

## II.D.2 Patient Understanding

### *Patient Comprehension Questions*

Program Steps	
One goal of the iPLEDGE Program is making sure pregnant women do not take isotretinoin	<ol style="list-style-type: none"> <li>1. True</li> <li>2. False</li> </ol>
You are in your third month of treatment, in order to get your isotretinoin prescription, you must	<ol style="list-style-type: none"> <li>1. Have a urine test for infection.</li> <li>2. Have a negative pregnancy test done in a laboratory, discuss birth control with your doctor and answer questions in the iPLEDGE Program system.</li> </ol>
The confidential iPLEDGE Program Pregnancy Registry collects information on pregnancies that happen during isotretinoin treatment or within 1 month after the last dose	<ol style="list-style-type: none"> <li>1. True</li> <li>2. False</li> </ol>
Each month you need to answer questions and:	<ol style="list-style-type: none"> <li>1. Enter 2 forms of birth control you are using.</li> <li>2. Do a home pregnancy test to show the pharmacist.</li> </ol>
For 1 month after your last dose, you must use 2 effective forms of birth control together all the time	<ol style="list-style-type: none"> <li>1. True</li> <li>2. False</li> </ol>
Your doctor tells you that you to come back 1 month after your final dose. You return to the office to:	<ol style="list-style-type: none"> <li>1. Get a prescription for 30 days.</li> <li>2. Talk with your doctor about birth control.</li> <li>3. Get the last pregnancy test.</li> </ol>
Your doctor tells you that you need to have a pregnancy test each month. You would:	<ol style="list-style-type: none"> <li>1. Refuse the test because you know you are not pregnant.</li> <li>2. Agree to have the pregnancy test because it is important to know if you are pregnant before taking isotretinoin.</li> <li>3. Wait a week before getting the test done.</li> </ol>
You must keep your appointment every month because:	<ol style="list-style-type: none"> <li>1. It is important for you and your doctor to interact before you get a maximum 30 day supply of isotretinoin each month.</li> <li>2. You need to sign a consent form each month.</li> </ol> <p>You need to tell your doctor where to call in your prescription.</p>

General Contraception Requirements	
Many women who became pregnant while taking isotretinoin were using only 1 form of birth control.	1. True
	2. False
Using alcohol and drugs can make it more difficult to use your birth control properly when having sex.	1. True
	2. False
You can change one primary form of birth control for another without talking with the doctor first.	1. True
	2. False
You can use any forms of birth control for the iPLEDGE Program	1. True
	2. False
You are using 2 effective forms of birth control in the month after your last dose. Your partner's condom breaks. You would:	1. Forget about it since you have finished isotretinoin
	2. Call your doctor to see if you might need emergency birth control.
	3. Get a home pregnancy test kit to see if you are pregnant.
While you are taking isotretinoin, you must use 2 effective forms of birth control together all the time	1. True
	2. False
You should talk to your doctor about birth control:	1. Each month during your office visit.
	2. Only when you have a problem.
	3. Only when you sign the second consent form.
You have finished your last dose of isotretinoin. Your doctor has ordered a pregnancy test. For the next month, you:	1. Continue to use 2 effective forms of birth control together all the time.
	2. Stop using your secondary form because you are not taking isotretinoin.
	3. Go for the pregnancy test at any time during the month.

Birth Defects and Pregnancy	
Which of the following are signs you might be pregnant?	1. You miss your menstrual period
	2. You have nausea, sometimes referred to as morning sickness.
	3. Your breasts feel tender, like at the beginning of a menstrual period.
	4. Any of the above is a sign you might be pregnancy.
The risk for birth defects for a baby whose mother took isotretinoin is	1. So low that you do not have to worry.
	2. Low enough so you do not need birth control.
	3. Very high even if a woman takes a small amount of isotretinoin.
You cannot get pregnant if you have sex under water	1. True
	2. False
You can get pregnant any time and anywhere you have sex, particularly unprotected sex.	1. True
	2. False
You can get pregnant if you have not started having menstrual periods.	1. True
	2. False
Which of the following birth defects may be caused by isotretinoin?	1. No ears
	2. Heart problems
	3. Small jaw and misshaped head
	4. A child could have any or all of these birth defects.
You think you may be pregnant and you have taken isotretinoin. You would:	1. Not worry because it was only a few doses.
	2. Stop isotretinoin and call your doctor. Even the smallest amount of isotretinoin may cause birth defects.
It's okay to take isotretinoin when	1. You are using one effective form of birth control.
	2. You are using 2 effective forms of birth control all the time.
	3. You may be pregnant.
You cannot get pregnant if:	1. You never have sex with a man.
	2. You miss your hormone shots.
	3. You use only a condom with spermicide.

Safety Information	
I must not give blood while taking isotretinoin and 1 month after stopping isotretinoin.	1. True 2. False
I will not share my isotretinoin with anyone.	1. Agree 2. Disagree
Your neighbor wants to try your isotretinoin. You tell her or him:	1. I must not share isotretinoin. 2. It might be harmful to her or him. 3. You tell her or him both of these reasons.
The Red Cross calls you to give blood right after your last dose. You tell them:	1. I can never give blood again. 2. I cannot give blood until 1 month after my last dose of isotretinoin.
The Red Cross calls you to give blood during your first month after your last dose. You tell them:	1. Giving blood is not safe for me. 2. I cannot give blood until 1 month after my last dose of isotretinoin. 3. I can never give blood again.

Obtaining a Prescription	
Your pharmacist can fill and dispense your prescription only after:	<ol style="list-style-type: none"> <li>1. You phone it in.</li> <li>2. Checking with the iPLEDGE Program system to see if you can get isotretinoin.</li> <li>3. You email it in.</li> </ol>
You can get a prescription for isotretinoin only if:	<ol style="list-style-type: none"> <li>1. Your pregnancy test is negative.</li> <li>2. You answered the questions correctly.</li> <li>3. You entered your 2 forms of birth control.</li> <li>4. Your doctor entered your 2 forms of birth control.</li> <li>5. All of these.</li> </ol>
You had a pregnancy test on Tuesday for your next prescription. What is the last day you can obtain your prescription?	<ol style="list-style-type: none"> <li>1. Later that same day (7 hours later)</li> <li>2. By Friday before the pharmacy closes</li> <li>3. On Monday of the next week</li> </ol>
You can obtain your prescription any time you want	<ol style="list-style-type: none"> <li>1. True</li> <li>2. False</li> </ol>
Your doctor has entered your negative pregnancy test results and your two forms of birth control into the iPLEDGE Program system and gives you a prescription. Before you can obtain the prescription you must:	<ol style="list-style-type: none"> <li>1. Answer your comprehension questions in the iPLEDGE Program system.</li> <li>2. Schedule your next appointment with your doctor</li> <li>3. Sign your informed consent each month.</li> </ol>

Contraception Choices	
You missed 2 birth control pills earlier this week. You would:	1. Not have sex for the rest of the cycle, but keep taking the birth control pills as prescribed
	2. Have sex whenever you want.
I have been using birth control pills for 5 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail
	2. The birth defects are too severe to risk getting pregnant
	3. Isotretinoin may change how well some forms of birth control work
	4. All of these
Birth control pills work best when you take them every day as prescribed.	1. True
	2. False
You can switch to the progesterone-only mini-pill for your primary form of birth control while you are taking isotretinoin.	1. True
	2. False
Birth control pills may not work as well when you are taking isotretinoin. It is important to:	1. Take two birth control pills every day.
	2. Remember to take your birth control pill every day and always use a second effective method to help prevent pregnancy.
	3. Take your birth control pill only before having sex
I use my primary form of birth control exactly as prescribed and my partner uses condoms as the second form. My partner does not have any condoms with him tonight. We would:	1. Have sex anyway.
	2. Wait until he can buy a condom.
	3. Have sex but use withdrawal.
I use my primary form of birth control exactly as prescribed and my partner uses condoms with spermicide as the second form. My partner's condom breaks. I would:	1. Not worry about getting pregnant.
	2. Worry that I may become pregnant but not do anything.
	3. Call my doctor to talk about emergency birth control.
My partner has only one condom with him. We would:	1. Have sex more than once and reuse the condom.
	2. Have sex once and wait until he can buy more condoms.
	3. Have sex but use withdrawal.
For the iPLEDGE Program, condoms can be used with or without spermicide.	1. True
	2. False
If you use lubricant with a latex condom, it should be a water-based lubricant.	1. True
	2. False
Your partner should put his condom on:	1. Any time during sex.
	2. As soon as he gets an erection, because waiting too long lets sperm leak out.
	3. Only when he remembers.

You find a hole in your diaphragm after you had sex. You should:	1. Forget about it since you were near your period.
	2. Call your doctor to see if you might need emergency birth control.
For the iPLEDGE Program, diaphragms can be used with or without spermicide.	1. True
	2. False
After sex, your diaphragm should stay in place for:	1. 24 hours or more.
	2. 2 to 4 hours
	3. At least 6 hours and up to 24 hours.
You and your partner want to have sex a second time after you put in your diaphragm. You must:	1. Put spermicide in your vagina again before you have sex.
	2. Have sex again without using more spermicide for up to 24 hours at a time.
	3. Take out your diaphragm and clean it before having sex again.
Your gynecologist or family doctor needs to check how your diaphragm fits:	1. Every time you have sex.
	2. Every 2 years or if you gain or lose 10 pounds.
	3. Every 2 months.
The diaphragm with spermicide can help prevent:	1. Pregnancy
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
I use my primary form of birth control exactly as prescribed and a cervical cap with spermicide as my second form. I forgot my cap at home. I would:	1. Have sex anyway.
	2. Wait until I can use the cervical cap with spermicide.
	3. Have sex but use withdrawal.
For the iPLEDGE Program cervical caps can be used with or without spermicide.	1. True
	2. False
If you use a lubricant with your cervical cap, it should be a water-based lubricant.	1. True
	2. False
You find a hole in your cervical cap after you had sex. You should:	1. Forget about it since you were near your period.
	2. Call your doctor to see if you might need emergency birth control.
You and your partner want to have sex a second time after you put in your cervical cap. You do not need to put in more spermicide.	1. True
	2. False
After sex, your cervical cap should stay in place for:	1. 24 hours.
	2. 4 to 8 hours.
	3. At least 6 hours and up to 48 hours.

The cervical cap with spermicide can help prevent:	1. Pregnancy.
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
I use my primary form of birth control exactly as prescribed and use a vaginal sponge as my second form. I ran out of sponges tonight. My partner and I would:	1. Wait until I can buy more sponges or some other secondary form of birth control.
	2. Have sex anyway.
	3. Have sex but use withdrawal.
I use my primary form of birth control exactly as prescribed, but I forgot to put in my vaginal sponge this one time. I would:	1. Not worry that I could have gotten pregnant.
	2. Worry that I may become pregnant, but do nothing.
	3. Call my doctor to talk about emergency birth control.
The vaginal sponge can help prevent:	1. The spread of HIV (AIDS)
	2. The spread of other sexually transmitted infections (STIs)
	3. Pregnancy
You should insert your sponge:	1. Any time during sex.
	2. Any time up to 30 hours before you have sex.
	3. Only when you remember.
After sex, your sponge should stay in place for:	1. 24 hours or more.
	2. 2 to 4 hours.
	3. At least 6 hours.
If you and your partner want to have sex a second time after you put in your sponge:	1. You must put spermicide in your vagina again before you have sex.
	2. You can have sex again without using a new sponge for up to 30 hours at a time.
	3. You must take out your sponge and out in a new one before having sex.
I have been using the hormonal skin patch perfectly for over a year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
I have been using the hormonal skin patch, but I was 2 days late changing it. I would:	1. Not have sex for the rest of my cycle, but keep using the hormonal patch as prescribed.
	2. Have sex when I want to, my partner's condom is enough.

I am using the hormonal skin patch exactly as my doctor tells me. I should not put it on:	1. My upper outer arm.
	2. My stomach or upper body.
	3. My breasts.
The hormonal skin patch works best when you change it every week as prescribed.	1. True
	2. False
You can get pregnant using the hormonal patch if:	1. It becomes loose or falls off for more than 24 hours.
	2. You leave the same hormonal patch on more than one week.
	3. Both 1 and 2.
My hormonal vaginal ring slipped out and I did not replace it within 3 hours, I would:	1. Not have sex for the rest of my cycle, but keep using the hormonal vaginal ring as prescribed.
	2. Have sex when I want to, my partner's condom with spermicide is enough.
I have been using a hormonal vaginal ring for 1 year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
I am using the hormonal vaginal ring as my primary form. I can use it with which of the following barrier methods?	1. Cervical cap with spermicide.
	2. Condom with or without spermicide.
	3. Diaphragm with spermicide.
The hormonal ring works best when you change it on time every month, as prescribed.	1. True
	2. False
Pregnancy can happen when you are using a hormonal vaginal ring if:	1. The unopened package containing the hormonal vaginal ring is put into direct sunlight or gets hot.
	2. It slips out of your vagina and you do not replace it within 3 hours.
	3. It does not stay in your vagina for 3 weeks.
	4. You leave it in your vagina for more than 3 weeks.
	5. All of these reasons.

I have been getting hormone shots for 1 year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
You get hormone shots:	1. Every 4 or 12 weeks, depending on the brand of the product.
	2. In your arm, belly, or buttocks.
	3. Both are true.
You are using hormonal shots as your primary form of birth control, you should remember:	1. You are not protected against HIV (AIDS)
	2. You need to see your doctor to get the hormonal shot
	3. They might delay your ability to get pregnant after you stop using hormonal shots.
	4. All of the above.
One advantage of hormone shots is that they also protect against sexually transmitted infections (STIs).	1. True
	2. False
You have chosen hormone shots as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
You have received a prescription for isotretinoin from your doctor but have not had the prescription filled. It is OK to have unprotected sex since you have had a negative pregnancy test.	1. True
	2. False
You check for the strings on your IUD, but cannot feel them. You would:	1. Not worry because you are also using a diaphragm with spermicide.
	2. Call your gynecologist.
I have been using an IUD for 3 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
Your IUD needs to be checked by your doctor:	1. Within 3 months after you had it inserted.
	2. If you can feel the strings.
	3. If your weight stays the same.

You have chosen an IUD as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
I had tubal sterilization (my tubes tied) 5 years ago and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail, including tubal sterilization (having my tubes tied).
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is tubal sterilization (having my tubes tied). I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin:	1. True
	2. False
Important information to know about tubal sterilization (tying your tubes) is:	1. Tubal sterilization (tying your tubes) does not protect against sexually transmitted infections (STIs).
	2. Tubal sterilization (tying your tubes) does not require surgery.
	3. It is easy to re-open the tubes.
Tubal sterilization (tying your tubes) is a highly effective form of birth control and does not require use of another effective form of birth control while taking isotretinoin:	1. True
	2. False
You have chosen tubal sterilization (tying your tubes) as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
My only partner had a vasectomy 5 years ago and I have not gotten pregnant. Why do I need another form of birth control now?	1. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	2. Any form of birth control can fail.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is my only partner's vasectomy. I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin.	1. True
	2. False

Important information to know about your partner's vasectomy is:	1. Your partner's vasectomy does not protect against sexually transmitted infections (STIs).
	2. Your partner's vasectomy does not require surgery.
	3. It is easy to open the tubes again if your partner wants a child later.
Your partner's vasectomy is a highly effective form of birth control and does not require use of another effective form of birth control while taking isotretinoin:	1. True
	2. False
You have chosen your partner's vasectomy as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
I have had implanted hormones for 2 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	2. Any form of birth control can fail.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is implanted hormones. I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin.	1. True
	2. False
My implantable hormone will only be effective through the first month while I am taking isotretinoin, after that I only need to use one effective form of birth control for the rest of my treatment.	1. True
	2. False
You have chosen implantable hormones as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
Abstinence means no sex at all, 24 hours a day, 7 days a week.	1. True
	2. False
One of the most common causes of unplanned pregnancy is not being able to avoid sex.	1. True
	2. False

<p>You planned not to have sex while taking isotretinoin, so you do not use any birth control. If you decide to have sex, you need to:</p>	1. Work with your doctor to develop a plan to go on birth control before having sex.
	2. Stop having sex until you use your new birth control form for at least 1 month and have a negative pregnancy test.
	3. Start using three forms of effective birth control, just to be sure.
	4. 1 and 2 are correct.
<p>Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.</p>	1. True
	2. False
<p>Important information to know about birth control pills is:</p>	1. You cannot get pregnant while using birth control pills even if you skip pills.
	2. Birth control pills do not protect against sexually transmitted infections (STIs) or HIV (AIDS)
	3. There are no side effects from using birth control pills.
<p>The male condom can help prevent:</p>	1. Pregnancy.
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
	4. All of the above.
<p>For 1 month after your last dose, you must use 2 effective forms of birth control together all the time.</p>	1. True
	2. False