



The following slides are intended to familiarize nurses and clinicians with oral contraceptive pills (OCPs) used in the NM Family Planning Program (FPP). The FPP does not intend for this information to supersede the Family Planning Protocol particularly on the requirement for Public Health Nurses in the Public Health Offices to consult a clinician as stated in the Protocol when in doubt or if it is necessary to switch the client's OCP type.

Presentation Objective

Provides

- The basic principles of how to choose oral contraceptive pills (OCPs).



Selecting a (combined E+P) OCP to initiate

- Choose an estrogen dosage
 - E provides endometrial stability = cycle control
 - ↑ E = ↑ VTE (clot) risk
- Choose a progestin type (generation)
 - P provides most of the contraceptive effect
 - Prevents LH surge, thickens cervical mucus
- Monophasic vs. Multiphasic

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Combined oral contraceptives (COCs) contain two hormones; estrogen and progestin. In general, any combined OCP is good for most women who are eligible to take estrogen according to the CDC U.S. Medical Eligibility Criteria (MEC). Once again, refer to the US MEC chart to find out if OCP is a suitable choice for clients with specific health conditions.

To learn a little bit about what each hormone does, the FPP is providing the following summary:

Estrogen: provides endometrial stability = menstrual cycle control.

A higher estrogen dose increases the venous thromboembolism (VTE) or clot risk but OCP clot risk is still less harmful than the clot risk related to pregnancy and giving birth.





Progestin: provides most of the contraceptive effect by

- Preventing luteinizing hormone (LH) surge /ovulation
- Thickening the cervical mucus to prevent sperm entry.

Two major OCP formations are available.

Monophasic: There is only one dose of estrogen and progestin in each active pill in the packet; and

Multiphasic: There are varying doses of hormones, particularly progestin in the active pills.

<i>Class</i>	<i>First Choice</i>	<i>Second Choice</i>	<i>Third Choice</i>
I. 20 mcg. ethinyl estradiol (ee) (CI-20)	0.1 mg levonorgestrel/ 20 mcg ee <i>May include:</i> Aviane Orsythia Lessina Sronyx Lutera	1 mg. norethindrone/ 20 mcg ee <i>May include:</i> Gildess Fe 1/20 Junel Fe 1/20 Loestrin Fe 1/20 Microgestin Fe 1/20	
II. 30 mcg. ee (CII-30) 	0.3 mg. norgestrel/ 30 mcg. ee <i>May include:</i> Cryselle Low-Ogestrel Lo/Ovral	0.15 mg.levonorgestrel/ 30 mcg. ee <i>May include:</i> Altavera 0.15/30 Levora Nordette Portia Seasonique	1.5 mg norethindrone/ 30 mcg ee <i>May include:</i> Gildess Fe 1.5/30 Junel Fe 1.5/30 Loestrin Fe 1.5/30 Microgestin Fe 1.5/30
III. 35 mcg. ee/ Norethindrone (CIII-35)	1 mg. norethindrone/ 35 mcg. ee <i>May include:</i> Alyacen 1/35 Cyclafem 1/35 Necon 1/35 Norinyl 1+35 Nortrel 1/35 ON 1/35	0.5 mg. norethindrone/ 35 mcg. ee <i>May include:</i> Aranelle Brevicon 0.5/35 Modicon Necon 0.5/35 Nortrel 0.5/35	0.4 norethindrone/ 35 mcg. ee <i>May include:</i> Balziva Briellyn Ovcon 35 Zenchant 
IV. 35 mcg. ee/ Norgestimate (CIV-35) 	0.25 mg.norgestimate/ 35 mcg. ee <i>May include:</i> MonoNessa Ortho Cyclen Previfem Sprintec	OCP Substitute Table	

Section 3 of the FPP Protocol contains the OCP Substitute Table, which groups OCPs into 6 classes according to the estrogen dosage, the type of progestin and the formulations. The slide shown here only captures 4 classes, Classes I, II, III and IV. The other 2 classes: Class V is progestin-only pills (POP) and Class VI is triphasic OCPs.

The First, Second and Third Choice columns grouped OCPs with the same estrogen dose and the same progestin type together.

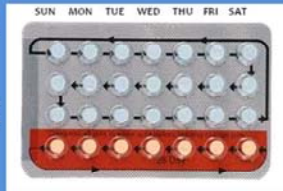
When placing a Title X FPP pharmacy order, it may be helpful to refer to this table because the FPP will assure that Pharmacy warehouse carries at least one kind of pill in each class at all times.

In addition, having the OCP poster shown in the background of the previous slide is useful in educating clients that there are many kinds of pill with identical hormone contents.

Ethinyl Estradiol (EE) in most OCP's Dosage: 20, 25, 30 and 35 mcg – low dose

MONOPHASIC

- Class I 20 mcg EE
- Class II 30 mcg EE
- Class III 35 mcg EE
Norethindrone
- Class IV 35 mcg EE
Norgestimate



MULTIPHASIC

- Class VI Tri-phasic Pills
25 mcg EE



Class V PROGESTIN ONLY PILL (POP)

Speaking a little bit more about estrogen and its dosage in the OCPs. The woman's ovaries produce estradiol. Most COCs in the U.S. contain a synthetic estrogen, ethinyl estradiol (EE). All of the FPP pills contain low dose estrogen: 20, 25, 30 and 35 mcg. They are equally effective and very safe. Notice that Classes III and IV OCPs both contain 35 mcg EE but they have a different progestin type.

The monophasics generally come with two pill colors; 21 active pills of the same color and the 7 placebo pills with a different color.

The triphasic pills have 4 sets of colors. Each of the 3 active pill sets contains 7 pills. Each set has a different color, which is not the same as the seven placebo pills.

Class V progestin only pills (POP) contains 28 active pills; all in the same color. There are no placebo pills. It is very important that all the pills in POPs are taken around the same time every day.

20 mcg vs. 30-35 mcg EE

- No difference in pregnancy rate
- 20 mcg:
 - may be considered in clients who wish to lower estrogenic side effects e.g. clients with nausea, CV or VTE risk factors
 - may have higher rate of BTB/amenorrhea
- 30-35 mcg:
 - better for bone density due to higher estrogen dose
 - may be considered for BTB

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In preventing pregnancy, there is no difference in the efficacy among various COCs. But in certain clinical situations, there may be an advantage in choosing a specific estrogen dosage, such as:

- If a woman has nausea with a OCP containing >20mcg of estrogen, switching to a OCP with a lower estrogen dose or taking it with food or at bedtime can help.
- If a woman has break through bleeding (BTB)/spotting or amenorrhea, switching to a higher estrogen OCP might help.
- If a woman develops breast tenderness/enlargement or darkening of facial skin, switching to a lower estrogen OCP might help.
- If a woman has multiple cardiovascular/VTE risk factors such as >35 yr. old, obese, smoker, diabetes mellitus, hypertension, a lower estrogen pill might be more suitable.

Monophasic vs. Multiphasic Formulations

- **Monophasic** – same estrogen and progestin dose for all active pills
- **Multiphasic** – usually triphasic increasing progestin dose weeks 1-3



Mimics luteal phase
Less total progestin per cycle
Theory: minimize (progestin) side effects e.g.
bloating, depressive symptoms, fatigue, constipation

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In terms of formulations, the multiphasic pills were designed to mimic luteal phase of a women's cycle. They contain less total progestin per cycle and in theory, could minimize progestin side effects such as bloating, depressive symptoms, fatigue and constipation.

Choosing a Progestin in OCPs

- First generation: Norethindrone
- Second generation: Norgestrel, Levonorgestrel
- Third generation: Norgestimate
- **Fourth generation: Drospirenone**
not on the FP formulary b/c VTE risk concern

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Now let's talk about progestins. There are 4 major generations of progestins in the U.S. OCPs. The fourth generation, Drospirenone was found in a 2008 FDA-funded study that it *may* increase risk of VTE. The FPP does not have OCPs containing Drospirenone, 4th generation progestin.

The next slide will provide an overview of the differences between the 3 progestin generations:
Norethindone (1st generation), Norgestrel and Levonorgestrel (2nd generation), and Norgestimate (3rd generation).

Dosing of progestins can't be compared mg to mg from one type to another.


	Progesterogenic Potency	Androgenic Side Effects	
		↑	↓
Norethindrone (1 st generation) Class III: Norinyl 1/35, Nortrel POP: Micronor, Nor-QD	+	Negligible androgenic S/E	
Norgestrel Levonorgestrel (2 nd generation) Class II: Cryselle, Levora, Portia	+++	-Lipids adverse effects -Acne -Oily skin -Facial hair -↑ Libido	Class I
Norgestimate (3 rd generation) Class IV: Orthocyclen, Previfem Class VI: Ortho TriCyclen Lo	++ -Less moody -Less bloating		-Treat cystic acne -Prevent hirsutism

Table adapted from Contraceptive Technology, 20th Edition, Chapter 11

When looking at progestins in OCPs, there are two clinical aspects to consider :

- its potency as progestin
- the androgenic side effects.

1st generation progestins are not very potent and have negligible androgenic side effects. Pills that contain 1st generation progestin/Norethindrone are Class III OCPs e.g. Norinyl 1/35, Nortrel and POP (Class V) e.g. Micronor.

2nd generation progestins were designed to be significantly more potent than the 1st generation and have longer half life. They are also used in Mirena. They are associated with more androgenic effects such as ↑ Low-density lipoprotein or LDL cholesterol, acne, oily skin, facial hair and increased libido. OCPs that contain 2nd generation progestin/Norgestrel or Levonorgestrel are Class I and Class II OCPs.

3rd generation progestins are just as potent but designed to reduce androgenic side effects allowing a fuller expression of the pill's estrogen effect. This has some clinical benefits such as use to treat cystic acne, prevent hirsutism. OCPs that contain 3rd generation progestin/Norgestimate are Class IV OCPs e.g. Orthocyclen and Class VI phasic pills e.g. Ortho Tri-Cyclen Lo.

Extended-Cycle OCPs



Seasonique

- Is considered a Class II OCP that is continuous, with no placebo intervals.
- 84/7
 - 84 pills containing 30 mcg EE and 2nd generation progestin-levonorgestrel.
 - 7 pills containing 10 mcg EE in an attempt to reduce *unscheduled* bleeding/spotting sometimes associated with a hormone-free interval .
- With Seasonique, the period cycle is expected every 3 months and to last approximately 4 days.

The FPP has one extended-cycle OCPs in the formulary, Seasonique. It is considered a Class II OCP that is continuous with no placebo pills.

There are 84 pills containing:

-30 mcg EE and levonorgestrel progestin, and

-7 pills containing only 10 mcg EE with no progestin. The addition of 10 mcg EE is an attempt to reduce unscheduled bleeding/spotting that is sometimes associated with a hormone-free interval seen in the discontinued produce, Seasonale.

With Seasonique, the period is expected to occur every approximately 3 months and expected to last approximately 4 days (as opposed to 7 days with Seasonale).