

Division of Diabetes Treatment and Prevention

Diabetes and Birth Control: What the Health Care Team Should Know - July 2014

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Jean Howe:

I'm Jean Howe. I'm an OB/GYN that works at Northern Navajo Medical Center. Prior to working in Shiprock, I also worked at Chinle Comprehensive Health Care Facility. I've worked with the Indian Health Service for 17 years, and I serve as the IHS Chief Clinical Consultant for Obstetrics and Gynecology. I am really happy to talk to you all about birth control, in general and specifically for women with diabetes and pre-diabetes, and history of gestational diabetes, today. I think it's really important and often forgotten. We get caught up in all the other things we need to do for our diabetic patients, and sometimes they don't get access to the birth control that they need.

So with that introduction, let's see how much we can cover in an hour. I have no financial disclosures. I realize that it's recommended to only use generic names for medications but some of these birth control methods, there is only one kind of certain methods, and they're widely-known by their trade names. So despite my best efforts, I may occasionally lapse into using a brand name for a product.

I would like to acknowledge Tony Ogburn and Eve Espey, both past IHS physicians and contraceptive experts who prepared some of these slides. Other slides, I was able to obtain from ARHP, and some are my own.

The objectives are to discuss safe methods of birth control for women with diabetes, to talk about long-acting birth control methods. These are relatively new and very important to know about. To think about which methods are most effective and to think about strategies where we can help women with diabetes avoid unintended pregnancies.

So, what percentage of pregnancies in the United States are unintended? You have some numbers there, take a moment and think about how many people that got pregnant actually planned to get pregnant? So here is the answer. Of the 6.7 million pregnancies in 2010, just under half were unplanned or unintended pregnancies. And of that, 49% of pregnancies, about half of them resulted in an unintended birth, and almost half again resulted in abortion with about 5% ending in miscarriage or fetal loss.

What percentage of women who were having sex with a male partner are using birth control? What do you think? 20 percent? 53? 89? So the answer turns out to be 89%. So if we're looking here -- let me get my little pointer. Let's see if I can move it around. So 89% of women are using birth control and 11% aren't. That 11% that aren't, are half of the unplanned pregnancies. So it's really important we find that 11% and help them get on a method if they don't want to be pregnant right now. Equally important, a little over half were using birth control. So these women are either using birth control inconsistently or using a method that isn't completely effective and may benefit from considering alternative methods of birth control.

So what methods are most women in the U.S. choosing at this point? You've got some choices there. Think about what you think most people are on, and then here is the answer. A survey in 2006 to 2008 looking at most effective, somewhat effective, and less effective methods of birth control, showed that the highest percentage of women are relying on sterilization for their birth control method, with the next



most popular method being oral contraceptives or birth control pills. IUD is only 5.5% nationally at that point. I think in Indian Health Service, we actually see a higher proportion of patients using IUD.

What do women choose when they have access to all available methods and really good information about those methods, because not everyone is able to get birth control without high insurance copays and other barriers to care. So to find that out, there is this really well done, very exciting study, at least exciting to those of us that care a lot about birth control. It's called the, "Choice Study" and it was done in Saint Louis. It's actually still ongoing, the follow up is. They enrolled 10,000 women who wanted birth control with the criteria being they had to be willing to switch to a different method. They just couldn't use it to stay on the method they were already on.

They got industrial strength, evidence-based counseling. They had access to all of the methods of birth control, free of charge, and they were followed for three years. In that circumstance, which is a lot like the circumstance that we are in at sites where all methods are available, almost half of the women picked a levonorgestrel IUD also known as the Mirena.

The next most popular method was a contraceptive implant, it used to be called Implanon, it's now known as Nexplanon, and then the copper IUD was the next most popular after that. Some women are picking Depo, and then pills, patches, and rings followed along after that as well.

So what you see here is 75% of the women are picking what's called a long-acting reversible contraceptive method or a LARC. And here, is a picture of the LARCs that we have available. So that's the Mirena or the Skyla IUD, which is good for five years for the Mirena, three for the Skyla. Highly effective, releases a small amount of progesterone from this part of the IUD. This little implant is really flexible. It's not rigid or anything. It's quite easy to insert. The copper IUD works because there's copper ions that are released to kill sperm. It's effective for up to 10 years, and then this shows you the implant, the Nexplanon, and that's good for up to three years.

So all three of these methods are very effective and long acting. Once they are placed, you don't have to do anything to keep contracepting. In fact, you have to do something to stop contracepting so you don't have to come in to pick up pills or get new prescriptions, or new shots, or anything.

But what adolescents choose is slightly different. The younger adolescents are particularly more likely to favor the implant and older adolescents are more likely to choose the IUD, although, adolescents of any age, like any women, are often candidates for either method.

How do people feel about the methods they picked? Well, it turns out if they pick something long acting like the progesterone or copper IUD or the implant, 80% of them were likely to be highly satisfied with that method. The rates were below 50% for Depo-Provera or for birth control pills.

How long do they keep using them? So the review after 12 months of use showed that women using the long-acting methods, 86% of them were still using their method and plan to continue use, whereas only about half of the women using shots or pills, patches, or rings were likely to be continuing the method they started on. So the other half of these women would be unprotected and that's a concern.

I think this may well be the most important slide in the set. It shows the women that got pregnant during the time that the study was following them. So you see here, the women using a long-acting method or Depo, or pills, patches, or rings, and how many of them were pregnant at the end of the first year. So 4.8% of the pill, patch, or ring users were pregnant after one year, 7.8% after two years, and 9.3% after three years, many more pregnancies than in the groups using the longer-acting methods or that small subset of women who use Depo and really liked the Depo.

So what we've learn from the Choice's Study is that the long-acting methods, the IUDs and the implants, are 20 times more effective than birth control pills, or patches, or rings. If we had a diabetes medication that was 20 times more effective, I think we'd start everybody on that diabetes medication. So we should probably start our discussion of birth control with the most effective methods too and go from there.

The long-acting methods also have very high continuation and satisfaction rates, and ACOG says they should be first line for most women. Another important outcome separately published from the Choice Study, was that the use of LARCs resulted in lower abortion rates and teen pregnancy rates. And for every 108 women who received contraception, one abortion was prevented.

So let's think about individual patients and let's start with a diabetic patient. A 29-year-old who's never been pregnant, who has insulin-dependent diabetes, and she's had PID in the past. She comes in and asks for an IUD. Does that sound okay? Are we worried because of her diabetes, or the fact she's never been pregnant, or the fact that she's had PID before? Where could we go to find out if that's a good idea?

So the CDC has come up with wonderful tools to help us use contraception safely and well. In 2010, they came out with this document, The Medical Eligibility Criteria for Contraceptive Use. It's based on WHO work that has been in place for decades, modified for use in the U.S. to adjust for certain diseases that we have that may not be a problem internationally, medical conditions like after bariatric surgery for example. It sets a standard of care and it provides an evidence-based resource about safety.

A second document was issued last year and it's called "The Selected Practice Recommendations for Contraceptive Use". It includes lots of practical guidance on how to do birth control well in a clinic setting, how to tell if a women is a pregnant or not, what about PID, does she need a pap smear before she starts pills? It addresses all those kinds of nuts and bolts, how to run a family planning program questions. It's great.

So the first document assesses different medical conditions and assigns them a risk category for each method. So a method may be a Category One, no restriction. A woman with a particular condition could use that method quite safely. Or Category Two, the advantages of that birth control probably outweigh any risk from that birth control. Three introduces some caution, the risks with that method probably outweigh the advantages of that birth control, and the Category Four is methods that are considered unacceptable for a woman with that particular medical condition.

Distilled down, green is good. Category Three, the pink category, we should very cautious about, and Category Four, the red category, we should avoid. They initially published this information in the form of a table like this, with different medical conditions listed down along the side here and different methods across here. You can see there's so much green on this table. Most kinds of birth control are safe for most women, which is great news. The table is twice as long, you can print it on the website, you can laminate it, you can have it readily available, or you can get the app. It's free from the CDC website, you can use it on your smartphone and you will have great information about birth control right there, ready for you to use.

Let's look at diabetes in particular and see what they say about the different kinds of methods. So for the condition of diabetes, and then divided out by history of GDM, nonvascular disease-associated diabetes without or with insulin, and then with nephropathy, retinopathy or other vascular diseases. Then the methods, the pills, patches, and rings are the methods that contain estrogen and progesterone. The "I" is for initiation; the "C" is to continue use. Progesterone-only pills, the injection, the Depo-Provera or DMPA injection, the contraceptive implant, or Nexplanon, levonorgestrel IUD or copper IUD.

For women who have a history of gestational diabetes or nonvascular disease-associated diabetes, it's all green. It's fine to use those methods. We do introduce some cautions and concerns here though for women with vascular disease with estrogen containing methods and also with Depo-Provera injections.

So let's just go through those methods and think about what that's about. For women with diabetes, the pink and the red is because of the increased risk of thrombosis or blood clots for women who have vascular disease or long-standing diabetes. So the pills, the patches, and the rings may be a good choice for the women who are early in their diabetic disease, but it's probably something they shouldn't be on later on with advanced diabetes.

The progesterone only method, so these are the progesterone only pills. There are no reminder pills, the person takes a pill every single day, and these are typically used by breastfeeding moms. There's a Depo-Provera shot or the implant. These are mostly green and okay, but there's caution about the Depo-Provera because it seems to alter the lipid profile in a way that may not be good for women with advanced vascular disease.

What about IUDs? Well, it's all green. IUDs are great for women with diabetes. The Copper IUD is a Category One, the Mirena or progesterone IUD is a Category Two because of the tiny bit of progesterone that's on the IUD. However, many women with diabetes are also obese and at risk for endometrial cancer and this progesterone can help decrease their risk of endometrial hyperplasia or cancer. So it may be appropriate to consider either of these IUDs depending on what the woman is interested in and her other risk factors.

To shift gears for a minute, we're still going to talk about IUDs, but let's talk about Trudy, a 16-year-old, who's had four boyfriends in the past year. She has been sexually active with three of them. Her older sister has a Mirena IUD that she likes and she is wondering if she should get one. She was treated for chlamydia four months ago. What do you think? What should we tell her? You're probably thinking D but let's explore the options for her and specifically, let's think about what she is asking for, which is an IUD.

So again, we're seeing the Mirena, very low failure rate, and the copper IUD, and I want to mention the Skyla. The Skyla is the three-year IUD that's a little bit smaller and the introducer is a little bit slimmer, so they're marketing it particularly to the nulliparous women and it's pink which seems to be a lovely marketing technique. This is not widely available at the federal facilities at this point, as I understand it, because it's about twice as expensive as the other IUDs. Paragard and Mirena are in the low \$200s and this in the upper \$400 at federal pricing. It could cost over a \$1,000 at a non-federal site.

Does the IUD cause PID? Well, for the first 20 days after it's placed, there can be a transient increase in the risk of infection, from the placement. After that, the IUD is not shown to increase PID at all. The rates of PID for women using IUDs are no higher than the baseline rate. It's considered a green, Category One or Two, in terms of whether or not someone should have an IUD if they have any history of PID in the past. Obviously, it shouldn't be placed when a person actually has an active infection. It doesn't cause infertility. It's safe to use in nulliparous women. It's safe to use in teenagers, and teenagers are particularly bad pill takers making the IUD even more appropriate, and it's safe for women with a history of an ectopic pregnancy.

There is no particular screening that has to be done beforehand if she's due for gonorrhea or chlamydia screen that can be collected when the IUD is placed. If she's due for a Pap smear that can be done at the same time as the IUD is placed. If she's ready for an IUD, please don't delay it.

There are many times it's appropriate to place an IUD whenever someone comes in looking for birth control. Immediately postpartum, four to six weeks after delivery, after an abortion, or if the IUD has completed its time, it can be removed and a new one inserted at the same visit. So in summary, IUDs are good and Trudy decides she wants an IUD, but she says that by the way, she had unprotected sex two days ago, what should we do about that?

So we have ready access to emergency contraception. All IHS facilities have Plan B available on the formulary and available directly from the pharmacy without a medical visit. This can be either in a single dose or in two tablets that can be taken together or twelve hours apart. There's a second kind of emergency contraception available now by prescription. It's called, Ulipristal or Ella and it is effective up to five days after unprotected intercourse, and it seems to be more effective than Plan B especially further out from the exposure, and it's especially an issue for overweight women. Women who are obese are three times less likely to be protected by emergency contraception Plan B and they may be better served by the Ulipristal. Another alternative for any women seeking emergency contraception is an IUD. The copper IUD is the most effective form of emergency contraception available, and up to 12% of women in one study indicated that that's what they would choose if they could have it the same day.

Another patient to think about, and use our medical eligibility criteria for, is Samantha. Samantha is a 17-year-old, who is breastfeeding the baby girl she delivered yesterday. She wants to get an implant before she goes home. What do you think? Is that a good idea and what advice do we have for her about birth control? So, consulting our medical eligibility criteria, we see that the methods with estrogen are not a good choice immediately after delivery. We can see that the pills, patches and rings for the first three weeks are absolutely forbidden because of the combined risk of blood clots from the estrogen-containing method and from the recent pregnancy. That from three weeks to six weeks out, it's still in Category Three and better avoided but starting -- I'm sorry, 42 days out without other risk factors, it would be appropriate to consider those methods. The progesterone-only method, since she's asking about an implant, are Category One and Two for breastfeeding and non-breastfeeding women and could be started prior to her going home from the hospital.

This shows the Nexplanon. It's a slim little capsule. It's a single capsule some of you may remember Norplant, six capsules. This is just one capsule, and it works by preventing ovulation and thickening the cervical mucus. It provides three years of protection. Very, very low failure rate, and very few women who can't use it. It's four centimeters long, two millimeters wide, has this etonogestrel progesterone in it and a rate controlling membrane to slowly release it, and it's placed with this nifty little inserter device. You can see the inserter needle is here underneath this plastic sheath that's removed, and it slips under the skin and then the inserter is designed so you can't place it too deeply. Typically, you can't see across the room that a woman has an implant in her arm but if you ran your finger over the skin, you would be able to feel it just under the skin. And I'm sorry, at the end of three years, an implant can be removed and a new one placed at the same time, in the same spot.

The Depo-Provera shot; it's a three-month injection. I'm sure most of the people listening are familiar with it. Our concerns about Depo-Provera are irregular bleeding, and many women experience weight gain. The manufacturer says the weight gain is five pounds a year. The overall weight gain experienced by Native women in one study was more on the order of seven pounds a year. We've seen women gain as much as 20 pounds a year with Depo. For the women who don't gain weight or otherwise love this method, it can be a good fit for them, or they may use it as a bridge to getting a longer-acting method.

Some of you may have been cautioned away from Depo-Provera by a black box warning with concerns about bone mineral density. The FDA recommended that Depo-Provera not be used for more than two years, but concluded that it was still safe and effective. Evidence, when reviewed by the World Health Organization with CDC, shows that bone density is lower in current users but when people stop using

Depo, their bone density rebounds quickly. You can use Depo right up to menopause and women who then stop it at menopause actually have slower bone loss than those experiencing natural menopause. There is no documented link between Depo-Provera use and increased menopausal osteoporosis or fracture. So, for people that desire to use Depo they should be allowed and encouraged to do that, as long as they meet the medical eligibility criteria.

Another patient, moving right along here, Mandy comes in. She's there because she has a bladder infection, but by the way she's been having sex for three months. She has a negative pregnancy test, that day and she doesn't want to get pregnant, she's interested in starting birth control pills. So if she needs birth control today, that's an emergency today, and we need to go ahead and help her get started on something.

So before we give her pills, do we need to do any of these things? Pap smear? She's only 17, not until she's 21, and we wouldn't do it before we gave her pills as a requirement anyway. Does she need a screening for gonorrhea, chlamydia, or other sex infections? What does she need done? So she doesn't need a pelvic exam. If she's due for gonorrhea and chlamydia screen, she can do that with a urine test. She should only really need a pelvic exam if she has other particular symptoms that would necessitate that evaluation. The selected practice recommendations for contraceptive use say it's not required.

So you're going to give her pills after discussing all her alternatives with her. Should she start them the next Sunday after the next period? On the first day of her next period? Today? What should she do? So traditionally, we've told people to start birth control pills with taking the first pill on the first Sunday of their next period, and then to continue on from there. By the time people get to the next period, they may not start the pill at all. They may not get to that next period. They may be pregnant in the meantime.

So instead, what's recommended is a quick start approach where she can start on any day of the cycle. She can be given the first pill to take right there in the clinic. She should be encouraged to use a backup method for seven days. And this is really good evidence that a quick start approach is appropriate. Women who started pills with a quick start were three times more likely to start their second pack of pills as women who did not start that day. Many women get pills and then don't continue them.

There's also extended dosing regimens. These are packages that have 84 active pills and then 7 placebo pills so that ideally people will have their withdrawal bleed at the end of three months or once a season, instead of every 28 days. Initially, people can experience more breakthrough bleeding. This improves over time.

Morgan, yet another patient. Morgan is a patch user but she's heard that the patch might be causing more blood clots. She really doesn't want to get pregnant and she's thinking about switching to condoms because she's scared, what should she do? So Ortho Evra is a brand name of the transdermal patch, its estrogen and progesterone. It is applied and worn for a week, replaced with another patch then another patch, and then there's a patch free week where she has her menses.

In general, people like patches a little bit more than pills, but there's an FDA black box warning for both the patch and for drospirenone, which is progesterone in some pills, in both cases citing a concern for increased risk of venous thromboembolic disease or blood clots. Blood clots are also more common in pregnancy. Women deserve to know this information and choose their method appropriately. All contraceptive methods are safer than pregnancy, but this is of concern to many young women, and she may want to switch to a different method or continue the patch with reassurance.

The NuvaRing, one of the newest methods available, is a little flexible ring that's placed in the vagina and worn for three weeks and then removed, and during that ring-free week, a person will experience her menses and then place the next ring for three weeks. It's very effective when used as directed and has rare breakthrough bleeding. The NuvaRing just needs to be folded and place in the vagina. If it's in the vagina, it's in place. It doesn't fall out very much, only 1% to 2% of the time, and if it falls out, it just needs to be put back in. It can be rinsed off with lukewarm water and replaced as long as it's not out for more than three hours, it doesn't suffer any decrease in effectiveness.

Yet another patient, Sylvia. Sylvia comes in and says she wants her tubes tied. Sylvia is 38 years old. She's had four pregnancies with C-sections. She's morbidly obese and has severe asthma. She's also had a history of a blood clot. Everybody's idea of a great surgical candidate, right? So what can we offer Sylvia? She tried a Mirena in the past, and she was one of the rare women who had constant bleeding with it and so ceased use and would like to switch to something else.

So I would to just let you know about one other method that may be appropriate for a patient like Sylvia, and that's Essure. So this is a hysteroscopic sterilization procedure. So it works through the vagina and then up through the cervix. A little flexible coil is placed in either tube and both tubes are then blocked over time by some scarring that occurs around the coil.

It's highly effective, and can be a great method for women who may have increased risk with traditional surgical sterilization because it avoids an abdominal incision. It generally requires less sedation and has a pretty quick recovery. But it isn't effective immediately, an x-ray needs to be done three months later to make sure the tubes are indeed blocked so someone will need back up contraception and you need someone who's trained to place it.

Our last patient is Melva. Melva is 21 and comes in asking for birth control. She got pregnant on the pill and she's heavier, and she reports that her mom told her the pills don't work when you're heavy, she heard that on TV. So what is the effect of weight on pills, patches, and rings? Well, for patches, there is some concern for decreased effectiveness. The package insert says that it can't be considered highly effective for women weighing over 198 pounds. Some women still do choose to use it at a weight over that. For the pills there's limited data but concern that they may be somewhat less effective in heavier women, and for the ring, no increase in pregnancy rates has been documented in a single study.

So what should we tell our obese patients? Overall, maybe a two-fold increase in pregnancy with hormonal methods over long-acting methods but they can still be highly effective if they're used as directed. Still much safer than pregnancy. And why not consider a long-acting method instead? As far as the Implanon and weight, in the Choice Study, they compared Implanon users and IUD users, and at the three-year follow up rate, the pregnancy rate was less than 1% in both groups and did not vary by the patients' weights.

For diabetic patients, I think we should consider every visit a preconception visit for our reproductive age diabetic women. We should be asking women about their pregnancy plans, and if they don't plan to be pregnant right now, we need to ask them about their needs for contraception, and their interest in contraception. And one particular concern I really couldn't give this talk without sharing with you, is about starting metformin. It's a very common scenario for us to see women who got started on metformin for their diabetes, and maybe were told that it might make some a little more fertile and offered contraception, they said, "No, I haven't gotten pregnant for years. I don't need anything." And then six months later they're in our clinic, with a new diagnosis of pregnancy and hopefully a better controlled A1C but not always.

I hope you all realize that we actually use metformin as an infertility treatment, and women who thought they didn't need anything before metformin may well-benefit from considering contraception at the time they're going to start metformin. But really, you should be talking to everyone about birth control.

Diabetes preconception care, it really matters what someone's A1C is, when they conceive. That high glucose in the first trimester is teratogenic. It also causes very high rates of miscarriage. This is an old graph using hemoglobin A1, not A1C, but if this were the A1C, this would be about 8.5, and then 9.5, and you can see the percent of pregnancies in this particular study that had either congenital anomalies or miscarriage.

Women with diabetes, to help mitigate this risk, really need to get their glucose under good control preconceptionally, if at all possible. They should be on supplemental folic acid, striving to get to a healthy weight prior to pregnancy and stopping any teratogenic drugs. We especially encourage them to not be on statins or ACE inhibitors to name a couple of drugs that are commonly used in diabetes care.

Of course the best method for birth control is the one that patient likes and wants to use, so how can we help her decide? There are a couple of great online tools. One is Method Match. It's from the Association of Reproductive Health Professionals. It's a great website. It offers you this listing; here I've got it sorted by effectiveness. It will also sort by a number of other criteria. You can do, so here's the sorting by criteria, here's selecting some methods and comparing them. Each method has a nice little video. There is also prepared handouts in there so you could click through methods with someone and then print the evidence-based handout directly from the website for them.

Another more risqué, but quite fun website for birth control is bedsider.org. This has a very nice interactive interface where you can click on each of these methods and learn more about them. What I particularly like about Bedsider for couples is that each of the methods has two or three videos of a young woman choosing the method but there is always at least one video of her partner and what he thinks about her using the method. It can be a great tool for young couples deciding what they'd like to use for contraception.

Of course, we don't want to forget about condoms. They are somewhat effective for birth control, also highly recommended to prevent sex infections. And my closing thoughts, consider every visit with a reproductive age woman an opportunity to discuss birth control. If nothing else, let her know she can get Plan B, if she doesn't need anything now but might have unanticipated need for something in the future. And if she wants birth control, get her something that day.

Here are some links to the resources, and these two websites are the great patient education tools. Thank you so much.

Jan Frederick:

Thank you Dr. Howe. We do have time for questions if anyone wants to enter questions in the question box on the bottom of your screen. We had one really early on Dr. Howe from Deborah. Can you see that one or do you want me to read that comment?

Jean Howe:

I can see that, it looks like it's about a type I diabetic who is using Depo, and is having more trouble with her blood sugar. So whether Depo is a good choice for her would depend on how long and how severe the effects of her diabetes were. But if she's putting on extra weight, that could be interfering with her diabetic control as well and she could consider switching to any of the other methods with a special emphasis on the long-acting methods.