The Daunting Downside of Depo Provera Injections

1. High discontinuation rates & high pregnancy rates in typical users.
2. They are not on hand when needed
3. They are not on hand when needed
4. Missed periods or very, very light periods
5. Spotted or irregular vaginal bleeding
6. Missed periods or very, very light periods

Summary of other negative aspects of providing Depo Provera:

1. High discontinuation rates & high pregnancy rates in typical users.
2. Requires women to return to a clinic every 3 months.
3. Requires women to return to a clinic every 3 months.
4. Weight gain - particularly in women who are over-weight when they start to receive Depo injections. The average weight gain is 5.4 lbs in the first year and 16.1 lbs after 5 years. (Schwalme 1993)
5. Irregular bleeding for the first few months leading to the absence of bleeding in 50% of women at 1 year.
6. The final word is not in bone mineral density and Depo Provera. All women using DepoProvera including terms should be taking in sufficient calcium in diet or be encouraged to take calcium supplements.
7. What mistake Bob Hatcher, was the most serious mistake you make repeated in providing contraceptives over the past several decades?

Example: Structured counseling for Depo-Provera*

- The message: Depo-Provera will change your periods. No woman-periods stay the same as they were before starting Depo-Provera. Ask: “Will you find it acceptable if there are major changes in your periods?” If no, steer clear of DMPA (as well as progestin-only pills, Implanon, Mirena).
- Have the patient repeat back her understanding of the message, particularly the fact that, over time, women stop having periods most months. Women tend to have very irregular menstrual cycles almost immediately.
- Use of a clear, concise videotape
- Asking the patient if she has questions about the videotape
- Written instructions that clearly highlight the key messages
- Asking at each 3-month visit what has happened to a woman’s pattern of bleeding, whether amenorrhea has begun and how she feels about her pattern of bleeding

Checklist for Depo-Provera patient to fill out at each follow-up visit.

- Please check yes or no. Tell us if you have/are:
  - Spotted or irregular vaginal bleeding
  - Missed periods or very, very light periods
  - Concern over your pattern of vaginal bleeding
  - Depression, severe anxiety or mood changes
  - Gained 5 pounds or more
  - Questions you have about Depo-Provera injections
  - Any wrist, hip or other fractures
  - Using calcium supplements
  - Getting regular exercise

Structured Counseling

Carefully planned structure counseling may include:

- Repetition of a specific message at the time of the initial visit
- Having the patient repeat her understanding of a message
- Use of a clear, concise videotape
- Asking the patient if she has questions about the videotape
- Written information and instructions that highlight key messages
- Repetition at each follow-up visit
- Checklist for patient to fill out at each follow-up visit

Structured Counseling for Depo-Provera Patients Works!

- Discontinuation rates for DMPA users at one year are high in the absence of structured counseling: 40.6% in a large U.S. study of 3857 women leading to FDA approval of Depo-Provera (Schwalme, Fertil Steril 1973); 53% in a New York study of low-income women (Paleneczky, 1996); 71% in an urban Texas setting (San-Gio-Haghpeykar 1996).
- Importance of focused, structured, repeated counseling at initiation and follow-up visits can’t be overstated.
- Structured counseling may increase adherence, having patient repeat back instructions, showing videotapes, providing videotapes, audiotapecs and written instructions and asking focused questions such as “What has happened to your pattern of bleeding?” “Have your periods become extremely light?” or “Does your pattern of bleeding bother you?” rather than unfocused questions like “Do you have any problems?”

Structured counseling in Mexico lowered DMPA discontinuation associated with three bleeding problems: amenorrhea, irregular bleeding and heavy bleeding, from 52% to 8%. Discontinuation from amenorrhea fell from 71% to 3%; from SFP or BTP from 10% to 2%; and from heavy bleeding from 5% to 2%. (Canto-DeCetina, 2001).

- Weight should be taken at each visit and weight control discussed carefully if there has been weight gain.

Example: Structured counseling for Depo-Provera*

1. They are not on hand when needed
2. We are not all at risk/stop couples from using condoms
3. The 18% failure rate in the next 12 months for typical women depending on condoms is simply too high!
4. In some relationships women are subjected to violence if they strongly request a certain method used.
5. Given the embarrassment it causes men and women to return repeatedly to clinics, providing them only 3-12 condoms per visit is ineffective and insensitive.
6. 2-3% of American men and women are allergic to latex.
7. The complaint that condoms blunt sensation or feel unnatural is a common reason to stop using condoms.

Condoms, Pills, and Depo-Provera injections are the three reversible contraceptives most commonly used in the United States. Each of them has failure rates in typical users many, many times higher than the failure rates of implants and IUDs.

The Daunting Downside of Condoms, Pills, and Injections.

Note the absence of decimal points. This chart points out how much more effective Nexplanon is than pills.

Nexplanon has a typical use failure rate of 0.6%. But what does 0.6% mean?

This chart shows you!

- Estrogen increases risk for stroke, heart attack, and blood clots.

This ingenious method of explaining the differences in typical use failure rates by placing the number of pregnancies in the first year in 10,000 typical users. It comes to you because of the creative genius of Dr. Claude Burnett in Athens, GA. It was derived from James Trussell’s table 5.2 on page 50 of Contraceptive Technology, 20th ed. 2011.

WORLD’S BEST BIRTH CONTROL

CONTRACEPTIVE METHOD

PREGNANCIES
IN 10,000 TYPICAL WOMEN

NEXPLANON
5
MALE STERILIZATION
15
MIRENA IUD
20
FEMALE STERILIZATION
50
PARAGARD IUD
80

Condoms

- Condom breakage happens during from 1 in 50 to 1 in 100 acts of intercourse.

When we see women and men who have experienced multiple breaks or slippages, we would be wise to encourage them to use 2 condoms.

Here are the problems with condoms:

1. They are not on hand when needed
2. We are not at risk/stop couples from using condoms
3. The 18% failure rate in the next 12 months for typical women depending on condoms is simply too high!
4. In some relationships women are subjected to violence if they strongly request a certain method used.
5. Given the embarrassment it causes men and women to return repeatedly to clinics, providing them only 3-12 condoms per visit is ineffective and insensitive.
6. 2-3% of American men and women are allergic to latex.
7. The complaint that condoms blunt sensation or feel unnatural is a common reason to stop using condoms.

Condom breakage happens during from 1 in 50 to 1 in 100 acts of intercourse.
By far the most important downside of oral contraceptive pills is that they must be taken every day, but the average woman misses 4.2 pills each month leading to a 9% failure rate in typical women. Consider this: of the 11 million women using pills each year, 1 million become pregnant (Nelson, Satak, Contraceptive Technology 20th Ed., p249) and 40% of those women choose to have an abortion. If we are to continue using combined pills it becomes the responsibility of all providers and of women using pills to do something about this 9% failure rate. It is analogous of the FBI telling us "if you see something, do something.

Although quite uncommon estrogenic birth control pills may cause blood clots and pulmonary emboli. These may be fatal if not recognized and treated quickly. See A-C-H-E-S mneumonic used to teach the pill danger signals:


NOTE: Many of the symptoms women complain of after starting pills (nausea, headaches, bloating) occur more frequently during the days a woman is on placebo pills. Therefore, ask women when they have these symptoms. Symptoms occurring primarily during the placebo days may be an indication for continuous or extended use of pills (Suk-2002).

• Venous thromboembolism (VTE)

Pregnancy/Postpartum 200/100,000 women per year

COC use 100/100,000 women per year

Pill, Patch and Ring Warning Signals

Abdominal pain - Blood clot in pelvis, liver or mesenteric vein

Chest pain - Blood clot in lungs, cough, cough up blood, placebo gain or pain

Headache - Severe pain, visual problems, numbness or paresthesias

Eye problems - Retinal vein thrombosis, tunnel vision, partial or complete loss of vision

Severe leg pain - Swelling, heat, redness or tenderness in lower leg or thigh

NOTE: None of these symptoms is an indication for discontinuing COCs; all patients should be reassured that the continued use of pills is not itself associated with these problems. However, clinicians should carefully evaluate women who report these symptoms, especially if they are accompanied by evidence of a serious illness, such as chest pain or stroke.

"Nocebo" Phenomenon:

• According to Dr. Grimes and Ken Schulz, leading epidemiologists, counseling about side effects from OCPs and including them in the product label, is "unwarranted and probably unethical" since placebo-controlled randomized trials show no difference in side effects. They call this the "nocebo" phenomenon: if women are told to expect noxious side effects, they may occur due to power of suggestion. Or they may reflect prevalence of side effects in the population. (Non-specific side effects of OCPs: nocebo or noise? Grimes DA, Schulz KF; Contraception 83 (2011) 5-9.

Menstrual:

• Spotting, particularly during first few cycles and with inconsistent use

• Scarf or missed menses possible, not clinically significant but can cause worry

• Post-pill amenorrhea (lasts up to 6 months). Uncommon and usually in women with history of irregular periods prior to taking pills

Sexual/psychological:

• Decreased libido and anorgasmia ARE possible.

• Mood changes, depression, anxiety, irritability, fatigue may develop while on COCs, but no more frequent than with placebo. Rule out other issues before implicating COC.

• In a longitudinal study of over 9000 women in Australia, OCP use was not associated with depressive symptoms (Duke-2007).

• Daily pill taking may be stressful (especially if privacy is an issue)

Cervical cancer:

• No consistent increased risk seen for squamous cell cervical cancer (85% of all cervical cancer) after controlling for confounding variables, such as number of sex partners, smoking and parity

• Risk of adenocarcinoma, a relatively uncommon type of cervical cancer, is increased 60%, but no extra screening required other than recommended Pap screening

• Hepatocellular adenoma: risk increased among COC users (only in > 50 μg formulations). Risk of hepatic carcinoma not increased, even in populations with high prevalence of hepatitis B

Other:

• No protection against STIs, including HIV

• Sheding of HIV may be slightly increased with use of some antiretrovirals

• Nausea or vomiting, especially in first few cycles

• Breast tenderness or pain

• Headaches: may increase

• Increased varicocities, chloasma, spider veins

• Daily dosage is difficult for some women

• Average weight gain no different among COC users than in placebo users (see note below)

**NOTE:** Medical problems and symptom complaints are frequently attributed by patients and providers to COC use. While some women may be particularly sensitive to sex steroids, a recent placebo-controlled study found that the incidence of all of the frequently mentioned hormone-related side effects was not significantly different in the COC group than it was in the placebo group (Redmond, 1999). For example, headaches occurred in 18.4% of women on Ortho Tricyclen and in 20.5% of women in the placebo group. Nausea occurred in 12.7% of women on Ortho Tricyclen and in 9.0% of women on placebo pills. Weight gain occurred in 2.2% of women on Ortho Tricyclen and in 2.1% of women on placebo pills. For some women, however, these complaints may actually be related to pill use

COMPLICATIONS

Venous thromboembolism (VTE)

• The risk of VTE with COC use is less than with pregnancy:

DVT risk is associated with the dose of estrogen; the risk of VTE in 50 μg pills is greater than in 20-35 μg pills. The type of proges- tin may slightly influence DVT risk. A meta-analysis by Hennessy et al (2002) included 12 observational studies and found a summary relative risk of 1.7 (1.3 - 2.1; heterogeneity p = 0.09) but could not rule out confounding given nature of observational studies. If read, the excess risk was 11 per 100,000 women per year. The current labeling for desogestrel pills states that "generally, available studies indicate that third generation OCs, including those containing desogestrel (Drospirenone), are associated with a higher risk of venous thromboembolism than certain second generation OCs. In general, these studies indicate an approximate 2-fold increase in risk. However, data from additional studies have not shown this 2-fold increase in risk. According to leading epidemiologists, counseling about side effects from OCPs and including them in the product label, is "unwarranted and probably unethical" since placebo-controlled randomized trials show no difference in side effects. They call this the "nocebo" phenomenon: if women are told to expect noxious side effects, they may occur due to power of suggestion. Or they may reflect prevalence of side effects in the population. (Non-specific side effects of OCPs: nocebo or noise? Grimes DA, Schulz KF; Contraception 83 (2011) 5-9.

Myocardial infarction (MI) and stroke

• There is no increased risk of MI or stroke for young women who are using low-dose COCs who do not smoke, do not have hypertension and do not have migraine headaches with neurological findings

• Women at risk:

Smokers over 35 shouldn't use COCs; all smokers should be encouraged to stop smoking.

Smokers over 35 have MI rate of 396 per million COC users per year vs. 88 per million non-COC users per year

Women with hypertension, diabetes, hyperlipidemia or obesity

Women with migraine with aura (only stroke risk increases)

Hypertension: 1% of users develop hypertension which (usually) is reversible within 1-3 months of discontinuing COCs. Most users have a very small increase if any in blood pressure.

Neoplastic COC users (early use of COCs) are at higher risk of developing adenocarcinoma (rare) of the cervix and hepatic adenomas (rare). See boxed message on Page 114 of Managing Contraception for an answer to the question: Do birth control pills cause breast cancer?

Many years after stopping oral contraceptive use, the main effect may be against medistatic disease. Spillers and Denny-2001 [World Health Organization Collaborative Group, Lancet-1996].

Cholelithiasis/cholecystitis: higher dose formulations were associated with increased risk of symptomatic gallbladder disease

Sub-50 mcg formulations may be neutral or have a slightly increased risk

Use COCs with caution in women with known gallstones. Asymptomatic (US MEC2), treated by cholecystectomy (US MEC2), symptomatic and being treated medically (US MEC3) and current and symptomatic (US MEC3).

Visual changes: Rare cases of retinal thrombosis (must stop pills). Contact lens users may have dry eyes. May need to recommend eye drops or need to switch methods.