

Pharmacist's Letter Online Continuing Education and Webinars

Hormonal Contraceptive Counseling

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Accreditation, Goals and Objectives

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Course Accreditation Information, Goals and Objectives

Nicole is a 25-year-old patient who is picking up a prescription for the transdermal contraceptive patch. This is the first time she is filling this prescription at your pharmacy, so you meet her at the consultation window to speak with her. You first confirm with Nicole that this is the first time she is using this medication. You ask her what her prescriber explained about the medication. Nicole explains that the only thing she really knows is that all she has to do is put on the patch and not worry about it for a few days. She says she wanted to ask her prescriber when she can start using it but didn't get a chance to. She tells you that she is currently menstruating and wasn't sure if she had to wait until her period was over to start using the patch.

What counseling points would you include in your discussion with Nicole? How would you advise her on when she can start using the transdermal contraceptive patch?

Introduction

It's estimated that over 60% of women use some form of contraception. The most commonly used method in the U.S. is female sterilization, followed by the oral contraceptive pill and long-acting reversible contraceptives which includes intrauterine devices (IUDs) and contraceptive implants. Pharmacists play an important role in helping patients navigate and understand contraceptive methods. Pharmacists can help patients understand how effective different methods of contraception are with perfect use and typical use. Most options are close to 99% effective when used perfectly, which means using the method consistently and correctly according to instructions. Unfortunately, with patient typical use, efficacy decreases as the average person doesn't always use methods correctly or consistently.²

Estimated Efficacy Rates for Contraceptive Methods ^{2,3,4,5}		
	Perfect Use	Typical Use
Implant	>99%	>99%
IUD	>99%	>99%
Depot Medroxyprogesterone (DMPA)	>99%	94%
Oral Contraceptives	99%	91%
Patch	99%	91%
Ring	99%	91%
Male Condom	98%	82%
Withdrawal	96%	78%
Female Condom	95%	79%
Diaphragm	94%	88%
Sponge (has never given birth)	91%	88%
Spermicide	82%	72%
Sponge (has given birth)	80%	76%

Oral contraceptives have been associated with efficacy of greater than 99% when used consistently and correctly; however, discontinuation or interruptions in taking oral contraceptives can lead to unintended pregnancies.⁶ While side effects can contribute to discontinuation of a hormonal contraceptive, more common reasons for discontinuation include logistical barriers such as running out of pills, forgetting to take the pill, being unable to get back to the clinic for refill authorization, etc.⁷

States are expanding the pharmacist's scope of practice to address many of these logistical issues. For example, in some states, properly trained pharmacists can prescribe certain types of hormonal contraceptives (oral pills, patch, vaginal ring, or injection) for patients who meet eligibility requirements. Patients who meet pregnancies, which is close to half of all pregnancies in the U.S. 11,12 However, it isn't enough to just prescribe therapy to a patient. Patients need to understand how to use their prescribed hormonal contraceptive consistently and correctly so that they can benefit from the perfect-use efficacy rates. To help patients do this, focus on providing counseling in the following areas:

• When to start their medication, especially if it's being initiated for the first time

- The importance of adherence
- What to do in the event of a late or missed dose
- Side effects to expect
- · Drug-drug interactions that could decrease efficacy

Although this course will specifically focus on counseling points for self-administered hormonal contraceptives (pill, patch, ring) and the depot injection, keep in mind that not all patients will be good candidates for these hormonal contraceptives due to adherence or other lifestyle-related factors. Be prepared to counsel patients and answer questions about other effective forms of contraception, such as the implant and IUD by using our CE, *Helping Patients Navigate Contraceptive Options*

What counseling points do you focus on when talking to patients about their hormonal contraceptive prescription? What do you think are the most important pieces of information that the patient should understand? What additional tools, resources, or information do you need to help you educate patients?

Initiating Therapy

Hormonal contraceptives can be categorized into combination hormonal contraceptives (CHCs) and progestin-only hormonal contraceptives. CHCs include a combination of estrogen and progestin and are available as self-administered oral pills, the transdermal patch, and the vaginal ring. Progestin-only contraceptives are available as self-administered oral pills and an injection. Progestin-only contraceptives that require insertion by a healthcare professional include the implant and IUD. The implant releases etonogestrel over three years and IUDs release levonorgestrel over three or five years, depending upon the product.

Become familiar with the different types of estrogen and progestin combinations. For a detailed chart that includes the various estrogens and progestins and their accompanying doses, along with brand names and manufacturers, refer to our chart, *Comparison of Oral Contraceptives and Non-Oral Alternatives*.

Before initiating therapy with hormonal contraception, pharmacists and other prescribing healthcare professionals need to be reasonably certain that the patient isn't pregnant, that the patient doesn't have any contraindications for use, that they aren't on any interacting medications, and that their blood pressure is less than 140 mmHg/90 mmHg.¹³ If the provider is reasonably certain that the patient is not pregnant and if there are no contraindications, hormonal contraception can usually be initiated. A Sunday start date may be recommended with some CHCs so that a patient can have "period-free" weekends, and for ease of remembrance. It is generally recommended to start the Sunday after the last menses if possible. Having said this, the Centers for Disease Control and Prevention (CDC) states that a patient may start their medication at any time. Additional backup contraception (condom, spermicide, etc) may need to be reasonably certain that their periodication at any time. Additional backup contraception (condom, spermicide, etc) may need to be reasonably certain that their periodication at a patient of the last menses. Whether you are the one prescribing the hormonal contraceptive or if you are just dispensing the prescription, find out when the patient last had their period if this is a new Rx. Counsel the patient on whether or not they need additional backup contraception based on the chart below. Backup contraception is necessary for a specific period of time to ensure prevention of pregnancy until the hormonal contraceptive can reach effective serum concentration. Alternatively, patients can choose to abstain from sex during the period when additional contraception would be needed.¹³

When to Use Additional Contraception Upon Initiating Select Hormonal Contraceptives 13*		
Contraceptive Method	Number of Days Since the Start of Menses	Additional Contraception Needed (for how many days)?
CHC (including pill, patch, and ring)	≤ 5 days	No
	> 5 days	Yes (for at least 7 days)
Progestin-only pill	≤ 5 days	No
	> 5 days	Yes (for at least 2 days)
Depot injection	≤ 7 days	No
	> 7 days	Yes for at least 7 days)

*This is the guidance provided by the Centers for Disease Control and Prevention's U.S. Selected Practice Recommendations for Contraceptive Use. Refer to the prescribing information for individual products for more specific guidance.

In addition to counseling patients about the use of backup contraception, it's also important to counsel patients about appropriate use of their hormonal contraceptive. Each method of contraception has its own unique counseling points.

Before initiating therapy with a CHC, prescribing practitioners should check the patient's blood pressure. Since estrogen can increase blood pressure, CHCs should be used cautiously in patients with hypertension. The prescriber must also make sure that the patient doesn't have any contraindicating conditions or isn't taking any interacting medications. More details on initiating a hormonal contraceptive in patients with other medical conditions can be found in our CE, *Hormonal Contraceptive Selection*.

Also, before initiating any kind of hormonal contraception, healthcare providers should be reasonably certain that the patient isn't pregnant. To be reasonably certain, the patient should have no signs or symptoms of pregnancy and meet at least one of several criteria, such as having recently started menses, recently given birth, not had sex since the last period, etc. ¹³ Review our CE, *Women's Reproductive Health*, to learn more details about the criteria that should be used to be reasonably certain that a patient isn't pregnant.

You explain Nicole's options for starting the transdermal contraceptive patch, and she decides to go with a Sunday start. You let her know that this is okay, but that the manufacturer recommends that she either abstain from sex or use backup contraception, such as condoms, for at least seven days. She confirms that she will make sure to follow these instructions. Nicole is wondering how exactly she should apply the patch once she is ready to. How would you explain this to Nicole?

Combined Oral Contraceptive Pills

Combined oral contraceptive pills (COCs) come in a variety of different formulations, such as monophasic and multiphasic, as well as extendedand continuous-cycle formulations. Monophasic COCs are the most common and contain the same amounts of estrogen and progestin for 21 days, typically followed by a seven-day hormone-free interval (unless it's an extended-cycle regimen). The multiphasic formulations have different amounts of estrogen and progestin provided over 21 days, and are also typically followed by a seven-day hormone-free interval. Monophasic and multiphasic products may be provided in a blister pack containing all the pills that should be taken that month. Each row of pills in the pack represents a week and above each pill will be a preprinted day, typically starting with Sunday. Tablet dispensers are also available with some products (e.g., *Ortho-Cyclen, Ortho Tri-Cyclen*, etc) which provide the pills to be taken in a circular dial instead of in linear rows. These tablet dispensers allow the patient to move the dial to the specific day of the week.

Package inserts for COCs will often provide information on starting the new pack on the first day of the menstrual period or on the first Sunday after the start of the menstrual period. Keep in mind, CDC recommends all hormonal contraceptive pills can be started at any time as long as backup contraception is used when indicated in the chart above. Since not all patients will actually be starting their pack on a Sunday, packages contain stickers with the days of the week that the patient can use to put over the pre-printed days of the week. Let your patients know about this feature since it may be overlooked and can help with adherence by allowing patients to visually see if they missed a dose.

The first three weeks of many COC pill packs contain active pills. Some pill packs will only have three weeks' worth of pills if they are 21-day packs. Unless the patient is prescribed a continuous regimen (i.e., skipping the hormone-free interval and taking active pills continuously), instruct patients to start their next pack seven days after the last pill in a 21-day pill pack. The 28-day pill packs will typically have an additional week of seven "inactive" pills, which may also be referred to as "placebo" pills. These pills may contain either no medication, iron, or low estrogen without progestin to help prevent menstrual migraines. Taking these pills throughout the hormone-free interval may help with adherence, so encourage patients to take them, unless they have been prescribed a continuous-cycle regimen. These patients will experience a menstrual cycle which will begin on the second or third day of the hormone-free week. If a patient is to be using a 28-day pill pack as a continuous-cycle regimen, instruct them to skip the last week of pills and immediately start a new pill pack on day 22. Patients taking COCs continuously will not experience a menstrual cycle, as continuous exposure to hormones will not cause withdrawal bleeding. However, breakthrough bleeding can occur, usually when first starting a continuous regimen.

Extended-cycle regimens provide more days of hormones, with some products providing up to 84 days of hormone-containing pills followed by a seven-day hormone-free interval. Pill packs provided in these packages will look very similar to the monophasic and multiphasic pill packs. The difference is that all pills will be active until the very last week of the very last pill pack (week 13). Week 13 will typically contain the inactive pills. Continuous-cycle regimens involve taking hormone-containing pills daily throughout the year (365 days of active pills), with no hormone-free interval. As previously mentioned, monophasic pills could be used for a continuous-cycle regimen and in such cases, patients should start a new pack as soon as they finish their previous pack (in the case of 21-days' supply packs) or skip the last row of their pills and immediately start a new pack (in the case of a 28-days' supply pack).

Counsel patients to take their pill at the same time each day so that they can get into a routine and remember to take it. More details will be provided on how to counsel patients on late or missed doses.

You get a call from a patient who is about to start using a 28-day monophasic COC for the first time. She is confused because she knows her doctor said that she could start taking the medication right away, but it's Tuesday and the pill pack indicates that she should take the first pill on Sunday. How would you advise this patient?

You should make sure to reassure the patient that she can start taking the medication immediately. Reconfirm whether or not she needs backup contraception since you weren't involved in the initial discussion. And let the patient know that there should be stickers with days of the week that she could place over the pre-printed days to help her stay on track with taking her medication.

Progestin-only Pills

Progestin-only pills only come in one formulation, which is available as a 28-day pack. This pack looks very similar to COC pill packs; however, each pill contains active medication. Educate patients that a pill will be taken every day with no breaks. This counseling point is especially important for patients with prior COC experience. Patients need to know that it's not okay to miss ANY pills, including those in the last row of their pack. Unlike COCs, the progestin-only pill has a very short half-life. Because of this, the progestin-only pill must be taken at the same time each day. If a pill is taken more than three hours late, patients have to use backup contraception for at least 48 hours. ¹⁴ Recommending that the progestin-only pill be taken at the same time each day is important both for helping patients remember to take their medication as part of a routine, as well as for efficacy. The progestin-only pill has fallen out of favor in recent years because of lower efficacy rates with typical use, and because of the availability of long-acting progestin-only options, such as the injection, implant, and IUD. However, it may be used in breastfeeding women, since the progestin-only pill doesn't negatively impact milk supply like estrogen-containing contraceptives.

You have a patient who is switching from a COC to the progestin-only pill due to a recent onset of migraine headaches. What counseling points should you make sure to share with this patient regarding how to use the progestin-only pill?

Make sure to stress that unlike COCs, it's extremely important to take the progestin-only pill at the same time each day because drug levels don't stay around as long as COCs. Taking the progestin-only pill more than a few hours late can decrease its efficacy, and potentially result in an unplanned pregnancy. If the patient does take the progestin-only pill more than three hours late, they should use backup contraception for at least 48 hours. Also let the patient know that it's important to take ALL pills in the pill pack and start a new pack immediately.

Transdermal Patch¹⁵

The transdermal patch is a CHC that uses a 28-day cycle. Instruct patients to apply a new patch on the same day each week for three weeks. Week four is the patch-free, hormone-free week. If patients will be using the patch continuously, they should skip the patch-free week and apply a new patch every week. Tell patients not to cut or alter the patch in any way and to only wear one patch at a time. The patch can be placed in a location where it won't be rubbed on the upper outer arm, abdomen, buttock, or back. Let patients know that they should rotate the patch location each week and they should watch to make sure that they aren't applying the patch to irritated or cut skin. The skin area where the patch will be applied should be clean and dry, and free from any lotions, creams, oils, powders, or make-up. When applying the patch, instruct patients to press firmly on the patch with the palm of their hand for ten seconds. Wrinkles should be smoothed out so that the patch adheres completely to the skin. Advise patients to check their patch every day to make sure the edges are sticking correctly. Let patients know that they could bath, shower, swim, and exercise while wearing the patch. ¹⁶

Vaginal Ring^{17,18}

There are two different types of vaginal rings available. You are probably most familiar with the ethinyl estradiol/etonogestrel (*NuvaRing*) product, since this has been on the market for a while. This ring is inserted for three weeks and then disposed of. A new ring is inserted one week later.

In contrast, the ethinyl estradiol/segesterone (*Annovera*) vaginal ring is reusable for up to one year (or 13 cycles). Similar to *NuvaRing*, there is an off week, but patients reinsert the same *Annovera*ring to start the next cycle.

Be aware that *NuvaRing* should remain refrigerated before dispensing, but patients can keep it at room temperature for up to 4 months. *Annovera* does NOT require refrigeration.

With both *NuvaRing* and *Annovera*, one ring is inserted into the vagina and remains there for three weeks. The ring is removed for one week to allow menses to occur, and then a new *NuvaRing* ring, or the same *Annovera* ring, is inserted (or reinserted for *Annovera*) one week after the previous ring was removed (on the same day of the week). Instruct patients to store their *Annovera* ring in the black compact case that comes with it during the off week. And emphasize the importance of keeping this case away from children and pets. Patients should also be educated to wash *Annovera* with mild soap and warm water, then pat it dry with a clean towel. This should be done each time before use and after removing the ring, prior to storing.

Let patients know that they should be removing the vaginal ring three weeks after insertion, on the same day of the week that it was inserted. Patients who will be using *NuvaRing* continuously should be instructed to keep the ring in for four weeks instead of three weeks. ¹⁹ Tell patients using the ring continuously to replace the old ring with a new ring right away every four weeks. ¹⁹ Note that the manufacturer advises that patients using *Annovera* shouldn't skip the "off" week.

For both types of rings, instruct patients to use an insertion position that is most comfortable for them. This can include standing with one leg up, squatting, or lying down. When inserting the ring into the vagina, the ring should be squeezed together to compress it and make it easier to insert. Tell patients that the exact position of the ring in the vagina isn't critical for its function. Inform patients that they don't need to worry about pushing the ring too far into the vagina because the cervix will prevent it from moving too far into the genital tract. ¹⁴ The ring is removed by hooking the index finger under the rim of the ring or by grabbing hold of the rim with the index and middle finger and pulling it out.

Let patients know that diaphragms, cervical caps, and female condoms aren't recommended as methods for backup contraception with the vaginal ring. In the case of *NuvaRing*, the ring can interfere with the correct placement and position of these barrier methods, and in the case of *Annovera*, its use hasn't been studied with these barrier methods. Antifungal creams and spermicides can be used with the ring, but douching should be avoided. ¹⁴ Be aware that with *Annovera*, only water-based creams and lubricants can be used. Use of oil-based creams, lubricants, suppositories, or gels are not recommended with *Annovera*.

If patients are initiating vaginal ring therapy during menses, let them know that tampons can be used safely with the vaginal ring, but the ring should be inserted before inserting a tampon. Tell patients to pay close attention when removing a tampon to make sure that the ring isn't accidentally pulled out.²⁰ The ring also doesn't need to be removed during sex. But, if preferable for the patient or the patient's partner, the ring can be removed for up to three hours without risking contraceptive failure.

Depot Injection

Another type of hormonal contraceptive that can potentially be self-administered is the depot injection, medroxyprogesterone acetate. This progestin-only hormonal contraceptive is available as either a subcutaneous (SQ) or intramuscular injection (IM) that is administered every three months (13 weeks). The SQ injection contains less progestin (104 mg/0.65 mL) than the IM injection (150 mg/mL). Tell patients the SQ shot may cause less injection pain compared to the IM shot, but that the progestin-related adverse effects are similar. Since the SQ injection is available as a brand-drug only, insurance companies may only cover the IM injection, which has a generic.

While many patients get the injection at a clinic, it is possible to train patients to give themselves the SQ injection. Although less convenient and more risky, the IM injection can be self-administered as well with appropriate training. 21,22,23 Depending on state law and company policies, pharmacists may also be able to administer the SQ or IM injection at the pharmacy and can choose to charge a fee for administration. 24

Self-administration of injectable medroxyprogesterone can help address some barriers to continuation such as time, expense, and inconvenience of clinic visits. ²⁵ Advise patients who you know will be self-administering depot medroxyprogesterone that the prefilled syringe must be vigorously shaken for at least one minute to create a uniform suspension before attaching the needle. ²³ The SQ injection can be given in the lower abdomen or upper thigh, while the IM injection is given in the gluteal or deltoid muscle. ^{26,27} Educate patients who will be self-administering the drug on aseptic technique. Tell them to wash hands thoroughly with soap and water before preparing the injection site, wipe down the injection site with an alcohol swab, and let the injection site dry completely before injecting. The needle and syringe should be pointed at a 90-degree angle for IM injections. For SQ injections, instruct patients to pinch a large area of the skin and insert the needle at a 45-degree angle. While still pinching the skin, the medication should be injected slowly until the medication is gone (this should take about five to seven seconds). ²⁶ With both IM and SQ injections, patients should be advised to discard the used syringe immediately in a sharps container, or a household container that is heavy-duty plastic and can be sealed. Tell patients that they can press a clean cotton pad onto the injection area if it starts to bleed, but they should not rub the area.

Let patients know that hormonal contraceptives do not protect against sexually transmitted infections (STIs) or HIV (human immunodeficiency virus). In order to protect against STIs and HIV, CDC recommends the following:²⁸

- Use condoms
- Practice abstinence
- Have fewer partners agree to only have sex with one person who agrees to only have sex with you, and get tested before
 having sex with one another
- Get vaccinated with the HPV vaccine

Adherence Considerations



It has been estimated that about four out of ten unintended pregnancies are due to inconsistent contraceptive use.²⁹ Despite the availability of long-acting reversible contraceptives that are much less susceptible to user error, oral contraceptive pills continue to be one of the most commonly used forms of hormonal contraception in the United States. Part of the reason for the widespread use of oral contraceptive pills is that general practitioners are most comfortable prescribing this method of contraception and are less familiar with long-acting reversible contraceptives and the insertion techniques involved.³⁰ The expansion of pharmacy practice in states allowing pharmacists to prescribe hormonal contraceptives is limited to self-administered contraceptives, of which oral contraceptive pills are likely to be the most commonly

selected by pharmacists, and the depot injection. As pharmacists begin to prescribe these medications, counseling on adherence becomes even more important. For some patients, the visit with the pharmacist may be the first time they speak to a healthcare provider about hormonal contraceptives.

Take the time to explain how the medication works to prevent pregnancy as a way to help patients understand why strict adherence is so important. Our CE, *Pharmacology of Hormonal Contraceptives*, can help you gain the knowledge you need to explain how the various hormonal contraceptives work.

Stress the importance of setting reminders so that patients remember to take their medication at the same time each day. We have several tips for helping patients remember to take their medication in our clinical resource, *Medication Adherence Strategies*. Medication reminders are especially important for progestin-only pills since they have very little room for user error.

Providing patients with a one-year supply of their oral contraceptive up front can help improve adherence and has been found to decrease unintended pregnancies by up to 30% when compared to patients who only receive a one-month or three-month supply.³¹ However, providing an entire year's supply of oral contraceptives in one visit isn't common practice since insurers typically only cover a one- to three-month supply. States are looking to change this by passing laws that require private insurers to pay for a whole year's supply of medication at once. For example, several states, such as, Washington DC, Hawaii, and Oregon, have passed laws requiring private insurers to cover a one-year supply of birth control.^{32,33,34}

Keep an eye out for patients who are prescribed more than a one-month supply. While there are adherence benefits due to improved access and convenience, not seeing the pharmacist and getting reinforcement on adherence could be problematic for some whose adherence issues are unrelated to access and convenience. It's important to still check-in with all patients, whether you see them every month, every three months, or every year. Call patients on the phone if you know you won't see them for a while, especially if they are new to therapy. Talk to patients who come into the pharmacy for refills of one- or three-month supplies if dispensing history suggests that there is an adherence problem. Ask these patients open-ended questions such as, "How are you finding taking the pill every day?" or "What do you do when you miss a pill?" to uncover issues. ³⁰ Patients who continue to have problems remembering to take their medication should receive information on other dosage forms with less potential for error, such as the patch, ring, injection, or longer acting reversible contraceptives, such as the implant or IUD.

Missed Doses

Rena, a 27-year-old patient who is taking a 28-day monophasic COC calls the pharmacy at around 11:30 am and asks to speak to a pharmacist. She tells you that she usually takes her pill every day at 5 pm around dinner, but yesterday she went to a concert and completely forgot to take her pill. She's wondering what she should do. How would you advise Rena? Does she need backup contraception? How would this advice change if Rena was taking the progestin-only pill? What recommendations can you give Rena to help always remember to take her medicine, even if there's a change in her daily routine?

Despite your attempts to stress the importance of adherence with your patients, mistakes can happen. Educating patients on what to do in the event of a missed or late dose of medication is important for preventing unintended pregnancies. The instruction that should be provided to patients depends on the type of hormonal contraceptive they are using. Each individual product has its own specific recommendations in the package insert for how to handle missed or delayed doses. CDC provides a summary for all products to make it easier for patients and clinicians to quickly provide actionable information that is based on a larger body of research and clinical opinion. A summary of CDC's recommendations will be provided here, but be advised that details specific to each individual product as studied by the manufacturer can be found in the prescribing information. You can also use our patient education handout, What I Need to Know About Missed Birth Control Doses, to help emphasize the importance of not missing any doses.

Combined Hormonal Contraceptive Pills

With combined hormonal contraceptive pills a dose is considered missed if it has been 24 hours or longer since the dose should have been taken. ¹³ Different actions should be taken based on the time frame since the last dose.

Missed or late dose that is less than 48 hours since last dose taken: Tell patients to take the late or missed pill as soon as possible. They should continue to take their next scheduled dose at the same time. This means that they may be taking two pills on the same day or at the same time. Let patients know that no backup contraception is needed. It is also not necessary to offer emergency contraception in this situation.

Missed dose is 48 hours or longer since last dose taken: Tell the patient to take the most recent missed pill as soon as possible. Any other missed pills should be discarded. The patient should take the next scheduled dose at the usual time, even if it means taking two pills in one day. Backup contraception or abstinence should be used until hormonal pills have been taken for seven consecutive days. If these pills were missed during the third week of the 28-day cycle (days 15 through 21), instruct patients to finish the rest of the pills in their pack but omit the hormone-free interval and begin a new pack after the last active pill is taken. If they are unable to start a new pack immediately, backup contraception or abstinence should be used until the new pack can be started and pills from the new pack have been taken for seven consecutive days. Let patients know that emergency contraception should be considered if the pills were missed in the first week of the 28-day cycle and unprotected sex occurred in the previous five days.

<u>Vomiting or severe diarrhea for less than 48 hours after taking a dose</u>: ¹³ Tell the patient that they don't need to repeat the dose, but should continue taking their pills daily at the usual time. No additional contraception is needed.

<u>Vomiting or severe diarrhea that continues for 48 hours or longer</u>: ¹³ Tell the patient to continue taking pills daily at the usual time during the vomiting and diarrhea if possible. If the vomiting or severe diarrhea occurs during the last week of hormonal pills (days 15 through 21), instruct patients to skip the hormone-free interval and start a new pack immediately. Backup contraception or abstinence is needed until hormonal pills have been taken for seven consecutive days after the vomiting or diarrhea has resolved.

Transdermal Patch

Patients may forget to apply a new patch on time, or might experience situations where patches detach. This is one of the reasons why you should counsel patients to check their patch every day to make sure it's still sticking to the skin completely. If a patch edge lifts up, the patient needs to press down firmly on the patch with the palm of their hand for ten seconds. ¹⁵ If the patch doesn't stick completely, the patient should remove it and apply a replacement patch. Patches that become partially detached from the skin do not sufficiently deliver the drug, which can

decrease efficacy. ¹⁵ Patients should not use tape or a wrap to secure the patch.

Less than 48 hours since a new patch should have been applied or since a patch has been detached: Tell patients that if it has been less than 24 hours since the patch was applied and detachment occurs, they should try to reapply the patch or replace the patch with a new one. 13 If it has been over 24 hours, but less than 48 hours, since detachment has occurred, or if it has been less than 48 hours since a new patch should have been applied, patients should apply a new patch as soon as possible. No backup contraception is needed in this scenario. Advise patients to keep their patch change day the same. 13 For example, if a patient who usually changes their patch on Mondays forgets and has to apply the patch on Tuesday instead, the next week they should apply a new patch on Monday again (not Tuesday).

Has been 48 hours or longer since a new patch should have been applied or since a patch has been detached: Tell patients to apply a new patch as soon as possible, keeping the original patch change day the same. Patients will need to use backup contraception or abstinence until a patch has been worn for seven consecutive days. ¹³ Note that if detachment takes place but a patient is unsure of when it first occurred, they should assume that the patch has been detached for 48 hours or more and follow these same instructions. Special instructions are required if this delayed application or detachment occurred in the third patch week. Patients should finish off the third week with the newly applied patch. On their patch change day, instead of removing the patch and having a hormone-free week, they should apply a new patch immediately. If the patient isn't able to start a new patch immediately, backup contraception or abstinence should be used until a new patch has been worn for seven consecutive days. Let patients know that emergency contraception should be considered if the delayed application or detachment occurred within the first week of patch use, and unprotected sex occurred in the previous five days. ¹³

Vaginal Ring

Although not common, it is possible for the vaginal ring to come out accidentally after it has been inserted. ^{17,35} This may happen in situations where the position of the ring is disrupted such as during sex, removing a tampon, or straining during a bowel movement. ¹⁷ The prescribing information for the vaginal ring products have specific instructions for what to do if the ring falls out and needs to be reinserted. ¹⁷

The prescribing information for *NuvaRing* advises that if it has been less than three hours since displacement, the ring can be washed off with lukewarm water and reinserted with no backup contraception needed.¹⁷ If it has been displaced for more than three hours, *NuvaRing* should be reinserted as soon as possible and backup contraception is needed until the ring has been in place for at least seven days in a row. If ring displacement for more than three hours occurs during the third week of the cycle, the *NuvaRing* prescribing information advises to skip the "off" week and begin using a **new** ring.

The prescribing information for *Annovera* advises that if it has been less than **two** hours since displacement, it can be washed and reinserted without the need for backup contraception. ¹⁸ However, if it the ring has been out of the vagina for two consecutive hours, or if it has been out of the vagina at different times during the 21-day cycle that add up to be more than two hours, backup contraception is required until *Annovera* has been in the vagina for seven days.

Keep in mind that these instructions are more cautious than the CDC's recommendations. CDC recommends the same instructions for delayed insertion (i.e., forgetting to insert a new ring) and reinsertion (i.e., forgetting to reinsert a ring that fell out or was removed). Consider recommending the more cautious approach to ensure prevention of unintended pregnancy. However, be aware of the CDC recommendations, especially for delayed insertion. Also be aware that as of the publication of this course, the CDC recommendations are based on clinical data available for *NuvaRing* only. It does not take into account clinical data for *Annovera*. Refer to the advice provided by the prescribing information for *Annovera*.

CDC recommendations are as follows:

Less than 48 hours since a new ring should have been inserted or a previously inserted ring needs to be reinserted: 13 Tell patients they should insert or reinsert the ring as soon as possible and keep the ring in until the original scheduled removal day. No additional backup contraception is needed.

Has been 48 hours or longer since a new ring should have been inserted or a previously inserted ring needs to be reinserted: Tell patients to insert or reinsert the ring as soon as possible and keep the ring in until the original scheduled removal day. Inform patients that they should use backup contraception or abstinence until a ring has been worn for seven consecutive days. If this delay happens during the third week of ring use, tell patients to skip the hormone-free week by finishing the third week of ring use and inserting a new ring immediately. If the patient isn't able to start a new ring immediately, backup contraception or abstinence should be used until a new ring has been worn for seven consecutive days. Inform patients that emergency contraception should be considered if the delay occurs within the first week of ring use and unprotected sex occurred in the previous five days.

Progestin-only Pills

With the progestin-only pill, a dose is considered missed if it has been three hours or more since the dose should have been taken. Reasons for this small room for error include the fact that the progestin-only pill inhibits ovulation in only about half of menstrual cycles, and the progestin-only pill is so rapidly distributed and eliminated that at 24 hours after administration, serum steroid levels are close to baseline. ¹³ Instruct patients that if it has been three hours or longer since a dose should have been taken, they should take one pill as soon as possible. Patients should also use backup contraception or abstinence for at least 48 hours.

If patients experience vomiting or severe diarrhea within three hours of taking the progestin-only pill, they should take another pill as soon as possible. They should continue taking their medication daily at the same time each day. Backup contraception or abstinence should be used until the progestin-only pill has been taken for two consecutive days after the vomiting or diarrhea has resolved.

Depot Injection

Although it's recommended to give the injection every three months (13 weeks), the injection can be given every 12 to 14 weeks without any efficacy concerns. In fact, the depot injection can be given up to two weeks late (15 weeks) since the last injection without requiring any additional backup contraception. ¹³ If the injection is given more than two weeks late (more than 15 weeks after the last injection), the healthcare provider should be reasonably certain that the patient is not pregnant before giving the shot. Backup contraception or abstinence should be used for the next seven days after getting the shot.

Side Effects

What are the side effects that your patients taking hormonal contraceptives complain of most often? How do you advise your patients on the management of these side effects? How do you prepare patients starting hormonal contraceptives on what to expect in terms of side effects?

Side effects can negatively impact adherence, so it's important to discuss the possible side effects a patient may experience prior to starting a hormonal contraceptive. Common side effects of hormonal contraceptives are caused by excessive or deficient amounts of estrogen or progestin, and the extent of activity of progestin on androgen receptors. ^{14,36}

Hormone	Too Much	Too Little
		Spotting, breakthrough bleeding early/mid- cycle
Progestin	Breast tenderness, headache, fatigue, mood changes	Breakthrough bleeding late cycle
Androgen	Weight gain, acne, hirsutism, ↑ LDL, ↓ HDL	Decreased sex drive

The good news is that many of these side effects go away with continued use (usually by the third cycle), once the body has adjusted to the change in hormone levels. Let patients know that side effects, such as nausea/vomiting, breast tenderness, and weight gain, can occur with hormonal contraceptives but that these symptoms may improve after two to three cycles. If Irregular bleeding or spotting can also occur, usually in the first couple of months of therapy. Tell patients that this symptom is common, not harmful, and does improve with persistent use of their hormonal contraception. Beducate patients that taking their hormonal contraceptive pill consistently at the same time each day can help prevent irregular bleeding from occurring. Advise patients getting the depot injection that the absence of bleeding is common, especially after one or more years of continuous use. Counseling patients on the potential for irregular bleeding and eventual cessation of bleeding with the injection has been found to decrease discontinuation rates.

Any of the above side effects that don't get better with continued use, and other side effects, such as acne, oily skin, or fatigue, may be improved by switching to a different type of product. Inform patients that if they experience any of these bothersome symptoms to continue taking their medication, but to let you or their prescriber know so that they can be evaluated for a change in therapy. For more details on how to manage common side effects with hormonal contraceptives, check out our chart, *Choosing a Hormonal Contraceptive*.

There are some less common, severe side effects that may be caused by hormonal contraceptives. These side effects are sometimes accompanied by severe symptoms. Let patients know that if they experience any of these severe symptoms, they should immediately contact a healthcare provider. ¹⁴ An acronym you can use to help you remember some of these warning signs is ACHES: Abdominal pain, Chest pain, Headaches, Eye problems, and Severe leg pain. ¹⁴

Serious Symptoms Potentially Associated with Combined Hormonal Contraceptives ¹⁴			
Serious Symptom	Possible Cause		
Abdominal pain, hepatic mass or tenderness, jaundice, itchy skin	Gallbladder disease, liver problem, pancreatitis, thrombosis of abdominal artery or vein		
Chest pain (radiating to left arm or neck), shortness of breath, coughing up blood	Pulmonary embolism		
Migraine headaches	Vascular spasm or stroke		
Blurred vision, double vision, flashing lights, blindness	Stroke, hypertension, retinal artery thrombosis		
Severe leg pain, tenderness, swelling, warmth	Blood clot		
Numbness, weakness, tingling in extremities, slurred speech	Stroke		

Drug-Drug Interactions



You are conducting a final check on a prescription for azithromycin and notice that the computer system is flagging a drug interaction with the combined oral contraceptive that the patient is also taking. Why did this alert show up? How would you manage this interaction alert? What will you tell the patient?

What are some drug interaction alerts you see often with hormonal contraceptives? How do you manage these interactions?

The CDC has an easy-to-read chart to help you identify drugs that should be avoided with the different forms of hormonal contraceptives. The Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) includes over 50 conditions and select drug interactions along with recommendations for initiation and continued use of CHCs, the progestin-only pill, the depot injection, implant, and IUDs. The details on the U.S. MEC and how to use it can be found in our CE, Hormonal Contraceptive Selection.

Inform patients that it's important for them to make sure their healthcare providers know about the hormonal contraceptive they are using and any other medications they take. Since estrogens and progestins are metabolized by CYP3A4, drugs that induce this enzyme are of particular concern. The Drugs that induce CYP3A4 can increase the metabolism of certain hormonal contraceptives and potentially decrease their efficacy. These drugs include many antiseizure meds, such as phenytoin, carbamazepine, oxcarbazepine, and barbiturates; and rifamycin antibiotics, such as rifampin and rifabutin. Contraceptive methods not likely to be impacted by induction of CYP3A4, such as the injection, implant, or IUD, might be best for patients on these drugs to help ensure contraceptive efficacy. Keep in mind that many of these interactions are theoretical. Data looking at patient-oriented clinical outcomes, such as pregnancy rates from randomized trials or large cohort studies, are lacking.

You may have seen warnings about using more common antibiotics, such as penicillins, cephalosporins, macrolides, or tetracyclines, with hormonal contraceptives. Intestinal bacteria are responsible for enterohepatic recirculation of hormone metabolites, which is thought to contribute

to the efficacy of oral contraceptives. Antibiotics can disrupt the intestinal bacterial flora and potentially interfere with enterohepatic recirculation. There is controversy on the clinical implications of this interaction, but individually, some patients may experience large decreases in plasma concentrations of ethinyl estradiol when taking certain antibiotics. 43,44,45,46,47 Since it isn't possible to identify which patients would experience these large decreases, it would be prudent to educate patients on this risk, and many pharmacy computer systems will print warnings on Rxs for antibiotics. If this interaction does in fact exist, it is rare and at a population level, this potential increased risk is still consistent with the acceptable failure rate of oral contraceptives seen with typical use. While we know that the clinical significance may be in doubt, to be on the safe side, concerned patients can be advised to use backup contraception or abstinence during the duration of therapy and up to seven days after the last dose of the antibiotic.48

For more details on managing antibiotic and hormonal contraceptive interactions, check out our chart, Managing Antibiotic and Hormonal Contraceptive Interactions. This resource covers additional information on managing the interaction between rifamycin antibiotics (rifampin, rifabutin, etc) and hormonal contraceptives.

Interactions with hormonal contraceptives can also impact the efficacy of drugs like lamotrigine or fosamprenavir. Lamotrigine is primarily metabolized by the UDP-glucuronosyltransferase enzyme (UGT). Ethinyl estradiol may induce UGT enzymes which can increase the metabolism of lamotrigine and decrease its efficacy. Estrogen-containing contraceptives can decrease lamotrigine concentrations by about 50%. 49 Estrogencontaining contraceptives have also been found to decrease serum concentrations of fosamprenavir, which can lead to a loss of virological response.50

Due to the decreasing amounts of estrogens being used in combined hormonal contraceptives, some experts believe the major mechanism of the contraceptive effect of combined hormonal contraceptives is due to the progestin component. ⁴⁰ There is an increasing interest in studying the different progestin components when designing studies to assess drug interactions in the future. ⁵¹ FDA is attempting to work on developing clear guidelines on what kinds of studies manufacturers should be conducting to assess drug interactions with hormonal contraceptives. 52,53 In the future, the hope is that we will have more specific and actionable data on drug interactions with hormonal contraceptives to be able to share with patients in order to help them make informed decisions. This is especially important as new drugs come out.

The Bottom Line

Hormonal contraceptives can be very effective when used correctly, with most options being over 90% effective with typical use. Pharmacists can help maximize efficacy by counseling patients on important topics that empower patients to use their medication consistently and correctly. Topics that should be covered include how to take or use their medication, the importance of adherence, what to do if a dose is missed, what side effects to expect, and drug interactions to be aware of.

Quiz Questions	2
Question #1	_
ou are counseling a patient who will be starting a combination hormonal contraceptive pill. She hat negative pregnancy test yesterday when she was at the clinic getting this prescription. It has been wo weeks since the last day of her last period. What would be the best advice you could give her?	n
 a. Start the medication right away and use backup contraception for 24 to 48 hours. 	
b. Start the medication right away and use backup contraception for the next seven days.	
o. Wait until next Sunday to start the medication and don't worry about backup contraception.	
d. Wait until your next period to start the medication and don't worry about backup contraception.	
Question #2	
occording to the U.S. Selected Practice Recommendations for Contraceptive Use, which contraceptive method could be initiated without additional backup contraception if it has been within week since the start of menses?	n
a. Depot injection	
b. Vaginal ring	
C. Progestin-only pill	
d. Combined hormonal contraceptive pill	
Question #3	
our patient has a new prescription for the transdermal patch hormonal contraceptive. She asks yo low she should use this medication. What counseling point can you share with her?	u
a. Check the location of the patch daily.	
b. Put on a new patch every three weeks.	
c. Apply the patch by pressing on it firmly for 1 second.	
d. Place the patch in the same location each time.	
Question #4	_
MACCHOIL II I	

Karen is picking up a new prescription for the vaginal ring hormonal contraceptive and she's wondering what she needs to know about the ring. What can you recommend regarding appropriate use of the vaginal ring?

a. A new ring should be inserted once every week.

b. A tampon can be used safely with the ring.					
c. Inserting the ring too far can cause it to enter the uterus.					
d. Diaphragms may be used for backup contraception	with the ring.				
Question #5					
What would be appropriate advice for a patient who accident combined hormonal contraceptive pill?	ally misses one or more doses of a				
 a. If you miss one dose, that's okay; just skip the misse the pills in the pack on the appropriate days. 	ed dose and continue taking the rest of				
 b. If you miss a dose and it has been 48 hours or longe all skipped doses as soon as you remember. 	 b. If you miss a dose and it has been 48 hours or longer since the last dose was taken, take all skipped doses as soon as you remember. 				
	c. If you miss a dose during the third week of the cycle and it has been 48 hours or longer since the last dose was taken, discard the rest of the active pills and start a new pack immediately.				
 d. If you miss taking a dose by just a few hours, take the don't worry about backup contraception. 	e pill as soon as you remember it and				
Question #6					
In which scenario would you most likely recommend a patien	t use backup contraception?				
 a. If a patient notices a detached patch after first apply 	ng it the day before				
b. If the depot injection is given at 14 weeks instead of	13 weeks after the last injection				
c. If a patient taking a progestin-only pill is late in taking	g the pill by four hours				
d. If the ethinyl estradiol/etonogestrel ring gets disrupte reinserted until two hours later	d and falls out but doesn't get				
Question #7					
Which side effect of combined oral contraceptives can be imported the same time each day?	proved by taking the pill consistently at				
a. Fatigue					
b. Oily skin					
c. Blurred vision					
d. Spotting					
o a spearing					
Question #8					
Laurel is picking up a new prescription for a combined oral co	ontraceptive. She tells you that she's				
worried about the side effects. Which common side effect cal cycles of consistent use?					
a. Itchy skin					
b. Leg tenderness					
c. Nausea/vomiting					
d. Weakness/numbness					
Question #9	1				
Which drug is likely okay to use in a patient taking a combine	ed oral contraceptive pill?				
a. Amoxicillin					
b. Fosamprenavir					
c. Lamotrigine					
d. Rifampin					
Question #10					
Lisa is currently taking oxcarbazepine and is interested in sta type of hormonal contraceptive could you recommend to Lisa					
a. Implant					
b. Progestin-only pill					
c. Transdermal patch					
d. Vaginal ring					

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Hormonal Contraceptive Counseling (19-249)

Needs: Hormonal contraceptives can be very effective if used consistently and correctly. Hormonal contraceptives that are used incorrectly can cause unplanned pregnancies. Pharmacists need to be able to counsel patients on the appropriate use of hormonal contraceptives to help decrease the chance that an unplanned pregnancy is caused by hormonal contraceptive misuse.

Target Audience: This activity is intended for pharmacists in any practice setting. There are no prerequisites.

Goals and Objectives: The goal of this application-based activity is to help pharmacists in all settings counsel patients using hormonal contraceptives.

Upon completion of this course, the learner will be able to:

- 1. Identify when it is necessary to use backup contraception when initiating a hormonal contraceptive.
- 2. Explain how to use the various types of hormonal contraceptives.
- 3. Recommend how to handle missed or delayed doses of hormonal contraceptives.
- 4. Identify strategies to prevent or manage side effects caused by hormonal contraceptives.
- 5. Assess hormonal contraceptive drug interactions.

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