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Safe Prescribing of Combined Hormonal Contraceptives Using the U.S. Medical Eligibility Criteria for Contraceptive Use Guideline

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Abstract

Safe prescribing of combined hormonal contraceptives is important to prevent unplanned pregnancies and adverse effects including thrombotic events. Combined hormonal contraceptives can be taken safely but this relies on appropriate prescribing techniques by the healthcare provider. Prior to prescribing any type of contraception, health care providers should perform a risk assessment to anticipate and prevent patient complications. The Centers for Disease Control and Prevention created the United States Medical Eligibility Criteria (U.S. MEC) for contraceptive use guideline to help direct healthcare providers to assess patient risk factors, prescribe the safest form of contraception, and provide necessary teaching and follow-up. This project includes a retrospective chart audit of 100 charts from university-based, outpatient, primary care clinics to examine contraceptive counseling and prescribing behaviors and compare these with the recommendations set forth by the guideline. This project will help identify guideline adherence and specifically assess prescriber documentation of risk factors associated with combined contraceptives, the safety of prescribing a combined hormonal contraceptive, and prescriber documentation of combined contraceptive counseling and follow-up.

Introduction

My sister-in-law was 21 when a pulmonary embolism threatened her life. The cause was attributed to combined hormonal contraceptive (CHC) use and she expressed feelings of resentment. She felt cheated that her providers never educated her regarding the serious risks of CHC use. At the time, my sister-in-law was by definition obese with undiagnosed hypertension, however, she would have chosen a different contraceptive method had she known about the risk of a thrombotic event. Like many women, the ease and convenience of the birth control pill drew her to choose the pill, despite other and potentially safer techniques to prevent unintended pregnancy. The purpose of this paper is to examine CHC prescribing to identify barriers of unsafe practices.

Background

Unplanned pregnancies contribute to a significant health disparity in the United States (US). In the US, unplanned pregnancies make up approximately half (51%) of all pregnancies and 40% of unintended pregnancies result in abortions (Finer & Zolna, 2014). Additionally, unintended pregnancies cost taxpayers nine billion U.S. dollars per year (Finer & Henshaw, 2006; Hoffman, 2006). Compared with the rest of the world, North America is the only continent in the world where rates of unplanned pregnancies are consistent or increasing over the past decade (Singh, Sedgh, & Hussain, 2010). Unplanned pregnancies also create health disparities for mothers and children affected.

Unintended pregnancies negatively impact the physical and psychological health of mom and baby. Unplanned pregnancies are associated with preterm birth, low birth weight (Shah et al., 2011), tobacco use during pregnancy, and late prenatal care (David, 2006; Logan, Holcombe, Manlove, & Ryan, 2007). Furthermore, infants of unplanned pregnancies are less likely to be

breastfeed and are more likely to have poorer health outcomes during childhood (Taylor & Cabral, 2002). Female babies born from unplanned pregnancies are more likely to have unplanned pregnancies themselves and male babies are more likely to experience incarceration later in life (Elfenbein & Felice, 2003). Mothers with unintended pregnancies also face challenges and are prone to depression and intimate partner violence, and are less likely to complete high school by age 22 (Logan, Holcombe, Manlove, & Ryan, 2007). Given these serious consequences, global leaders advocated for prevention of unplanned pregnancies.

In 2015, the World Health Organization (WHO) identified access to safe and effective contraception as a worldwide public health goal. To accomplish this goal, the U.S. Department of Health and Human Services focused on contraceptive counseling and family planning using the Healthy People 2020 objectives (Office of Disease Prevention and Health Promotion, 2014). Healthy People objectives identify chief health indicators that address health disparities, including promotion of family planning and reproductive health among females (Office of Disease Prevention and Health Promotion, 2014). For example, one objective in 2002 was to decrease unplanned pregnancies from 49% to 44% and increase contraceptive use at last intercourse from 83% to 92%. (Centers for Disease Control and Prevention, 2011). Preventing unplanned pregnancies by advocating for contraceptive use was not a simple solution. Although contraception use is effective at preventing unplanned pregnancies, the WHO goal of contraceptive safety is a concern.

Problem

Since the release of oral contraception, complications became associated with CHCs including venous thromboembolism (Piparva & Buch, 2011). Combined hormonal contraceptives include both estrogen and progesterone hormones, and pill, patch, and vaginal

ring methods. A venous thromboembolism (VTE) is a clot and can come in the form of a deep vein thrombosis (DVT) or pulmonary embolism (PE) and both are life-threatening as the thrombus can migrate into the arterial system resulting in stroke and heart attack (Hee, Kettner, & Vejtorp, 2013). If death is not the end result, quality of life is significantly and permanently impacted.

Although CHC related VTE events are arguably rare, the increased chance of PE, stroke, or heart attack among young women who use CHC is nonetheless a tragic consequence. Oral contraceptive pill users, especially those with certain risk factors and who use CHCs, are two to six times more likely to develop a VTE when compared to those who do not use the pill (Doma, Vucnik, Mijovski, Peternel, & Stegnar, 2013). In a systematic review and meta-analysis of 26 studies, CHC users were three to four times more likely to be diagnosed with a VTE compared with non-users (De Bastos et al., 2014). In a case-control study of 186 young women with diagnosis of VTE, 23% were CHC related (Westhoff, Yoon, Tang, Pulido, & Eisenberger, 2016). Finally, it is estimated that a new user of CHC increases her annual VTE risk from 4.5 to 14.5 per 10,000 woman-years (Manzoli, De Vito, Marzuillo, Boccia, & Villari, 2012). The increased risk, while small, still deserves prevention techniques.

Due to the importance of VTE prevention, it is recommended that both patients and health care providers communicate about contraceptive risk factors prior to CHC use. The American College of Obstetricians and Gynecologists (2012) recommended that prior to prescribing any type of CHC, health care providers perform a risk assessment to anticipate and prevent patient complications by communicating contraceptive risks (Vogt & Scheafer, 2011). The most notable CHC related VTE risks are age and smoking, and the FDA cautioned prescription of CHCs to women who smoke and are 35 years and older (World Health Organization, 2015). In addition to

age and smoking status, other conditions that predispose CHC users to VTE are the postpartum period (40–65 per 10,000 woman-years; Food and Drug Administration, 2012), recent surgery, migraines, active irritable bowel syndrome, Lupus, antiphospholipid antibodies, and previous VTE (American College of Obstetricians and Gynecologists, 2012; Mitic, 2014). Understanding these risks can help patients and providers choose the safest contraceptive method for the individual.

Before choosing a method of contraception, patients must understand their individual risk factors to identify and be cautious of potential side effects (American College of Obstetricians and Gynecologists, 2012). If women misjudge the safety of CHC use, diagnosis and treatment could be deferred because the patient may not take their symptoms seriously or may not report using a CHC to a health care provider (Vogt & Scheafer, 2011). The literature suggests preventing VTE among CHC users by encouraging women to make educated contraceptive decisions (Philipson et al., 2011). However, this is arguably dependent on the prescriber who has the responsibility to educate patients about the safety of contraceptives. Although patient teaching is necessary for CHC safety, there appear to be barriers to this practice.

It is concerning that prescribers are not adequately educating patients about contraceptive methods. Almost half of women in a study were unable to identify thrombosis and stroke as major risks associated with CHC use (Philipson et al., 2011). Almost half of these women also claimed not to have been educated about the risks of CHC use prior to having CHCs prescribed to them (Philipson et al., 2011). This lack of education by the provider was supported in another study where only 1 of 30 participants reported being more knowledgeable about the risks than the benefits (Vogt & Scheafer, 2011). This study recommended that providers not worry about overwhelming patients with too much information as those who had never used an CHC were

found to have the highest interest and lowest knowledge ratings (Vogt & Scheafer, 2011). Combined hormonal contraceptives can be taken safely but this relies on appropriate prescribing and education by the healthcare provider using an evidence-based guideline.

Guideline

The Centers for Disease Control and Prevention (CDC) created the United States Medical Eligibility Criteria (U.S. MEC) for contraceptive use to help guide healthcare providers to assess patient risk factors and prescribe the safest form of contraception (World Health Organization, 2009). The U.S. MEC for contraceptive use includes over 1,800 recommendations related to more than 60 medical conditions (World Health Organization, 2009). Specifically, this tool helps providers identify patient risk factors including age greater than 35 years, tobacco use, medications, and certain medical conditions including breast or liver cancer, diabetes, history of DVT/PE, migraine headaches, hypertension, and heart disease.

Utilizing the U.S. MEC for contraceptive use tool promotes evidence based prescribing practices and prevents complications associated with contraceptive use (World Health Organization, 2009). After evaluating patient risk history, the provider can use the tool to assign the patient to a category, one through four, that symbolizes their eligibility for CHC use (World Health Organization, 2009). Women with a CHC category 1 condition do not have any contraceptive restrictions and can be prescribed the contraception safely. Those with category 2 conditions also are eligible for CHCs given the benefits outweigh the risks. Combined hormonal contraceptive prescription to women with a category 3 condition, however, is deemed inappropriate and to category 4 individuals is contraindicated. Category 4 conditions, include migraine with aura, history of DVT or stroke, and stage two hypertension. The cardiovascular

risks associated with CHC use make it inappropriate to prescribe CHCs to women with category 3 or 4 conditions, especially given the availability of other contraceptive options.

Among oral contraceptive pill options, CHCs are the most popular but also have the most medical complications including VTE. Other contraceptive methods, including other oral forms, are available and are not associated with an increased risk for VTE (World Health Organization, 2009). Progestin-only pills (POPs) lack the estrogen component making them a safer oral contraceptive method for those with medical contraindications for CHC. In addition to POPs, other safer contraceptive options include injections, implants, and intrauterine devices (copper-containing and levonorgestrel-releasing). These methods of contraception provide women with long-term birth control, in many cases without the need of a daily pill.

No matter the contraception method or category, risks and benefits of each option are important for the patient and provider to discuss. There is a safe contraceptive method for every female who wants to prevent pregnancy. The most crucial aspects of contraceptive safety include counseling and follow-up (World Health Organization, 2009). In fact, the U.S. MEC for contraceptive use guideline mandates follow-up and contraceptive counseling regarding CHC risks and benefits when prescribing to patients with category 2 and 3 conditions (World Health Organization, 2009).

In July 2016, the U.S. MEC for contraceptive use guideline was updated to reflect current evidence based practice. The main updates included addition of women with cystic fibrosis, multiple sclerosis, and taking St. John's wort (World Health Organization, 2015). The CHC related changes included women with a history of dyslipidemia, migraine headaches, and human immunodeficiency virus. When prescribing a CHC, for example, hyperlipidemia was removed as a risk, emphasis was made on accurate assessment and documentation of a headache versus

migraine with aura, and identification of drug interactions with protease inhibitors and antiretrovirals were identified (World Health Organization, 2015). Drug interactions are important considerations as these may include increased risk for adverse effects, decreased effectiveness of the CHC, and decreased effectiveness of the other, non-contraceptive, medication. Notably, the 2016 edition stressed that patients with multiple category 2 and/or 3 conditions are at increased risk and it is unacceptable for CHC use given the likelihood of cardiovascular disease (World Health Organization, 2015). With that said, the 2016 edition also stated that the presence of two category 2 conditions does not necessitate a higher risk.

The U.S. MEC guideline is available in many user-friendly tools that are free to the public on the CDC website (World Health Organization, 2009). The recommendations are summarized in a chart format that is color and number coded to allow for quick reference. Guideline recommendations can also be displayed in a wheel format and similar to the pregnancy gestation wheel, the inner and outer circles can be rotated to narrow down recommendations for the individual (World Health Organization, 2009). The outer circle of the wheel includes medical conditions and patient characteristics, while the inner ring consists of contraceptive methods. When the wheel is rotated a display window uses the same risk categories, one through four, to determine the safest contraceptive option(s) for the patient. Additionally, the guideline can be utilized via a cellular phone application that is free to download through the CDC website. Easy accessibility is importance for guideline stakeholders.

Safe contraception use is a priority for local, state, and worldwide organizations that see the economic benefit in addition to the patient benefit. Other stakeholders include patients and health care providers. Patients are important stakeholders because they value their health and want to choose the safest and most effective contraceptive option. This guideline helps patients

avoid contraceptive methods that are riskier, and directs them to the method that is safest for them. Patients have an important role within this guideline because it is the responsibility of the patient to disclose their personal, social, and health history, and patient communication is key to guideline use and success.

Along with patients, health care providers are also key guideline stakeholders because of values of maleficence and beneficence. Doctors (MDs), nurse practitioners (NPs), and physician assistants (PAs) want to provide patients with contraception that meets their needs, but they also do not want their patients to experience potentially lethal complications. Health care providers are invested in this guideline because there are several methods and types of contraceptives and a helpful evidence based tool is needed. Health care professionals also appreciate the free and convenient format for accessibility to the guideline. A guideline that is easy to use is more likely to gain compliance.

The U.S. MEC for contraceptive use guideline had a strong rigor of development that is evident from its purpose and historical timeline. The CDC and WHO have worked together to create the U.S. MEC for contraceptive use and its purpose is to be used by policy makers to promote family planning at the national and global level (World Health Organization, 2009). Since the first edition of the contraceptive guideline that was released in 1996, there have been five revisions to reflect the most recent literature. This guideline can stand-alone but is strengthened by a similar guideline also developed by the CDC.

A sister guideline titled the U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) was created in 2013 and recommends how to overcome barriers for obtaining and appropriately using contraceptive options (World Health Organization, 2009). Specific recommendations from the U.S. SPR include when to initiate contraception (rule out pregnancy),

use backup contraception, which tests are needed prior to taking contraception, and what follow-up is needed to maintain contraceptive safety. In addition to the CDC and WHO, the U.S. SPR guideline is also supported by the American Congress of Obstetricians and Gynecologists organization.

Project

Aims

It is important for prescribers to assess patients for risk factors of developing complications from CHCs and counsel regarding the safest method of contraception. The aim of this project was to examine contraceptive counseling and prescribing behaviors and compare these behaviors with the recommendations set forth by the U.S. MEC for contraceptive use guideline. The aims of this project helped to identify guideline adherence with guideline recommendations. The specific aims this project accomplished include:

1. To assess rates of prescriber documentation of risk factors (age, smoking, medications, and medical history and conditions) associated with combined contraceptives.
2. To assess frequency of prescriber documentation of using a combined contraceptive that is considered safe by the U.S. MEC for contraceptive use guideline.
3. To assess rates of prescriber documentation of combined contraceptive counseling and follow-up.

Study Design

This was a descriptive study that examined provider adherence to the U.S. MEC for contraceptive use guideline when prescribing CHCs within a set of mid-west, university-based, primary health care clinics. It included a retrospective, cross-sectional chart review of 100 charts

that met inclusion and exclusion criteria. After approval was gained from the university's Institutional Review Board, the primary investigator worked with the university's Center for Clinical and Translational Sciences program to create a list of patient charts that met this study's criteria. Review of charts helped meet the aims of this study by identifying the safety of CHC prescription practices.

Patient age, provider type (MD, PA, or NP), and length of tenure were recorded. Length of tenure was determined by comparing the date the chart was written with the provider's graduation date found on the university website. Additional recorded variables were prescriber documentation of risk factors (age, smoking, medications, and medical history and conditions) associated with combined contraceptives, documentation of prescribing a combined contraceptive that is considered safe by the U.S. MEC for contraceptive use guideline, and lastly, documentation of contraceptive counseling and follow-up.

Study Population

Inclusion criteria included the following charts: service dates from August 1, 2014 to August 1, 2016, reviewed by the principal investigator from December 10, 2016 to April 1, 2017, prescribed by an MD, PA, or NP. Selected charts were also from non-pregnant females between the ages of 18 and 50 years of age. Charts included those that prescribed a CHC, were coded for encounter for contraceptive management (ICD-10 code Z30 or ICD-9 code V25), and had at least one (category 2, 3, or 4) risk for CHC use per the U.S. MEC for contraceptive use guideline. Additional inclusion criteria were identified with ICD-9 and ICD-10 codes that reflected a diagnosis of a category 2, 3, or 4 risk factor (see Table 1).

Methods

As part of routine patient care, clinic personnel had previously recorded the pertinent patient data that was used for this chart review. The primary outcome measure was guideline adherence. Primary outcome measures included the following:

1. Documented pertinent patient information including age, tobacco use, current and past medical history, current medications, and last pregnancy or hospitalization.
2. Did not prescribe a CHC if the patient had a category 4 condition as defined by the U.S. MEC for contraceptive use guideline.
3. Documented follow-up if the patient had a category 2 or 3 condition, as defined by the U.S. MEC for contraception use guideline.
4. Documented contraceptive counseling for patients with category 2 or 3 conditions, as defined by the U.S. MEC for contraceptive use guideline (patient teaching of CHC risks and/or adverse effects).

The secondary outcome measures were provider and patient specific variables. Provider variables included type of provider and practice tenure. Patient variables included age and condition.

This project's focus on guideline adherence was measured by inappropriate and contraindicated prescribing, and the use of follow-up and contraceptive counseling. Inappropriate prescribing was characterized if a category 3 condition was present where the risks generally outweigh the benefits, and contraindicated prescribing was determined if a category 4 condition was present. The contraceptive guideline does not support prescription of a CHC to women with a category 4 condition, and mandates follow-up and contraceptive counseling when prescribing a CHC to women with a category 2 or 3 condition (World Health Organization, 2009). Therefore,

complete guideline adherence was observed for charts that did not contain a category 4 condition and documented both follow-up and contraceptive counseling. Partial guideline adherence was measured if the chart lacked a category 4 condition and documented either contraceptive counseling or follow-up, and finally, no guideline adherence was defined as lack of both follow-up and contraceptive counseling.

Data Analysis

Descriptive statistics were used to summarize the study sample (see Table 2). To test for differences in degree of completeness by patient age and provider type, Spearman's rho correlation coefficient was used. The Mann-Whitney U test was used to compare differences in completeness by provider type (see Table 3). All data analysis was conducted using SPSS, version 24, and an alpha level of .05 was used throughout. Data was analyzed using the SPSS computer program to determine the proportion of charts that successfully documented all three aims. Chi-square analysis was used to assess differences among groups of providers and patients who participated in inappropriate use of CHC. This information, along with the results, was used to identify barriers to safe prescribing of CHCs.

Results

One hundred charts from mid-west, university based, primary care clinics that met inclusion and exclusion criteria were reviewed. Of the 100 charts, 66 were written by MDs (66%) and 34 were authored by Advanced Practice Providers (APPs; 34%). Among the 34 charts written by APPs, 26 were by NPs, and eight were by PAs. The patients' ages ranged from 18 to 49 years with a mean age of 26.67 years (SD=7.073). Provider tenure was categorized into intervals, zero to three years, four to five years, six to ten years, and over ten years, and tenure frequency was 20%, 28%, 24%, and 28% respectively (see Table 1).

Category 4

Four charts contained category 4 conditions (four percent) where CHCs were prescribed despite the presence of a contraindication. Among these four charts, all were written by MDs with a tenure that varied from one to ten years. Among charts with category 4 risks, patients' ages ranged from 20 to 30 years and category 4 conditions included Lamictal use, migraine with aura, and history of stroke. Migraine with aura was the most frequent category 4 condition that was prescribed a CHC, accounting for half of category 4 charts. Although three fourths of category 4 charts did recommended follow-up, all four charts did not document contraceptive counseling. Lastly, a quarter of charts with contraindicated CHC prescription did not document counseling or recommend follow-up.

Category 3

Fifteen charts contained category 3 conditions (15%), and listed by highest frequency included hypertension (53%), migraine with no aura (20%), smoking and 35 years or older (13%), and finally diabetes with neuropathy and malabsorptive surgery (7% each). Among the 15 charts with category 3 conditions, or inappropriate prescribing conditions, 80% were written by MDs while 20% were prescribed by APPs. In a comparison of guideline adherence completeness by the most common category 3 conditions, the Mann-Whitney U test was utilized, and found that both hypertension and migraine without aura had insignificant p-values ($p=.78$ and .33 respectively).

Category 2

Category 2 conditions were the most prevalent risk category accounting for 81% of all 100 charts. The most frequent category 2 conditions were obesity (42%), smoking less than 35 years of age (31%), and headaches (five percent). In a comparison of completeness by the most

common category 2 conditions using the Mann-Whitney U test, p-values for smoking (less than 35 years of age) and obesity were not significant (p=.20 and .37 respectively).

Completeness

The charts that contained category 4 conditions were eliminated from guideline adherence analysis due to the presence of a complete contraindication for CHC use. Among the remaining 96 charts that contained category 2 and 3 conditions, 28% recommended both follow-up and contraceptive counseling fulfilling complete guideline adherence. Forty nine percent of charts met one of the requirements, and had partial adherence, and finally 23% of charts lacked both follow-up and contraceptive counseling and had zero guideline compliance. A comparison of follow-up and contraceptive counseling, revealed that among charts with category 2 and 3 conditions, 69% recommended follow-up and 36% documented contraceptive counseling.

Completeness by Provider Type

Complete guideline adherence was observed for charts that did not contain a category 4 condition and documented both follow-up and contraceptive counseling. Among the 27 charts that exhibited complete guideline adherence, over half were written by MDs (56%) compared with 44% that were authored by APPs. No guideline adherence was defined as lack of both follow-up and contraceptive counseling. Among the 22 charts with no guideline compliance, over half were written by APPs (55%) compared to 45% of MDs. Of the charts that documented follow-up, 71% were written by MDs and only 29% were by APPs. This comparison between MD provider type and follow-up was significant with a chi-square of 4.1 (p=.044). Of the charts that documented contraceptive counseling, 57% were written by MDs, and 43% were by APPs and this was not significant (chi-square 0.25).

Completeness by Patient Age and Provider Tenure

The Mann-Whitney U test was used to compare differences in guideline compliance completeness by provider type (see Table 2) and was not significant with a chi-square of 0.2. Spearman's rho test was used to compare tenure and completeness, and was not significant at 0.39. There was also no difference in degree of completeness by patient age (rho=-0.11; p=.30), provider type (Chi-square=0.21; p=.65) or provider tenure (rho=-0.09; p=.39; see Table 2).

Completeness by Patient Condition

An association among the top five most frequent category 2 and 3 conditions (obesity, smoking, migraine with no aura, hypertension, and headaches) and completeness was not significant. However, obese patients were most likely to not receive any guideline adherence (29%), and patients with migraine and no aura were more likely to receive complete guideline adherence (36%). Thirty-one percent of charts with smoking had complete adherence and 25% of charts with hypertension had complete compliance. Of note, nine single conditions were not coded (Lamictal, history of stroke, valvular heart disease, malabsorptive bariatric surgery, Rheumatoid Arthritis, post-partum, Ulcerative Colitis, diabetes with neuropathy, family history of clot) and therefore not included in analysis of completeness by condition.

Limitations

The major limitations of this study were sample and information bias. The small sample size of 100 charts made it difficult to account for differences in variables like provider type and tenure. Additionally, the patients and providers included in this study were restricted to a university-based healthcare system located in the mid-west creating a more homogenous sample with weaker associations. The retrospective nature of this study also did not allow for a

comparison group to estimate the importance of risk factors (especially over time). Also true to a retrospective study, this chart review did not have the ability to control for accurate assessment and documentation within the electronic medical record (EMR).

Additional imitations of this study revolve around the use of the EMR. Only one type of EMR was utilized by this study, preventing comparison with other types of EMR. This particular EMR did not have automatic prompts regarding contraceptive counseling and follow-up that other EMR versions might enlist. Additionally, this EMR did not assess the quantity of cigarette use per day. The quantity of cigarettes is an important indicator of CHC related thrombotic risk under the U.S. MEC for contraceptive use guideline (World Health Organization, 2009). The EMR failed to prompt providers to quantify daily tobacco use when adding "Current everyday smoker" to a list of active problems. With that said, providers also frequently failed to document quantity of cigarette use per day in narration.

This study was also limited by not accounting for initiation versus continual use of CHC. This is significant to the guideline due to the increased risk of adverse effects within the first three months of use. It is estimated that venous thrombotic risks increase three-fold following initiation of a CHC due to adjustments in hormone levels that impact coagulation (Han & Jensen, 2015).

Discussion

This retrospective chart audit sought to describe adherence and CHC prescribing safety using a reputable national guideline. This study found that 19% percent of women were prescribed a CHC inappropriately, including four percent of patients with a category 4 contraindication to CHC use. This study found the most common risks included obesity, smoking, migraine (with and without aura), and hypertension. Compared to a much larger but

similar study, of 2,963 women, 33% were inappropriately prescribed a CHC, nine percent possessed category 4 risks, and the most common risk conditions included migraine (with and without aura), cardiovascular disease, and hypertension (Yu & Hu, 2013). Although the results of this study reflected better guideline adherence than the comparison study, the findings from both demonstrate the need for stricter compliance to prevent complications associated with contraceptive use. Identifying barriers to safe prescribing can help promote guideline compliance.

While most of the comparisons in this study were not significant, across all variables a major barrier to safe prescribing of CHC is lack of knowledge. MDs, PAs, and NPs were almost equally poor at completing contraceptive counseling, and achieving guideline adherence. Although less than a quarter of charts had no guideline adherence, only a little over a quarter had full compliance. Most important to discuss regarding guideline adherence and knowledge gaps were the four charts (4%) that prescribed a CHC in the presence of a category 4 condition.

Although charts with category 4 conditions accounted for only four percent of charts, prescribing a CHC in these instances is deemed "unacceptable" by the guideline and these charts deserve a closer evaluation (World Health Organization, 2009). In addition, the prevalence of prescribing a CHC to a patient who is obese, smokes, or has a history of migraines (with or without aura) or hypertension also requires discussion. These four CHC risk conditions are discussed more in-depth to help bridge these knowledge gaps.

Obesity

The first condition associated with a lack of provider comprehension when prescribing a CHC was obesity. Obesity is defined as a Body Mass Index of 30, kilograms per meter squared, or more and is classified as a category 2 condition under the U.S. MEC for contraceptive use

guideline (World Health Organization, 2009). In this study, obesity was a common condition with infrequent follow-up and contraceptive counseling. Obesity was the most frequent condition accounting for 44% of all conditions and 29% of obese patients did not receive follow-up or contraceptive counseling. Although only a category 2 condition, VTE risk has been shown to increase with degree of obesity (Horton, Simmons, & Curtis, 2016). In fact, five prospective cohort studies found a dose-response relationship between obesity and VTE risk (Horton, Simmons, & Curtis, 2016). Furthermore, obese CHC users were five to eight times more likely to experience VTE than obese non-users, and obese CHC users were also ten times more likely to experience VTE than normal weight users (Horton, Simmons, & Curtis, 2016).

Smoking

The second condition associated with a lack of provider comprehension when prescribing a CHC was smoking. Smoking restrictions among CHC users date back to 1989 when the FDA modified their CHC restrictions and allowed women of all ages to use CHC as long as they did not smoke (Food and Drug Administration, 2012). Under the U.S. MEC for contraceptive use guideline, smoking is a risk condition for CHC use that ranges from two to four due to its influence on cardiovascular disease (CVD; World Health Organization, 2009). Smoking is a category 2 condition for CHC use if the patient is less than 35 years of age. For women who are 35 years or older, smoking is a category 3 condition if use is less than 15 cigarettes per day, and finally, smoking is a category 4 condition if the female smokes 15 or more cigarettes per day.

In this study, smoking was a common condition with infrequent follow-up and contraceptive counseling. Women who smoked and were less than 35 years of age accounted for 31% of category 2 conditions, and females who smoked and were 35 years or older made up 13% of all category 3 conditions. Of importance, only 31% of charts with smoking (age less than

35 years) had complete adherence with documentation of both follow-up and contraceptive counseling. These shortcomings are significant because compared to non-smokers, CHC users who smoke are at risk for a heart attack and this risk increases with the number of cigarettes smoked per day (Nightingale et al., 2000). It is argued that health care providers can help prevent VTEs among patients who use OCPs by focusing on tobacco cessation (Grimes et al., 2012).

Headaches/Migraines

The third condition where providers lacked an understanding of CHC safety was headaches/migraines. Under the U.S. MEC for contraceptive use guideline, non-migrainous headaches are classified as a category 2 condition for CHC use, migraines without aura are a category 3 condition if the woman is 35 years or older, and finally migraine with aura (no matter the age) is a category 4 condition for CHC use (World Health Organization, 2009). Headaches were five percent of category 2 conditions, migraine with no aura accounted for 20% of category 3 charts, and migraine with aura made up half of charts with a category 4 contraindications to CHC use.

Migraines with aura are often overlooked as important contributors to cardiovascular disease (CVD) and VTE. Migraines with aura are associated with an increased risk for stroke due to changes in cortical depression, and likelihood of underlying genetic and co-morbid conditions (Kurth et al., 2006; Pezzini et al., 2009). In a study by the WHO that examined stroke among women of childbearing age, the risk for stroke was significantly related to the frequency of migraines with aura, and the risk of stroke was increased among CHC users, compared with women not using CHCs (Etminan, Takkouche, Isorna, & Samii, 2005). Cardiovascular disease is the major contributor of stroke and heart attack, and compared to women without migraines, women who experienced migraine with aura once a month were two times more likely to

develop CVD, and those with migraine with aura two or more times per week were four times more likely to develop CVD (Donaghy, Chang, & Poulter, 2002).

Hypertension

The final CHC condition where providers displayed a knowledge deficit was hypertension. Hypertension during pregnancy is deemed a category 2 condition for CHC use, and hypertension is a category 3 condition if it is adequately controlled by medication or is less than 160 systolic over 100 diastolic (160/100; World Health Organization, 2009). Hypertension is a category 4 condition if blood pressure measurement is 160/100 or more and a CHC is contraindicated (World Health Organization, 2009). Fifty-three percent of category 3 conditions were hypertension and only 25% of charts with hypertension had complete compliance. Hypertension is an important risk condition for providers to consider because the U.S. MEC for contraceptive use guideline found that women with hypertension who used CHCs were more prone to stroke, heart attack, and peripheral arterial disease compared with nonusers (Gillum, Mamidipudi, & Johnston, 2000; Khader, Rice, John, & Abueita, 2003). Furthermore, women with hypertension who stopped CHC use experienced better blood pressure control (Lubianca, Moreira, Gud, & Fuchs, 2005).

Follow-up and Counseling

The U.S. MEC for contraceptive use guideline mandates follow-up and contraceptive counseling regarding CHC risks and benefits when prescribing to patients with category 2 and 3 conditions (World Health Organization, 2009). Thus, when prescribing a CHC to a patient with category 2 and 3 risks, the provider must consider availability, acceptability, and access to clinical services. Using clinical judgment, the provider must assess these patient variables and

proceed with caution when prescribing a CHC to a woman with a history of appointment cancelations, no-shows, or with limited access to resources.

A guiding principle of the U.S. MEC for contraceptive use guideline is the patient's right to choose and make an informed decision and this encompasses contraceptive counseling (World Health Organization, 2009). The health care provider is the most important facilitator of this goal by emphasizing the serious risk of a thrombotic event while using a CHC. When providers teach patients about thrombotic risk factors, patients have the opportunity to modify their actions and prevent acquisition of new risks. Additionally, a patient who is taught about adverse effects of using a CHC, will not underestimate the severity and promptness if symptoms of a thrombotic event presents.

Counseling techniques are patient specific and can be divided into initiation and continuation. Important topics to consider with new users include mechanism of action, advantages and disadvantages of different contraceptive methods (including non-contraceptive benefits), warning signs of adverse effects, misconceptions, and need for follow-up (Wysocki, 1998). Important discussion points with follow-up and continual prescription of CHC includes identification of new symptoms or health problems, and reiteration of the increased risk of a thrombotic event while using a CHC and the risk factors that amplify this risk.

Conclusion

The U.S. Medical Eligibility Criteria for contraceptive use guideline helps healthcare providers to assess patient risk factors and prescribe the safest form of contraception. Utilizing this tool can help promote evidence based prescribing practices and assist in preventing complications associated with contraceptive use. Additionally, safe prescribing practices can also promote family planning and prevent unplanned pregnancies at the local level. Although this

study only found one strong comparison, it is concluded that all types of healthcare providers can better promote contraceptive safety by using the contraceptive guideline and utilizing thorough contraceptive counseling and timely follow-up. The patient has a right to make an informed decision and prevent health risks and a provider who utilizes the contraceptive guideline can facilitate patient and contraceptive safety.

Table 1: Inclusion and Exclusion Criteria

Inclusion	Exclusion
-Encounter for contraceptive management (ICD-10 code Z30 or ICD-9 code V25) -Family history of DVT or PE, current or personal history of DVT or PE (ICD-10 code Z86.718, I82, ICD-9 code V12.51) -Recent surgery requiring immobilization -Breast cancer (ICD-10 code C50, ICD-9 code 174) -Currently breastfeeding (ICD-10 code Z39.1 and ICD-9 code V24.1) -Gallbladder disease (ICD-10 code K82.8, K82.9, ICD-9 code 575.9), -Headaches or migraines (ICD-10 code R51, G43, ICD-9 code 339, 784, 346.9) -Sickle cell disease (ICD-10 code D57, ICD-9 code 282) -Ischemic heart disease (IDC-10 codes I25.9 and I24.9, ICD-9 code 414.9) -Benign or malignant liver tumor (ICD-10 code D13.4, ICD-9 code 211.5) -Diabetes (ICD-10 code E10 and E11, ICD-9 code 250.80 and 250.81), -Tobacco use (ICD-10 code Z72.0, ICD-9 code 305.1), -Hypertension (ICD-10 codes I10, I15, and O13, ICD-9 codes 401.0, 401.9, 405.91, 405.99, 642.3), -Hyperlipidemia (ICD-10 code E78.5, ICD-9 code 272) -Obesity (ICD-10 code E66, ICD-9 code 278) -Untreated cervical cancer (ICD-10 code Z85.41 and C53, ICD-9 code V10.41), -Ulcerative colitis and Chron's disease (ICD-10 code K51, ICD-9 code 556) -Rheumatoid arthritis (ICD-10 code M05, ICD-9 code 714) -Organ transplant (ICD-10 code Z94, ICD-9 code V42) -Stroke or TIA (ICD-10 code Z86.73, ICD-9 code V12.54) -Lupus/SLE (ICD-10 code M32.1, ICD-9 code 710), -Thrombogenic mutation (ICD-10 code D68, ICD-9 code 289.81), -Valvular heart disease (ICD-10 code I06, I07, ICD-9 code 397.1), -Viral hepatitis (ICD-10 code B15-B19, ICD-9 code 070.1).	-Less than 18 years of age or more than 50 years of age -Diagnosis of pregnancy -Not prescribed a CHC -Not written by an MD, PA, or NP -Written or reviewed outside the time parameters -No medical conditions including no category 2, 3, or 4 conditions for CHC use

Table 2: Study Population Demographics

	Mean (SD) or *n* (%)
Patient age	26.67 (7.073)

Provider type
- MD
- APP
  o NP
  o PA
	
	66 (66%)
	34 (34%)
	26 (26%)
	8 (8%)

Conditions (category) - Obesity (2) - Smoking (2-4*) - Migraine, no aura (2-3*) - Hypertension (3-4*) - Headaches (0-2*) - Hyperlipidemia (0-3*) - Cholecystectomy (2) - DM, no complications (2) - Migraine, with aura (4)	 42 (43.75%) 31 (32.39%) 22 (22.92%) 8 (8.33%) 5 (5.21%) 3 (3.13%) 3 (3.13%) 2 (2.08%) 2 (2.08%)
* Smoking: Age <35 = Category 2; age 35+ and <15 cigs/day = Category 3; age 35+ and 15+ cigs/day = Category 4. Migraine, no aura: Age <35 = Category 2; age 35+ = Category 3. Hypertension: <160/100 or medically controlled = Category 3; 160/100+ = Category 4. Headaches 2012 = Category 2. Hyperlipidemia 2012: Category 3. Nine single conditions not coded (Lamictal, CVA history, valvular heart disease, malabsorptive surgery, RA, post-partum, UC, DM with neuropathy, family	

history of clot; all conditions n=1).	
Provider tenure (years) -0-3 -4-5 -6-10 ->10	 18 (20.22) 25 (28.09) 21 (23.60) 25 (28.09)
Completeness Complete Partial None	 27 (28.13%) 47 (48.96%) 22 (22.92%)

Table 3: Comparison of Patient Age, Provider Type, and Provider Tenure by Completeness

	Complete Both F/U and CC (n=27)	Partial Either F/U or CC (n=47)	None Neither F/U nor CC (n=22)	*p*
Patient age	25.9 (6.6)	26.3 (6.7)	28.7 (8.5)	.30
Provider type				.65
NP/PA	12 (44.4%)	10 (21.3%)	12 (54.5%)	
MD	15 (55.6%)	37 (78.7)	10 (45.5)	
Provider tenure (years)				.39
0-3	7 (26.92)	9 (20.00)	2 (11.11)	
4-5	4 (15.38)	16 (35.56)	5 (27.78)	
6-10	9 (34.62)	6 (13.33)	6 (33.33)	
>10	6 (23.08)	14 (31.11)	5 (27.78)	

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