of women of reproductive age are currently using contraception (62%), and of the women using contraception, the most common method is oral contraception (Sech et al., 2017). As of 2012, 10.6 million women in the United States were using it for contraceptive purposes (Jones, Mosher, & Daniels, 2012). Despite the popularity of oral contraceptives, research has shown that almost half (45%) of the pregnancies in the United States are unintended (Fowler & Jack, 2008). To assess the reason for the staggering number of unintended pregnancies, despite the majority of women using oral contraceptives, the failure rate of oral contraceptives needs to be determined.

Failure rate is defined as the occurrence of pregnancies within the first year of use of oral contraceptives (CDC, 2017). The pill has a 0.3% failure rate with perfect use (Papadakis et al., 2017). Many women on the pill continue to experience unintended pregnancies and have a 9% failure rate with typical OC use (CDC, 2017). The question that then must be addressed: what factors contribute to this discrepancy? Is it from inadequacy of the pill itself or an inadequacy in adherence to the pill? If the pill has a 99% efficacy rate with perfect use, higher rates of unintended pregnancies must stem from inadequacy in adherence to the pill, which highlights a problem of user error. This brings up further questions such as: What causes this error? Are women provided adequate contraceptive counseling when prescribed contraceptives? Is there a relationship between patient adherence to OCs and contraceptive counseling? What is the quality of contraceptive counseling that currently exists?

According to Dehlendorf et al., (2017), contraceptive counseling has proven to play a significant role in reproductive outcomes, yet women usually find themselves dissatisfied with the amount of contraceptive counseling they receive. Dehlendorf et al., (2017), surveyed the relationship between OC adherence and medical counseling received by women of reproductive age at the University of Minnesota. Of 339 women surveyed, less than 20% displayed high adherence rates to their oral contraceptive, and the remaining 80% met either moderate or poor adherence standards. In addition, a positive correlation was found between contraceptive knowledge and their corresponding OC adherence rates (Dehlendorf et al., 2017). This study concluded that further research needed to be conducted on the relationship between contraceptive counseling and adherence rates to OCs (Dehlendorf et al., 2017). A different study conducted on

midwive's experience in providing contraceptive counseling to foreign-born women in the United States found that counseling had a strong, positive correlation with adherence rates (Kolak, Jensen, & Johansson, 2017). Adherence rates in this population are particularly important considering that foreign-born women in the United States have twice the family size of native-born women in the United States (Colby, & Ortman, 2014).

Based on existing research, OCs are the most popular form of birth control in the United States (Sech et al., 2017), and have a 99.7% efficacy rate with perfect use (Papadakis et al., 2017). However, OCs have a 9% failure rate, resulting in 6-12 pregnancies per 100 women per year (CDC, 2017). Of all unintended pregnancies in the United States, approximately 50% end in abortion (Papadakis et al., 2017). Of all unintended pregnancies, the highest rates were among women within the 18-24 age bracket, were of lower incomes, had not graduated from high school or were unmarried women who lived with their partners (CDC, 2017).

It has been shown that there is inadequate education and counseling provided to patients regarding their contraceptive needs (Dehlendeorf et al., 2017). Further research needs to be done on the quality of contraceptive counseling provided to patients who are prescribed contraceptives (Dehlendeorf et al., 2017). The relationship between contraceptive knowledge and OC adherence rates must be explored to determine the best interventions. These interventions may be used by medical providers, healthcare educators, educational institutions, and media to help improve patient's knowledge of OCs prior to use, improve adherence rates, and better serve women who have fallen through the cracks of medical counseling and medical care.

Statement of the Problem

Higher than expected failure rates with OC use indicates a disparity in the way OCs are prescribed and how women are in actuality taking OCs. The effect of education on women's knowledge and adherence rates to OCs have not been investigated adequately enough for providers to administer the best information to their patients. Without knowing the best patient education methods, lowering the failure rate of OCs and increasing medication adherence is difficult.

Purpose of the Study

The purpose of this study is to evaluate the relationship between the quality of contraceptive counseling provided to patients actively taking OCs, the amount of patient knowledge, and its corresponding relationship to OC adherence rates. The impact of various methods of counseling on patient knowledge of oral contraceptives has not been sufficiently studied. This study will survey college-aged women who are currently taking OCs to assess their knowledge of OCs, and the method of counseling they received.

Significance

Oral contraceptives are commonly prescribed by providers working in primary care and women's health (Lesnewski & Prine, 2006). Without knowing the best tools to provide education, providers are only guessing which educational methods work to increase patient knowledge and adherence. If educational methods can be identified that cause an increase in patient knowledge and medication adherence, providers can then implement the methods in their own practice. Implementing these educational methods will, hopefully, lower the failure rate of OCs and prevent unintended pregnancies.

The Research Question

The following research question will be evaluated in this study: How are oral contraceptive adherence rates affected by patient knowledge and quality of medical counseling?

Definitions

For this particular research study, oral contraceptives (OCs) include both combined oral contraceptives and progestin-only oral contraceptives. OCs are a once daily hormone pill that prevents ovulation, prevents pregnancy, and regulates menstrual cycles (Papadakis et al., 2017). OCs should be taken at the same time each day to maximize effectiveness, and variability in the administration time increases the failure rate of OCs (Papadakis et al., 2017). Since the administration of OCs has a strict time constraint, it is important that patients are well educated on how and when to take their prescription.

Education is a complex topic with multiple definitions. For the purpose of this study, patient education is an overarching term that recognizes any form of instructive counseling that a provider gives to a patient. These instructions may be verbal, written, or illustrated. A provider is defined as someone who has the authority to dispense prescriptions and educate patients. The failure rate of OCs is the percentage of unintended pregnancies that occurs in the first year of OC use. For this study, adherence is defined by whether a woman takes her OC as prescribed: once daily at a specified time.

Summary

As the research on prior education delivered by providers and public health agencies evolve, the importance of providing effective patient understanding will further

increase adherence to OCs. In the next chapter, our literature review will describe different OC methods, benefits, limitations, and efficient educational approaches, as well as the barriers women experience in receiving an adequate level of contraceptive education.

Chapter Two: Literature Review

Introduction

Contraceptives are a mainstay in medical care, and healthcare providers are educating about and researching contraceptives frequently (Shoupe & Mishell, 2016). Acknowledging current research, options, benefits, and risks of the medication is vital when collaborating with patients to find the best contraceptive for each individual. According to Papadakis, McPhee and Rabow, 2017, out of 213 million pregnancies in 2012, 40% were unintended and of those unintended pregnancies, 50% ended in abortion, 13% resulted in a miscarriage, and 38% ended in an unplanned birth. Due to the statistical prevalence of OC use for contraception, it is important for primary care providers to inform patients regarding proper contraceptive use **(**Sech, Segall-Gutierrez, Silverstein & Mishell, 2017).

Overall, current research has limited insight on education prior to OC use. This literature review will explore the various options, benefits, and the limitations of oral contraception along with the impact that patient education can have on adherence rates.

Commonly Used Female Contraception Options

Many different types of contraception are available on the market today. Sech, Segall-Gutierrez, Silverstein & Mishell, (2017) examined the most commonly used methods of contraception throughout the United States. Oral contraceptives were found to have the most predominant use among 28.1% of females. Female sterilization came in second at 27.1%, and male condoms came in third at 16.1%, followed by Intrauterine devices at 5.5% (Sech et al., 2017). This study reported that pregnancy rates tend to be the highest during the first year of contraceptive use and then decrease as women become more familiar with their method of choice (Sech et al., 2017).

One method of contraception is combined oral contraceptives (COCs). Estrogen and progestin are combined and taken daily in a pill form. COCs first mechanism of action (MOA) is to suppress ovulation, which prevents pregnancy (Papadakis et al., 2017). The second MOA is to thicken the cervical mucus, which deters sperm from advancing into the uterus, preventing fertilization (Shoupe & Mishell, 2016). According to Papdakis et al, "Any combination oral contraceptives containing 35mcg or less of ethinyl estradiol or 3 mg of estradiol valerate are suitable for most women," (Papadakis et al., 2017, p 785).

Progestin-only pills (POPs) are another type of daily dosed oral contraceptive pills. Shoupe and Mishell (2016) found that POPs are very similar to COCs, except there is no estrogen in POPs. POPs contain approximately 75% less progestin than COCs. POPs have the same MOA as COCs, with the addition of lowering endometrial activity (Shoupe & Mishell, 2016). Women prescribed POPs take the pill continuously without a hormone free interval. POPs have been found to have a higher failure rate and breakthrough spotting, which is likely related to the lower progestin dose (Shoupe & Mishell, 2016). Varied failure rates of POPs have been reported, but the average failure rate is 5-8% (Shoupe & Mishell, 2016).

Transdermal contraceptives are another form of hormonal birth control. Transdermal contraceptives (TDs) are manufactured with both estrogen and progestin or progestin alone. TDs are placed on a woman's skin for a week to administer the hormone dosage (Shoupe & Mishell, 2016). TDs hormones have higher serum albumin binding and in turn have higher bioavailability. It is controversial whether or not a higher blood concentration of hormone leads to increased side effects in women, such as increased risk

of thrombosis (Shoupe & Mishell, 2016). TDs have been found to have better regimen adherence than oral contraceptives, likely because of the once weekly dosing (Shoupe & Mishell, 2016).

Intrauterine devices are a form of long acting reversible contraception that is growing in prevalence. Intrauterine devices (IUDs) are available in both hormonal and non-hormonal forms. The non-hormonal form is a copper IUD, which can be used as an emergency contraceptive as well as conventional contraception. Copper IUDs are effective spermicidal agents and sperm entry inhibitors (Papadakis et al., 2016). Hormonal IUDs release levonorgestrel, which thickens the cervical mucus to decrease sperm motility and alters the endometrium to inhibit implantation (Shoupe & Mishell, 2016). IUDs are placed by a provider in a single visit to a clinic and require minimal maintenance. IUDs have extended effectiveness, ranging from three to ten years depending on the type of contraceptive. The failure rate of copper IUDs is 2.1-2.8% over ten years and the rate for hormonal IUDs is 1.1% over seven years (Shoupe & Mishell, 2016).

Another type of hormonal, long acting reversible contraception is an implant (Nexplanon). Implants are made of non-biodegradable material, which releases progestin at a sustained rate. Implants prevent conception through progestin release, which thickens the cervical mucus and suppresses ovulation to some degree. Implants are placed in the upper arm by a provider, remain effective for three years, and have a failure rate of 0.38% (Shoupe & Mishell, 2016).

Depot medroxyprogesterone acetate (Depoprovera) injections are a type of progestin only contraception. These injections are given intramuscularly every three

months in a clinic (Papadakis et al., 2016). The progestin dose thickens cervical mucus, thins the endometrium, and prevents ovulation. Since DMPA injections thin the endometrial lining, DPMA can also be a treatment for endometriosis. Injections have a failure rate of 0.2% with perfect use, and 6% with typical use (Shoupe & Mishell, 2016).

Barrier protection is a form of non-hormonal contraception. Barrier contraception includes male and female condoms, cervical caps, diaphragm, sponges, and spermicides. Male condoms are the most commonly used contraceptive method in this category. Male and female condoms both prevent pregnancy and decrease the infection rate of sexually transmitted infections (Shoupe & Mishell, 2016). Male condoms, female condoms, sponges, and spermicides are all available over the counter, which provides easy access for women and men. Each of these barrier forms of contraception has a higher failure rate than hormonal contraceptives previously mentioned; however, they can be combined with hormonal methods for extended protection (Shoupe & Mishell, 2016).

Emergency contraceptives are used after unprotected intercourse has occurred. Emergency contraceptives (EC) must be taken by women within five days of unprotected intercourse to be effective, and the sooner EC is taken after the incident the more effective it is (Papadakis et al., 2017). Options for EC are: progestin only, COC, a progesterone receptor modulator pill, and placement of the copper IUD. Hormonal ECs are available over the counter in most states for women 17 and older, but a provider must place the IUD (Shoupe & Mishell, 2016). The failure rate of EC ranges from 1-3%, and the failure rate decreases when the EC is taken as soon as possible after unprotected intercourse (Papadakis et al., 2016).

Female sterilization (FS) is a form of permanent contraception that is exceedingly popular in women 40 years old and above (Shoupe & Mishell, 2016). There are two types of FS, Bilateral Tubal Ligation and Essure, both with different mechanisms of action to prevents pregnancy. FS is performed surgically and can be an outpatient procedure if performed laparoscopically. The combined failure rate of all types of FS is 1.8% (Papadakis et al., 2016).

Oral Contraceptive Benefits

Taking OCs provides multiple benefits. According to Papadakis et al., 2017, OCs help to lighten menses, improve acne, reduce the probability of anemia, decrease the likelihood of functional ovarian cysts, and improve dysmenorrhea symptoms. Additionally, OCs reduce the risk of ovarian and endometrial cancer (Papadakis et al., 2017). Due to the multiple combinations of OCs, selection is of high importance when individuals present with different needs.

Many women of childbearing age are unaware of the benefits regarding continued use of oral contraception. Menstruation cycle control, treatment of dysfunctional uterine bleeding, possible protection from benign breast disease, as well as a reduced risk of colorectal cancer are among the many short term and long term benefits (Burkman, Collins, Shulman & Williams, 2001). OCs decrease the risk of ovarian cancer by up to 80% and decrease the likelihood of endometrial cancer by up to 40%-50% (Burkman et al., 2001). A survey study conducted by Brunnhuber and Kirchengast (2002) targeted adolescent females and explored the reasons they started using OCs. The survey revealed that reasons for initiating OCs included improvement of acne, dysmenorrhea, irregular menstruation, cysts and prevention of pregnancy (Brunnhuber & Kirchengast, 2002).

Oral Contraceptive Limitations

Oral contraceptives have a number of side effects. These side effects include: nausea, dizziness that may occur within the first month, decreased sexual desire, and increased fatigue, and migraines (Papadakis et al., 2017). The risk of hypertension, migraines, depression and cerebrovascular disease can increase with the use of oral contraceptives (Papadakis et al., 2017). Women may experience spotty bleeding between menstrual periods, known as breakthrough bleeding, and menstrual periods may be missed, especially when on low-dose pills (Papadakis et al., 2017). Breakthrough bleeding occurs due to breakdown of the tissue in which the endometrium is adjusting to a new state of being thinner, more fragile and atrophic (Basil et. al., 2017). Breakthrough bleeding is the most common side effect of OCs, and is found more in low-dose pills because the endometrium is stabilized by higher doses of estrogen (Basil et. al., 2017). Breakthrough bleeding is most commonly caused by missed OC doses (Basil et. al., 2017).

The use of contraceptives pills increases one's risk of myocardial infarctions (MI), and venous thromboembolism, particularly with the use of 50 mcg of estrogen, rather than 35mcg of estrogen (Papadakis et al., 2017). Due to this, 50mcg of estrogen is no longer being used. The risk of MI's are further compounded with comorbidities, such as hypertension, diabetes, and hypercholesterolemia and in women over age 35 who use tobacco (Papadakis et al., 2017). There is a minimal risk of venous thromboembolisms in women who use contraceptives with the progestin gestodene, drosperinone, desogestrel (Papadakis et al., 2017). The use of oral contraceptives are thus highly discouraged for women with known thrombophilia (Papadakis et al., 2017).

Oral contraceptive use is associated with increased blood pressure (Basil et. al., 2017). Estrogen stimulates the hepatic production of renin angiotensinogen, and is intricately involved in the renin-angiotensin aldosterone system (RAAS), which is thought to be the mechanism through which OCs produce elevated blood sugar effects on the body (Basil et. al., 2017). OCs may also activate the sympathetic nervous system. They do not affect muscular sympathetic nervous activity or systemic hemodynamics (Basil et. al., 2017). Increased risk of hypertension is dependent on the duration of OC use and the age of the individual (Papadakis et al., 2017). Due to the hypertensive risks of OCs, it is recommended that blood pressure be monitored three months after initiating OCs (Basil et. al., 2017). If migraines or vascular headaches develop while using OCs, other forms of birth control are indicated. OCs are contraindicated in patients who get migraines with an aura. (Papadakis et al., 2017).

The absolute risk of cerebrovascular diseases such as subarachnoid hemorrhages and hemorrhagic stroke is small in young women (Basil et. al., 2017), in contrast to the greater risk of thrombotic stroke, especially in women who smoke and are over the age of 35 (Papadakis et al., 2017). The uses of OCs are contraindicated in women greater than 35 years old who smoke (Basil et. al., 2017). OCs are further contraindicated in women with known thrombogenic mutations. The risk of ischemic stroke in women who were heterozygous for Factor V Leiden had an 11-fold increase in thrombosis with the use of OCs. This risk was further compounded by women who were positive for lupus anticoagulants (Basil et. al., 2017). These side effects bring up the question as to whether women need to be screened for thrombophilia before starting OC therapy, which is not currently being done due to financial considerations (Basil et. al., 2017).

The use of combined estrogen-progestin OCs result in a 2-4 fold increased risk for venous thromboembolism (VTE) (Basil et. al., 2017). Although the steroids content of OCs have decreased over the years, it has not decreased the risk for VTE (Basil et. al., 2017). Estrogen-progestin contraceptives containing levonorgestrel have been shown to have the lowest VTE risk (Basil et. al., 2017). The risk for VTE is increased with obesity as well; increasing 2-24-fold in women who are obese compared to women who are not obese (Basil et. al., 2017). The risk for VTE's was increased 10-fold in women who were obese and used OCs in comparison to women who had neither risk factor (Basil et. al., 2017). The risk for VTE is further compounded with increasing age, sharply rising in women older than 39 years (Basil et. al., 2017).

In conclusion, OCs are shown to have significant side effects in patients with certain comorbidities, such as hypertension, diabetes, and in women who smoke (Basil et. al., 2017). OCs are also contraindicated in women who have been diagnosed with certain conditions such as depression, vascular headaches, venous thromboembolism, history of stroke and known ischemic heart disease (Basil et. al., 2017). In young, healthy patients, the benefits of OCs may often outweigh the risks; which also proves true for women who have certain comorbidities but are able to manage their underlying conditions in an appropriate manner (Basil et. al., 2017).

Patient Education and Counseling

A study completed by Mullen et al., 1997, measured the effects of counseling on behavior among patients. The data consisted of whether behavior change required giving up current behaviors or adding new behaviors (Mullen et al., 1997). Behavior techniques, self-monitoring, media, and personal communication produced positive counseling in

prevention of disease (Mullen et al., 1997). Individualizing counseling depending on the patient's needs and abilities, allowing time for questions, self-pacing, and reinforcement for positive behavior were all factors that contributed to a successful behavior change (Mullen et al., 1997). Adequate patient counseling was achieved as a result of all methods described above and not one appeared more significant than another (Mullen et al., 1997). As a result, counseling is individualized and focused upon each person's needs as well as desired counseling method (Mullen et al., 1997).

Many different methods of patient education and counseling exist, including: verbal, written, illustrated, and multimedia methods. According to Gagliano, 1988, educational videos are more effective in increasing a patient's short-term knowledge when compared to verbal or written instructions. Despite the short-term knowledge increase, patients had equal amounts of retained, long-term knowledge when provided with any type of counseling (Gagliano, 1988). In contrast to educational videos, computer based patient education significantly increased patient knowledge when compared to verbal and written instructions (Lewis, 1999). Depending on the patient, any of these methods may be more successful in increasing patient knowledge and medication adherence.

Contraceptive Education Prior to Oral Contraceptive Use

Most females in the U.S. spend almost 3 decades using contraceptives to avoid unintended pregnancies (Salganicoff & Ranji, 2013), yet approximately half the pregnancies in the United States are unintended (Fowler & Jack, 2008). Contraceptive counseling has been shown to play a significant role in women's reproductive health, yet women usually find themselves dissatisfied with the amount of contraceptive counseling

they receive (Dehlendorf et al., 2017). Few studies have been done on the quality of contraceptive counseling in the United States (Dehlendorf et al., 2017). Of those, Dehlendorf et al, 2017, focused on the quality and content of patient-provider communication about contraception, done on a cohort of 339 women, ages 15-45, who presented for care at 6 different clinics in the San Francisco Bay Area. The clinics were primary care, family planning, and general gynecology clinics. It was found that only 51% of providers adequately addressed the family planning needs of their patients, 64% of providers addressed preferences specific for birth control and 53% of providers offered patients a chance to ask questions. It was concluded that there was inadequate education and counseling provided to patients regarding their contraceptive needs (Dehlendorf et al., 2017).

Amin and Chewning (2016) studied OCs education from a wider perspective by using a theoretical framework via the Theory of Planned Behavior (TPB). A self-administered survey was used among pharmacists to measure the extent of patient counseling provided by pharmacists prior to dispensing OCs. This research found that pharmacists educated patients on the importance of taking OCs at the same time everyday but seemed to miss the educational component on when to start taking OCs, side effects and the appropriate steps that are needed when a dose is missed (Amin & Chewing, 2016). This study also found that women would rather be educated on OCs by female pharmacists rather than male pharmacists (Amin & Chewing, 2016). Pharmacist counseling was directly correlated to whether pharmacists perceived that the woman to whom they were dispensing OCs welcomed the initiated counseling (Amin & Chewing, 2016).

On a national level, a 2011-2015 National Survey of Family Growth surveyed the extent of communication providers had with adolescents and young females during sexual and reproductive health visits (Liddon, Steiner, & Martinez, 2017). In regards to providers who administered contraceptive counseling for patients who came in for a pregnancy test, pap smear or pelvic exam, it was found that an overall average of approximately 64.0-66.8% of women had contraceptive counseling. The rates varied depending on factors such as age, race/ethnicity, parent's education, age of first vaginal sex, insurance and federal funding (Liddon, Steiner, & Martinez, 2017).

Women aged 15-19 years had higher rates of OC counseling compared to women aged 20-24 years (Liddon, Steiner, & Martinez, 2017). Hispanic/Latino patients had lower rates of OC counseling compared to Non-Hispanic black patients, with Non Hispanic white patients receiving the least amount of OC counseling (Liddon, Steiner, & Martinez, 2017). Patients with private insurance had higher percentages of OC counseling compared to patients with Medicaid or Medicare. Patient's whose mothers had some college education had higher OC counseling compared to patients whose mother's education levels may or may not have included high school (Liddon, Steiner, & Martinez, 2017). Patients whose age of first vaginal sex was <15 years old received less OC counseling than patients who's age of first vaginal sex was >15 years (Liddon, Steiner, & Martinez, 2017). Public, federally funded family planning clinics had the highest rates of OC counseling whereas public, non-federally funded clinics had the lowest rates of OC counseling (Liddon, Steiner, & Martinez, 2017). Overall, 64-68% of sexually active women who had appointments at family planning clinics for their sexual and reproductive health received education and information about contraception and birth

control. The level and rates of counseling differed based on numerous factors such as provider, clinic, demographics, age, sexual practices, and funding (Liddon, Steiner, & Martinez, 2017).

The factors that determine adherence rates are varied and diverse. Social factors, economic factors, religious factors, and cultural factors can play significant roles in a woman's reproductive decision making. According to Douglass, McKean, Van Dommelen, Meshbane, Poquette, & Curry, 2017, one influential economic factor in determining a woman's knowledge of OCs is poverty. Douglass et al, 2017, discovered that homeless women experienced high rates of unintended pregnancies, had a desire to avoid future pregnancies, but lacked the knowledge to do so. This study concluded that unique interventions needed to be made by the medical community in order to provide counselling and contraceptive education for women experiencing homelessness (Douglass et al., 2017).

The Relationship Between OC Education and Adherence

Tomaszewski et al, 2017, looked at the relationship between patient knowledge of oral contraceptives and adherence to oral contraceptives among college-age females at the University of Minnesota in 2017. Of 1559 females who responded to the survey, 670 reported use of OC's, and of those, a total of 44.3% met criteria for low adherence, 36.4% met criteria for medium adherence, and 19.3% met criteria for high adherence. There was a strong correlation between knowledge and adherence rates ($p<0.001$). The researchers concluded that less than 20% of those surveyed satisfied criteria for high adherence to OCs, and suggested that knowledge and education on OCs could raise adherence rates. Healthcare educators, providers and media discussed "targeted

interventions" that provide knowledge and education on the proper use, risks and benefits of OCs, which could prove to be an important component in seeing better outcomes (Tomaszewski, Aronson, Kading, & Morisky, 2017).

The study on adherence to contraception completed by Tomaszewki et.al., 2017, focused on a certain socio-economic demographic of the American population - educated females at a predominantly Caucasian university. According to Liddon et.al., 2017, race plays a role in a patient's knowledge of OC use. Evaluating the diverse array of people groups that contribute to the overall contraceptive usage and fertility rate of the country is important, including educated, uneducated, immigrant, native, and homeless populations. According to the United States Census Bureau, the U.S. 2010 population is comprised of over 13% who were foreign-born, defining foreign-born as "anyone who is not a U.S. citizen at birth," and native Americans as "anyone who is a U.S. citizen at birth." In a 2014 U.S Census Bureau study, half of foreign-born women were between the ages of 18 and 44, were more likely to be married, and on average, had households that were larger than native-born women. Foreign-born women were statistically more likely to bear children than native women, and foreign-born women had a fertility rate of 2.59 compared to 1.71 for native women (Colby & Ortman, 2014). Thus it can be inferred that foreign-born women had almost twice the family size as native-born women.

In the same context, a study of midwives' experiences on providing contraception counseling to women was done in 2017, evaluating the factors that played into the use of contraceptive options. According to Kolak, Jensen, & Johansson, 2017, it was acknowledged that the task of providing contraceptive knowledge sufficient to create high OC adherence rates was a complex and difficult one. Contraceptive understanding

varied greatly among immigrant women and was strongly influenced by cultures, religions and practices. Midwives that had a greater cultural understanding of the women they were counseling saw better adherence outcomes. Without adequate cultural proficiency, midwives were more likely to prescribe contraceptives and have poor adherence outcomes, resulting in unwanted pregnancies (Kolak, Jensen, & Johansson, 2017). Kolak et al., 2017, concluded that midwives who adapted their contraceptive counseling strategies to the specific cultures with whom they were working effectively saw improved adherence rates. This was in part due to education provided in a culturally sensitive manner. When healthcare workers, providers and educators are providing contraceptive counseling to foreign-born women, applying these same principles may help increase OC adherence rates.

Conclusion

Few studies have been done on the quality of education that was provided to patients on OCs. Within the studies that do exist, there is a lack of adequate OC education where it is needed the most - in family practice, family planning and gynecology clinics. Pharmacists that provide OC counseling educate patients on the importance of taking their contraceptives, but miss educating patients on side effects, dosage routine and what to do if a dose is missed (Amin & Chewing, 2016). OC education is markedly decreased in the homeless population with a high rate of unintended pregnancies (Douglass et al., 2017). OC education is found to be lacking in the foreign-born populations and the need to infuse and integrate cultural expertise into contraceptive education of immigrant populations is evident (Kolak, et al., 2017). There exists a correlation between OC education and high adherence rates to OCs, but further research needs to be done to

evaluate both the quality of counseling provided to patients, and the impact of that education on adherence rates and outcomes (Dehlendorf et al., 2017).

CHAPTER 3: Methodology

Introduction

The purpose of this study is to explore the current patient education provided to women of childbearing age prior to the use of OCs, and to determine how patient education affects adherence rates of OC use. This methods section addresses and analyzes the following question: "How are oral contraceptive adherence rates affected by patient knowledge and extent of medical counseling?" Adequate knowledge in this study is defined as being aware of side effects and correct OC use. The results will address the current gap in OC patient education use, which is relevant to current healthcare providers. The following sections will be discussed in the proceeding chapter: study design, population, experimental procedures and protocols, study tools, data collection process, statistical analysis, as well as delimitations and limitations.

Study Design

This study is a quantitative study that will utilize a questionnaire, which addresses the participant's basic knowledge of OCs, the education they were provided concerning OCs, and their adherence to their OCs. The amount of participants passing or failing the quiz will be analyzed using statistical analysis, and quantified based on the results. This study will therefore quantify the relationship between OC education provided to our participants and their knowledge.

Population

The inclusion criteria of this study are female's ages 18-35 that are enrolled as undergraduate participants at South Dakota State University in the course Biology 221.

The exclusion criteria include anyone not enrolled at South Dakota State University, males of any age, females not in the designated age range, and females not taking OCs.

Experimental protocols

The methodology of this research project includes designing and testing a survey that will be handed out at one time to undergraduate participants enrolled in BIO 221, an anatomy class at South Dakota State University, in late April, 2018. The primary reason for surveying this particular population is due to the large available sample size of 200 participants, which will allow for a more accurate statistical outcome. This group was also chosen due to personal connections and availability. Prior permission to survey this population was obtained via email correspondence with the undergraduate professor of Biology 221, John Pederson, PhD (see Appendix A). Dr. Pederson provided a written confirmation through email to allow researchers to administer the survey during one of his class periods and collect data from his participants. The surveys will be administered on paper by the researchers of this study and will be collected by those same researchers.

In order to prevent using information from media or outside resources when answering questions related to OC side effects and risks, the participants will be closely monitored by the researchers during the surveying period. The participants will be informed that every survey will remain entirely anonymous.

Identifying information will not be recorded or incorporated into the survey. Our study tool has a contingency that informs participants who have never been prescribed OCs to discontinue the survey, since it does not apply to them.

Our survey contains thirteen questions, eight of which address factual knowledge that OC users should possess (see Appendix B). Question three addresses who prescribed

the participants' prescription - a medical provider, pharmacist, Planned Parenthood, or other. Question four addresses whether the student felt the OC education received from their prescriber was adequate. Question five addresses whether the student needed outside sources to supplement the education received about OCs from their prescriber (see Appendix B). The following questions, six through thirteen, are used to determine adequate OC knowledge. A student has to answer questions six through thirteen correctly or only answer one question inaccurately, to be classified as having adequate OC knowledge. Therefore, if a student answers more than two questions out of the eight inaccurately, they are deemed to have inadequate knowledge of OCs.

Our variables are outlined as follows:

- The independent variable is whether or not our respondent's take OCs or not. The independent variable consists of two levels - respondents that take oral contraceptives and respondents that do not take oral contraceptives.
- The dependent variable is whether or not the respondents have adequate knowledge of oral contraceptives. The nature of the dependent variable is categorical - participants either have adequate knowledge of OCs, or they do not.

Based on the variables of this study, the data will be analyzed through a chi-square test analysis with JASP, an open source software package. Data collected from respondents will be stored in a locked safety drawer on an external hard drive within a locked room at the Anderson Center of Bethel University.

The subject of oral contraceptives is of a personal nature, which is why respondents will have a choice of whether they want to answer the questions. Participants do not have to take the survey if they choose not to, and will be informed that

participation is optional before the surveys are handed out. Participants will also be informed that their decision to participate or disregard the survey does not have any impact upon the course they are taking, their grades in the course, upon the relationship they have with their professor, South Dakota State University, or Bethel University. The informed consent will be administered to participants with the survey. Students will be given the opportunity to read the informed consent and sign prior to continuing if they wish to participate in the survey. The researchers will provide a copy of the informed consent if the participants wish to obtain one for their records via an on-campus printer. Once the respondents have completed the survey, they will hand in both the survey and the signed informed consent.

Data Collection

The tool being used is a self-reported survey consisting of eight questions that assess the participants' knowledge of oral contraceptive use, which was created by the researchers (see Appendix B). The survey was based on medical knowledge from the American Journal of Obstetrics and Gynecology, and it compiles information about use, side effects, and efficacy of OCs (Burkman, Shulman, & Williams, 2001).

An expert panel will review the survey to assess potential flaws and provide feedback on the nature of the survey. The expert panel will consist of participants in the current Bethel University Physician Assistant cohort, five in total. The study tool will be edited according to the feedback received. Having multiple systematic reviews and editing processes will assure the validity of the study tool. Although the survey will only be administered one time, the results will be reliable because the answers are dependent upon past and present actions, rather than on an emotional response. Prior to distribution

of the surveys, IRB approval will be obtained by SDSU and Bethel University to survey participants of Dr. Scott Pedersen's Biology 221 class.

Statistical Analysis

This research study is assessing the participants' knowledge of OCs using a pass/fail survey that will be analyzed using categorical/chi-square methodology. Questions six through thirteen were assigned correct and incorrect responses, which were determined by the American Academy of Obstetrics and Gynecology (Burkman, Shulman, & Williams, 2001). Once the surveys are collected, the amount of correct responses and overall percentage will be examined. If a student answers seven out of eight questions accurately, for a total score of 87.5%, the participant is assessed to have adequate knowledge of OC use. The responses from questions three, four and five are intended to measure whether the participant thought they had received adequate OC education prior to use by the prescribing agency (See Appendix B). Questions one and two are intended to assess whether the student met the inclusion criteria in order to participate in the survey. However, this data will not be used for our statistical analyses (See Appendix B).

Limitations and Delimitations

This study will be confidential because identifying information will not be recorded or incorporated into the survey. All information being self recorded truthfully and to the best of each participant's ability cannot be completely assured, and results may be skewed. The survey method is based on recall, which may increase participant error. Due to contraceptive practices being individualized and possibly involving sexual practice, recording information in regards to contraceptive use may be a sensitive subject

for participants. Birth control is largely a private matter, and women may not be open to sharing information regarding their contraceptive use.

The information will also be gathered at one location, South Dakota State University, limiting the sample by geographical area and a specific age cohort of college students. As physician assistant participants, the researchers have observed an insufficient level of contraceptive education amongst the general public, leading to research bias. This has led the researchers to evaluate whether their observations are valid which has lent itself to this study. Believing that there is not adequate OC education is a research bias that might exist even before the researchers measure the results of the current study.

This research includes delimitations, since only women of reproductive age will be asked to respond to the questionnaire. No other group besides women ages 18-35 enrolled at South Dakota State University will be surveyed. A limitation on college-aged women will be intentionally placed for the purposes of this study.

Conclusion

Through a hand-distributed paper survey, participants from South Dakota State University will be evaluated on whether or not they have had adequate oral contraceptive education provided to them by their prescribing agency. The data collected will be analyzed using a chi-square test. Results and discussion will be examined in the following two chapters.

Chapter 4: Results

This section indicates the results of the study by measuring and analyzing the self-reported questionnaire. The questionnaire evaluated the quality of contraceptive counseling provided to patients taking OCs, the amount of patient knowledge, and its corresponding relationship to OC adherence rates. The results collected demonstrated the resources used, assessed the participants knowledge of OCs by using a pass/fail method, determined whether the participant felt they had adequate knowledge, and if the participant used outside resources to gain further information. If the participants answered seven out of the eight questions correctly, they were evaluated to have adequate knowledge of OC use. If they answered six or less questions correctly, the participant was evaluated to have inadequate knowledge of OC use, and to be non-adherent to their regimen. Passing or failing the quiz was then compared to whether or not the participant received adequate OC education. The data suggests that oral contraceptive adherence rates are not dependent on the quality of education provided.

Data Analysis

Data was collected using paper surveys distributed to women enrolled in Dr. Scott Pedersen's Biology 221 class at South Dakota State University. Upon collection of the questionnaire, there were an estimated 200 participants in the class. Out of the 200 participants, 90 met the inclusion criteria and were able to participate in the survey. The data collected from the surveys was compiled and analyzed. Below is a discussion of the pass and fail rate of the survey, and the types of resources used for education, as well as a chi-square test.

The following tables represent whether or not a student is adherent to their OC regimen, indicated by whether or not they passed the survey, whether or not the student believed they received adequate education of OCs, and the types of resources used for further information of OCs.

Table 1.0

Pass or Fail

	Pass	**Fail**	**Total**
Participants	41	49	90

The participants in the study included college students enrolled in the course Biology 221 at South Dakota State University. Table 1.0 represents the 90 participants who fit the required criteria and filled out the questionnaire. Out of those 90 participants, 41 passed and 49 failed. Furthermore, 41 participants answered seven out of eight questions accurately, for a total score of 87.5% and were deemed to have adequate knowledge of OC use. The 49 participants who failed answered at least two questions out of eight inaccurately, for a total of 75% or below.

Table 1.1

Adequacy of Oral Contraceptive Education

	Adequate education	**Inadequate education**	**Total**
Pass	40	1	41
Fail	47	2	49

Table 1.1 represents the amount of participants who passed or failed the survey, and whether or not the participant believed they received adequate information regarding oral contraceptives. Of the 90 participants, 40 participants passed the survey and also felt they received adequate education. Only one participant who passed believed they received inadequate education. Of the 49 participants who failed the survey, 47 (95.9%) believed they received adequate education, and 2 (0.04%) participants believed they did not receive adequate education.

Table 1.2

Resources Used For Information About OCs

	Friends	**Family**	**Internet**	**Printed**	**No other resource**
Pass: Adequate Education	22	21	19	10	4
Pass: Inadequate Education			1		
Fail: Adequate Education	17	31	22	4	5
Fail: Inadequate Education	1	1	2		

The most commonly used resources for oral contraceptive education outside of a medical provider were listed on our survey: friends, family, printed information, and the Internet. Our participants were able to choose any resource they used and were able to choose more than one answer if the participant used multiple resources. The numbers above are the totality of usage indicating that of those that failed, family was the most

used resource, and of those that passed, friends were the most used resource. Of those who passed, four did not use resources besides their medical provider, and of those who failed, five did not use other resources.

Statistical Analysis

The chi-square statistic for the pass/fail rate was calculated to be 0.1869, with a p-value of 0.665495. For the results to be significant, the p value needed to be less than 0.05, indicating that the results are not significant, and the null hypothesis was not rejected. Therefore, no statistical correlation can be made between quality of patient education and oral contraceptive adherence rates from this data set.

Chapter 5: Discussion

This chapter discusses conclusions made from the completion of the research study. It evaluates the limitations, implications and recommendations for further research. It will address the implications and recommendations for future medical practice in regards to OC administration.

Study Conclusion

Based upon our research question, population surveyed and methods employed, we failed to reject the null hypothesis. The results do not indicate statistical correlation between oral contraceptive adherence rates and oral contraceptive education. After completing our data analysis, it became apparent that there was a flaw within our study. We were evaluating patients' education, an objective measure, in a subjective fashion. It became apparent that our evaluation of a participant's assessment of the education they were provided was in fact, solely subjective, as the majority of our participants who failed thought they did receive adequate education. However, the objective data, passing or failing the exam, clearly revealed that they did not have adequate knowledge. This flaw was demonstrated by the 97.9% of participants who believed they received adequate education, yet 54% failed the survey.

This suggests that most people are overconfident with their own knowledge, whether it is accurate or inaccurate, without realizing that they are lacking in their comprehension of the subject. As most do not realize their lack of knowledge, they see no reason to seek out further help, advice or expertise upon the subject, carrying out what they have been doing as usual with perfect contentment and with obvious detriment.

Limitations

This study had multiple limitations. The survey was distributed at one time, in one

location, South Dakota State University. This limited the sample to college students in one geographical area. Age confines were also placed, as only women between the ages of 18-35 were included in the study. Participants were also asked to answer the survey based on recall, which may have led to error. Additionally, some of the participants may have been unwilling to participate in the study, as birth control is a sensitive subject.

Perhaps the most significant limitation of this study was measuring the quality of education based on the participants subjective feelings, and compared it to their objective knowledge, whether they passed or failed the quiz. This measurement clearly did not correlate to quality of education, or at least retained information, as 97.9% of participants who failed the survey believed they received adequate education regarding OCs.

Implications and Recommendations for Future Practice and Further Research

Regarding further research in women who take OC, several observations were made from conducting this study. It would be beneficial to conduct a questionnaire that addresses the gap between participants feeling they receive adequate knowledge to take OCs and those who actually do have the knowledge for proper use of OCs. It would also be beneficial to have a larger population that is not specifically limited to a certain age group or a certain college institution and college class. This would enable the research to be broader and extend across multiple age groups.

Although statistically the data was inconclusive, a lesson can still be learned from this study in regards to patient education and knowledge. Over half of the participants failed the questionnaire, yet the overwhelming majority of participants believed that they received adequate education. This finding indicates that there is a gap in not only patient knowledge, but also awareness of the efficacy of patient education. The gap in patient

knowledge is clearly evident, as the majority of participants failed a questionnaire, which was simply testing basic information about their OC prescription. The awareness of patient education efficacy is subtler. Each participant received information of OCs from at least one source, the medical provider, and many used multiple different supplemental resources, and believe they had received adequate education. Participants who failed were not using resources that were efficacious in educating them, including the information given to them by a medical provider, as their knowledge was not accurate. This indicates that counseling by the medical provider clearly is not sufficient for participants to fully understand their OC regimen. If more efficacious methods of patient education are found, knowledge and adherence rates to OCs could dramatically increase. These findings suggest that better patient education is needed in order patients to retain knowledge about OCs.

In order to assess how patient education increases lasting knowledge of OCs, a new study would have to be completed. The study would assess the type of education given to a patient, and how it affects patient knowledge. The participants would not be given the power to assess subjectively whether or not they received adequate education; rather it would be evaluated by objective measures, such as time spent with medical provider initially, types of resources given, time spent researching, etc. This study would be able to compare how different types of education affect patient knowledge, and these techniques could be used in the future by any medical provider to better educate patients and increase medication adherence rates.

Conclusion

In conclusion, no correlation could be made from this study between patient education and adherence rates to oral contraceptive regimens. The results did indicate that the majority of participants had low adherence rates to their OC regimen, which is similar to the results found in previous literature. Participants were also eager to believe that they received adequate education of OCs. All participants had one information source in common; the medical provider, but most also used family and friends as a knowledge resource. The findings of this study, and past studies, indicate that a great need to increase patient adherence rates is present, which is most likely to be accomplished by improving patient education.

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Appendix A- Permission email from Dr. Pedersen

From: Pedersen, Scott
Sent: Thursday, January 18, 2018 11:49:16 AM
To: Anderson, Brook Marie - SDSU Student
Subject: Re: Graduate Research

I am so sorry for putting off my response, Brook.

I am happy to support your project.
The only concern I have is that an outside entity (you) will be using our students (human subjects), and such things need permission from SDSU.
3x attachments + https://www.sdstate.edu/research/human-subjects-protections

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Human Subjects Protections | South Dakota State University
www.sdstate.edu

The mission of the SDSU Human Subjects Committee is simple and straightforward: We assist researchers in protecting people from harm when they participate in research.

I can fill out the form and submit it for you - albeit, it will have to be processed under my name.
When were you thinking of doing this? See the class schedule.

That is very good news re: your coursework there!

Please advise

Appendix B- Questionnaire

Have you been prescribed birth control in the past or present?
Yes
No

If no, thank you for your participation. You may now discontinue this survey.

Age:
18-22
23-27
28-35

Who prescribed the birth control?
a. Medical Provider (Physician, Physician Assistant, Nurse Practitioner)
b. Planned Parenthood
c. Other _____

Did you feel you were given adequate education and instructions on how to take your birth control prescription?
a. Yes
b. No

Have you used other resources to acquire information about birth control use?
a. Friends
b. Family
c. Internet
d. Printed Resource
e. No, I did not use any other resource

Do you take your pill each day?
a. Yes
b. No

Do you take your pill at the same time each day?
a. Yes
b. No

Each month, how many times do you miss taking your pill?
a. 0 times
b. 1-3 times
c. 4-6 times
d. Greater than 7 missed pills a month

What protocol do you follow when you miss one pill?
a. Take two pills at the next appropriate time

b. Take one pill as soon as you realize you missed a dose

Do oral contraceptives need to be taken at the same time each day to be effective?
Yes
No

Do taking oral contraceptives increase your likelihood of developing a blood clot?
Yes
No

Do taking antibiotics decrease the effectiveness of your birth control?
a. Yes
b. No

Do birth control pills help protect you from contracting an STD?
a. Yes
b. No

Thank you for your participation. Please hand in your survey now.

Appendix C - Informed Consent

Dear South Dakota State University Student:

We are physician assistant participants from Bethel University's Physician Assistant Program, conducting research in partial fulfillment of the requirements for a Masters Degree in Physician Assistant Studies. Our study is investigating the adequate knowledge of birth control among women participants of reproductive age. We hope to learn how knowledge of birth control affects adherence rates.

You were selected as a possible participant in this study because you are a female of reproductive age.

If you decide to participate, participation involves filling out the following survey. The survey will take approximately 5 minutes to complete.

Any information obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. In any written reports or publications, no one will be identified or identifiable.

Your decision whether or not to participate will not affect your future relations with Dr. Scott Pedersen or South Dakota State University in any way. Your grade in Biology 221 will not be affected by your decision to opt into or out of this survey. If you decide to

participate, you are free to discontinue participation at any time without affecting such relationships.

This research project has been reviewed and approved in accordance with SDSU, IRB and Bethel University's Levels of Review for Research with Humans. If you have any questions about the research and/or research participants' rights or wish to report a research related injury, please call researchers:

Brook Anderson: 507-766-3296

Lydia Lutz: 218-280-1736

Anmol Clairmont: 406-890-0456

Jeanne Szarzynski: 805-607-4313

You will be offered a copy of this form to keep.

We understand that you have an extremely busy schedule and your time is limited. Please realize that your participation is vital to the success of this research. The information that you provide is essential to the validity of this study. Thank you in advance for your prompt response to this study. Please complete the survey by the end of the class period.

Thank you again for your help.

Sincerely,

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.

Signature _____ Date_____

Appendix D: Bethel IRB

For office use only:

Code number _____ Action:

Date reviewed _____

Request for Approval of Research with Human Participants
In Social and Behavioral Research

Institutional Review Board for Research with Humans

Bethel University
P.O. Box 2322 3900 Bethel Drive
St. Paul, MN 55112

College and Federal policies require that each project involving studies on humans be reviewed to consider 1) the rights and welfare of the individuals involved; 2) the appropriateness of the methods used to secure informed consent; and 3) the risk and potential benefits of the investigation. Bethel has a three-level review structure, such that not all research proposals need to come to the IRB committee. The levels of review and their associated criteria may be viewed on Bethel's website. **Research may not be initiated prior to formal, written approval by the appropriate committee or person.**

The information on the following pages is necessary for review. Answer each item thoroughly, and put N/A for those that do not apply. Label each piece of information by section letter (A – G), item number (1, 2, etc.), and the boldface headers for each item. **Proposals lacking information will be returned without review**. Attach your typewritten pages to this cover sheet.

Submit the completed form to the committee, either at the above address or, if this is Bethel student research, to your research advisor. You *will not* receive this proposal back, so be sure you keep a copy of the materials you submit. You will be notified by letter of the committee's decision.

A. Identifying Information

1) Date: April 3 2018

2) Principal Investigator

- Brook Anderson, Physician Assistant Student, bma57998@bethel.edu, P: 507-766-3296
- Lydia Lutz, Physician Assistant Student, lll33387@bethel.edu, 218-280-1736
- Anmol Clairmont, Physician Assistant Student, agm49758@bethel.edu, P: 406-890-0456
- College Department: Bethel University Physician Assistant Program
- Campus Address: 3901-3965 Snelling Ave N, Arden Hills, MN 55112

3) Co-investigator

- Dr. Scott Pedersen, South Dakota State University Department of Biology, 1175 Medary Ave, Brookings, SD, 57006, P: 605-688-5529, scott.pedersen@sdstate

4) Project Title- "The Effects of Patient Education on Oral Contraceptive Adherence Rates"

5) Key Words – Oral Contraceptive Pills, Medication Adherence, Patient Education

6) Inclusive Dates of Project – 07/1/2019

7) Research Advisor – Jeanne, Physician Assistant Certified, j-szarzynski@bethel.edu,
P: 651-635-8002

8) Funding Agency – N/A

9) Investigational Agents - N/A

B. Participants

1) Type of Participants – Adult females ages 18-35 who are taking oral contraceptives or have taken birth control in the past.

2) Institutional Affiliation – Participants are enrolled as undergraduate participants at South Dakota State University in the course Biology 221.

3) Approximate Number of Participants: 200 participants

4) How Participants are Chosen – Participants are chosen by attending the undergraduate class of BIOL 221, an anatomy class at South Dakota State University. Eligible participants include females who have or are currently taking oral contraceptives. The primary reason for surveying this particular population is due to the large available sample size of 200 participants, which will allow for a more accurate statistical outcome. This group was also chosen due to personal connections and availability. Prior permission to survey this population was obtained via email correspondence with the undergraduate professor of Biology 221, Dr. Pederson (see Appendix B). Dr. Pederson provided a written confirmation through email to allow researchers to administer the survey during one of his class periods and thus collect data from his participants. The surveys will be administered on paper by the researchers of this study and will be collected by those same researchers.

5) How Participants are Contacted – Every participant will be contacted directly during their class period on April 20th at South Dakota State University. The surveys will be handed out in the class period and the participants will not be contacted before or after survey administration.

6) Inducements – Brook Anderson PA-S, who will be in direct communication with the participants, will offer to stay after class and provide information about the PA profession, application to PA schools, and any other information regarding becoming a PA student to anyone who is interested.

7) Monetary Charges – No participant will be charged for their participation.

C. Informed Consent –

Dear Student:

We are conducting a research project entitled *"The Effects of Patient Education on Oral Contraceptive Adherence Rates"* as part of a a partial fulfillment of the requirements for the degree of masters of science in physician assistant at University In St. Paul, MN.

The purpose of the study is to evaluate the relationship between the quality of contraceptive counseling provided to patients actively taking birth control, the amount of patient knowledge, and its corresponding relationship to birth control adherence rates

You as a student are invited to participate in the study by completing the attached survey. We realize that your time is valuable and have attempted to keep the requested information as brief and concise as possible. It will take approximately 10 minutes of your time. Your participation in this project is voluntary. You may withdraw from the study at any time without consequence. Completing or not completing this survey does not affect your grade in this course in any way.

Participation in this study may cause minimal risk, as some participants may view oral contraceptive use as a private matter, and answering questions about use could cause emotional distress. Additionally, if you as a student have used oral contraceptives you may be identified by your peers, as you will be completing the survey. If at anytime you feel uncomfortable, you may discontinue the survey without any impact upon the anatomy course, your grades or relationship with your professor, South Dakota State University or Bethel University.

Your responses are strictly confidential. When the data and analysis are presented, you will not be linked to the data by your name, title or any other identifying item. Please assist us in our research and return the completed survey in the enclosed envelope.

Your consent is implied by the return of the completed questionnaire. You may obtain a copy of this cover letter upon request. If you have any questions, now or later, you may contact us using the information below. Thank you very much for your time and assistance. If you have any questions regarding your rights as a research participant in this study, you may contact the SDSU Research Compliance Coordinator at 605-688-6975, SDSU.IRB@sdstate.edu.

Sincerely,

Researchers:
Brook Anderson, Physician Assistant Student
bma57998@bethel.edu
507-766-3296

Lydia Lutz, Physician Assistant Student
lll33387@bethel.edu
218-280-1736

Anmol Clairmont, Physician Assistant Student
agm49758@bethel.edu
406-890-0456

Research Chair:
Jeanne Szarzynski, Physician Assistant Certified
j-szarzynski@bethel.edu
805-607-4313

Questionnaire

Have you been prescribed birth control in the past or present?

a. Yes

b. No

If no, thank you for your participation. You may now discontinue this survey.

Age:

a. 18-22

b. 23-27

c. 28-35

Who prescribed the birth control?

a. Medical Provider (Physician, Physician Assistant, Nurse Practitioner)

b. Planned Parenthood

c. Other _____

Did you feel you were given adequate education and instructions on how to take your birth control prescription?

a. Yes

b. No

Have you used other resources to acquire information about birth control use?

a. Friends

b. Family

c. Internet

d. Printed Resource

e. No, I did not use any other resource

Do you take your pill each day?

a. Yes

b. No

Do you take your pill at the same time each day?

a. Yes

b. No

Each month, how many times do you miss taking your pill?

a. 0 times

b. 1-3 times

c. 4-6 times

d. Greater than 7 missed pills a month

What protocol do you follow when you miss one pill?

a. Take two pills at the next appropriate time

b. Take one pill as soon as you realize you missed a dose

Do oral contraceptives need to be taken at the same time each day to be effective?

a. Yes

b. No

Do taking oral contraceptives increase your likelihood of developing a blood clot?

a. Yes

b. No

Do taking antibiotics decrease the effectiveness of your birth control?

a. Yes

b. No

Do birth control pills help protect you from contracting an STD?

a. Yes

b. No

Thank you for your participation. Please hand in your survey now.

D. Abstract and Protocol

1) Hypothesis and Research Design – The hypothesis of this study is that oral contraceptive adherence rates are dependent on the quality of oral contraceptive patient education provided. The purpose of this study is to evaluate the relationship between the quality of contraceptive counseling provided to patients actively taking OCs, the amount of patient knowledge, and its corresponding relationship to OC adherence rates.

The independent variable is whether the respondent's take OC's or not. The independent variable consists of two levels - respondents that take oral contraceptives and respondents that do not take oral contraceptives. The dependent variable is whether or not the respondents have adequate knowledge of oral contraceptives. The nature of the dependent variable is categorical - participants either have adequate knowledge of OC's, or they do not.

Our Research Question is as follows: "How are oral contraceptive adherence rates affected by patient knowledge and depth of medical counseling?" This question will be analyzed using a quantitative questionnaire. The data that is collected will be analyzed through categorical/chi-square methodology. The number of questions that are answered accurately or inaccurately will be measured numerically, run through statistical analysis and quantified based on the results.

2) Protocol

Brook Anderson will introduce herself as a Physician Assistant student at Bethel University who is conducting a research project titled "The Effects of Patient Education on Oral Contractive Adherence Rates". She will explain that this research study is assessing the participants knowledge of OC's using a pass/fail questionnaire within the survey. The participants will also be told that this study is a quantitative study that will utilize a questionnaire, which addresses the student's basic knowledge of OC's, the education they were provided concerning OC's, and their adherence to their OC's. This study will therefore quantify the relationship between OC education provided to our participants and their knowledge.

Brook will then explain how it is a voluntary survey and there will be no benefits nor repercussions for taking or refusing the survey. The participants will also be informed

that the survey is confidential as no self-identification information is included in the survey. The cover letter and survey will be distributed simultaneously to participants. The cover letter states that the participant's consent is implied by the return of the completed questionnaire. The participant may obtain a copy of the cover letter upon request. If the participant has any questions, now or later, they may contact us using the information provided on the cover letter.

The participants will be instructed that this survey will take approximately 10 minutes to complete. After the survey is completed, the participants will be advised to return the cover letter and survey back to Brook Anderson PA-C, the researcher. The researcher will explain that the actual paper surveys will be shredded in a confidential shredder and the data will be held on a password protected computer while it is being analyzed. The data will then be held on an external hard drive in a locked cabinet within a locked room at Bethel University for a minimum of 5 yrs. A copy of the survey is located with the cover letter. IRB approval from SDSU will be obtained prior to survey administration, and will be granted after Bethel University IRB permission. The study will take place on April 27, 2018 and the data will be collected in the Biology 221 course.

The data that is gathered will then be analyzed using categorical/chi-square methodology. The number of questions that are answered accurately or inaccurately will be measured numerically, run through statistical analysis and quantified based on the results. For details on the script that Brook will use to address the participants, see Appendix A.

E. Risks

Participation in this study may cause minimal risk, as some participants may view oral contraceptive use as a private matter, and answering questions about use could cause emotional distress. Additionally, participants who have used oral contraceptives may be identified by their peers, as they will be the only ones completing the survey. To reduce the risk for emotional distress, a disclaimer is included in the cover letter to discontinue the survey if the student feels oral contraceptive use is a private matter. To reduce the risk of participant identification, each student will turn the survey in at the same time, regardless of participation.

1) Privacy

When surveys are administered, the only personal identification on the survey is age. There are no names or other personal information that breaches privacy of the participants or their families. Participants will be informed that there will be no use of personal information or regards throughout the survey process, other than age. Participant surveys will be protected by keeping the electronic data stored in a locked drawer on an external hard drive within a locked room at the Anderson Center of Bethel University for a minimum of five years.

2) Physical stimuli – There is no administration of any stimulus other than sensory stimuli associated with normal classroom situations.

3) Deprivation – N/A

4) Deception – No deception has been utilized in the administration of this survey.

5) Sensitive information – Some participants may view oral contraceptive use as a private matter, and answering questions about use could cause emotional distress. Questions regarding oral contraceptive use address objective knowledge rather than emotional or personal reasons for use. Additionally, participants who have used oral contraceptives may be identified by their peers, as they will be the only ones completing the survey. To reduce the risk for emotional distress, a disclaimer is included in the cover letter to discontinue the survey if the student feels oral contraceptive use is a private matter. Students may discontinue the survey at any time without consequences to their grade or relationship to Dr. Pedersen. To reduce the risk of participant identification, each student will turn the survey in at the same time, regardless of participation.

6) Offensive materials – N/A

7) Physical exertion – N/A

F. Confidentiality – This survey is confidential as no self-identification information will be included. When surveys are administered, the only personal identification on the survey is age. There are no names connected to the research data, or other personal information that breaches confidentiality. The participants will be informed that every survey will remain entirely anonymous, because identifying information will not be recorded or incorporated into the survey.The actual paper surveys will be shredded in a

confidential shredder and the data will be held on a password protected computer while it is being analyzed. The data will then be held on an external hard drive in a locked cabinet within a locked room at Bethel University for a minimum of 5 yrs. The only individuals allowed to access the information would be the researchers and the research chair. There will be no direct participant identification or breaching of confidentiality while performing presentations or on documents due to lack of participant personal identification during the data collection. Data will not be reported in a way that violated participants' confidentiality due to lack of personal information recorded, other than the participants' age.

G. Signatures –

"I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any substantive modification in the proposal and will report promptly any unexpected or otherwise significant adverse effects in the course of this study."

Signatures

Researchers:

1. _____ Date _____

2. _____ Date _____

3. _____ Date _____

Advisor (if student project):

_____ Date _____

Department Head or Dean:

_____ Date _____

Appendix E - Script

"Hello, I am Brook Anderson, a Physician Assistant Student at Bethel University. I am conducting a research project titled "The Effects of Patient Education on Oral Contraceptive Adherence Rates" which is a research study assessing the participants knowledge of OC's using a pass/fail quiz within a survey. This is a quantitative study that will utilize a questionnaire, which will address your basic knowledge of OC's, the education you were provided concerning OC's, and your adherence to OC's. This study will quantify the relationship between OC education provided to you and your knowledge of OCs. This is a voluntary survey and there will be no benefits nor repercussions for taking or refusing the survey. This survey will take about 5 minutes of your time, and choosing to participate will not affect your grade in this class nor your relationship with Dr. Pedersen. No extra credit will be awarded for taking this survey.

This survey is confidential as no self-identification information will be included. The actual paper surveys will be shredded in a confidential shredder and the data will be held on a password protected computer while it is being analyzed. The data will then be held on an external hard drive in a locked cabinet within a locked room at Bethel University for a minimum of 5 yrs.

You are eligible to participate in this survey if you are a female between the ages of 18 and 35. Thank you for your time and participation, are there any questions?"