

Objectives

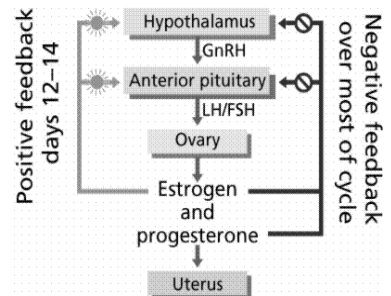
- * Review the menstrual cycle
- * Develop a detailed understanding of the risks and benefits of hormonal contraception
- * Understand the pros and cons of various contraceptive options
- * Be able to identify individual patient characteristics applicable to contraceptive choice

How is our control of fertility?

- * Half of pregnancies are unplanned
- * 25% of pregnancies end in abortion
- * One million unintended adolescent pregnancies each year
- * By age 19, 86% of males and 75% of females are sexually active
- * 12 million cases of STDs each year

- * 40% of women think using the pill is riskier than child birth
- * All methods of contraception have some risks associated
- * Best contraceptive---no sex

Menstrual Cycle Summary of Hormonal Changes



Menstrual Cycle

- * Average cycle is 28 days
- * Controlled by hormonal feedback

3 Main Phases

- * Follicular (Menstrual/Proliferative)
- * Ovulatory
- * Luteal or Secretory

Follicular or Proliferative Phase

Approximately 14 days in length and dominated by estrogen

- 1 Onset of menstruation
- 2 Proliferatory phase of uterus

Ovulatory Phase

- * Dominated by estrogen which remains high enough to cause LH surge
- * Ovulation occurs on day 14 - 15 in the average 28-day cycle

Luteal or Secretory Phase

- * Progesterone dominated
- * Progesterone causes the uterus to prepare for implantation of the fertilized ovum
- * Length 14 days

Role of the Clinician

- * Provide sufficient education for patients to make a choice of contraceptive.
- * Help make decisions based on an individual's personal, social and medical characteristics.

Patient Assessment Patient History

- * Medical & Family history
- * Gynecologic/Menstrual history
- * Sexual history
- * Smoking
- * Contraceptive history
- * Hormone sensitivity

Patient Assessment Baseline Parameters

Physical Exam

- * Blood pressure
- * Thyroid exam
- * Breast exam
- * Pelvic exam

Laboratory

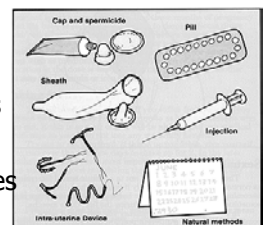
- * Pap smear
- * Cervical culture

Optional

- * Mammogram
- * Lipid profile

Contraceptive Alternatives

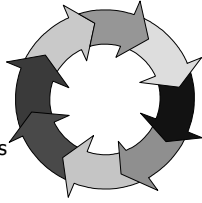
- * Hormonal Methods
- * Barrier Methods
- * Intrauterine Devices
- * Abstinence
- * Periodic Abstinence
- * Sterilization



Effective Contraception

* Depends on:

- Patient
 - > knowledge
 - > attitudes, beliefs, values
 - > behavior
- Healthcare provider
 - > knowledge
 - > attitudes, beliefs, values
 - > behavior



Contraceptive Choice

Safety vs. Efficacy

Hormonal Contraception

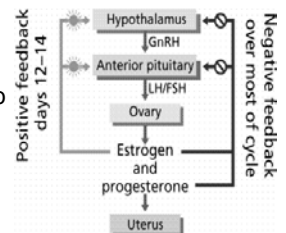
Choices:

- * Combination:
 - Estrogens & Progestins
- * Progestin alone
- * Multiple vehicles



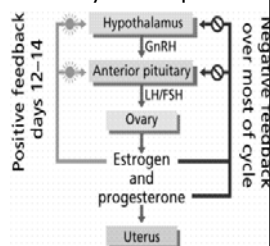
Combination Contraceptives Estrogen Mechanisms

- * Antiprogestational effects on the uterus inhibit implantation.
- * Accelerates ovum transport.
- * Negative feedback to the hypothalamus inhibits ovulation



Combination Contraceptives Progestin Mechanisms

- * Alter the midcycle surge of FSH and LH to decrease progestin produced by the corpus luteum and inhibit implantation
- * Alters the movement of sperm through the cervical canal.
- * Slows ovum transport



Estrogen Component Oral Contraceptives

- * 20 - 30 - 35 - 50mcg Ethinyl estradiol
- * 50mcg Mestranol

Always use the lowest effective dose

Cases in which higher dose may be needed:

- Spotting not controlled on low dose
- Contraceptive failure at low dose
- Menopausal symptoms on low dose

Progestin Component Oral Contraceptives

- * **Norethindrone (NE)**
(Norethindrone acetate & ethynodiol diacetate are metabolized to NE)
- * **Norgesterol or Levonorgestrel**
(d-norgestrel has little activity)
- * **3rd Generation Progestins ("Newer")**
Norgestimate, desogesterel, & gestodene
- * **Drospirenone**

Advantages vs. Disadvantages of "Newer" Progestins

- * Longer half-life
- * Less androgenic
- * Fewer metabolic effects on carbohydrates and lipids
- * Increases risk of thromboembolic disease

Relative Risk of Thromboembolic Events

- * 1/10,000 in reproductive age nonusers
- * 3-4/10,000 with levonorgestrel
- * 6-8/10,000 with newer progestins
- * 6/10,000 in pregnancy

Newest Progestin

- * Drospirenone
 - related to spironolactone
 - antiminerlocorticoid effect
 - ?less weight gain
 - acne
 - relative risk of thromboembolism unknown
 - risk of hyperkalemia

Combination OCP Risks

- * Venous thromboembolism
- * Stroke and Myocardial Infarction (smokers >35)
- * Minimal increase in breast cancer risk
- * Slight increase in cervical dysplasia
- * Increase in chlamydia infections
- * Hypertension
- * Increase risk of gall bladder disease

Contraindications for Combination Hormonal Contraception

- * Suspected pregnancy
- * Breast cancer history
- * DVT
- * IDDM with vascular disease
- * Impaired liver function
- * Liver disease
- * Smokers > 35 yo
- * Most breastfeeding mothers

Noncontraceptive Benefits Oral Contraceptives

- ✓ Improved menstrual symptoms
- ✓ Disease prevention -
PID, ectopic pregnancy, TSS, anemia, benign breast disease, osteoporosis
- ✓ Cancer reduction - endometrial, ovarian, colon
- ✓ Others - ovarian cysts, acne, hirsutism

Oral Contraceptive Products

- * **Monophasic** - Consistent amount of estrogen and progestin throughout cycle, 21 days of hormone and 7 days of non-hormone pills.
- * **Biphasic** - "10/11" or "7/14" change in hormone content.
- * **Triphasic** - Best mimics menstrual cycle with changes in estrogen/progestin doses every 7 days.

Alternative Schedules Monthly Cycling

- * 0.02 EE/0.15 desogestrel X 21 days
inert pills X 2 days,
0.01 EE X 5 days
- * 0.02 EE/1 norethindrone X 24 days
75mg ferrous fumarate X 4 days
or
0.20 EE/3mg drospirenone X 24 days
inert pills X 4 days

Alternative Schedules Continuous Dosing

0.03mg EE/0.15 levonorgestrel X 84 days
inert pills X 7 days

Alternative Oral Vehicle

- * Chewable
 - 0.35 EE/0.4 norethindrone X 21 days
 - 75mg ferrous fumarate X 7 days
 - Follow with a full glass of water

The Contraceptive Choice

- * Does the patient have any contraindications to hormonal therapy?
- * Does the patient have a condition that would benefit from OCPs?
- * Begin with the lowest hormone content.
- * What is the least expensive but effective product?

*** Patient education is the key to successful contraceptive use!!!!**

Patient Counseling

When to take the first pill:

- * First day of next menses
or
- * Sunday following onset of menses

Patient Counseling

What to do about missed pills:

- * **1 pill** - As soon as remembered or take 2 pills if it is time for next dose
- * **2 pills** - Take 2 pills per dose for next 2 days
- * **More than 2 pills** - Take 1 pill daily as if pills were not missed, start new pack as soon as previous pack is finished.
- * **Use additional barrier contraception**
 - Use back-up for at least 7 days.

Patient Counseling

Danger Signs for OCs



- ACHES**
- * **A**bdominal pain (severe)
 - * **C**hest pain (severe), shortness of breath or coughing up blood
 - * **H**eadaches (severe)
 - * **E**ye problems
 - * **S**evere leg pain (calf or thigh)

Minor Side-Effects

- * Nausea
- * Breakthrough bleeding
- * Amenorrhea
- * Weight gain
- * Acne
- * Breast tenderness
- * Headache

Side Effects:

- * Estrogen-related ?
- * Progestin-related ?
- * Androgenic ?

Management of Nausea

- * Take pill at bedtime or with food
- * Take pill from separate pack if vomiting occurs within 1 hour
- * Choose a pill with reduced estrogen
- * Rule out pregnancy
- * Rule out viral or bacterial infection

Breakthrough Bleeding

- * Missed pills
- * Interactions
- * Infection
- * Ectopic pregnancy
- * Hormonal cause

Dosage adjustments Breakthrough bleeding

- * **Early cycle** (Day 1-14)
 - Lack of estrogen
- * **Late cycle** (Day 15 +)
 - Lack of progestin

Dosage Adjustments Amenorrhea

- * Rule out pregnancy
- * Counsel and reassure patient about reduced endometrial build-up.
- * Add ethinyl estradiol 20mcg per day for 3 months

Weight Changes

- * How much? Is it related to use of the pill?
 - * Signs of pregnancy?
- Management Options:**
- * Anabolic effect: Decrease androgen
 - * Cyclic changes: Adjust estrogen or progestin
 - * Increases in breast tissue and subcutaneous fat: Decrease estrogen

Smokers

- * ***STOP***
- * < 30 years of age
- * ? 30-35 years of age
- * ≥ 35 ***NO***

Choices for Women over 40

- * Low dose estrogen OCPs are acceptable
- * Smoking is most significant risk factor
- * Measure FSH during "week off" around age 50
- * Switch to HRT at age 53



Patients with Hypertension

- * Development of HTN is dependent on age, smoking and other risk factors
- * Estrogen more likely
- * Diastolic > 90
 - Progestin-only
 - Non-hormonal



Choices for Diabetic Women

- * Effect on glucose control and insulin is not consistent or predictable
- * Acceptable following gestational diabetes
- * <35yo, nonsmoking and otherwise healthy
 - Low dose OCs are acceptable
- * >35yo, IDDM, risk factors
 - Use alternative forms of contraception

Hyperlipidemia

- * Acceptable except for very high triglycerides
- * High risk for CHD consider third generation progestins

Drugs Most Likely to Cause Contraceptive Failure

- * Antimicrobials
 - Penicillins
 - Tetracyclines
 - Rifampin
 - Griseofulvin
- * Anticonvulsants (except valproic acid)
- * Anti-HIV protease inhibitors
- * Herbal products
 - St. John's wort

Postpartum Use Non-nursing mothers:



When to start

- * Immediately
 - High risk of unplanned pregnancy
 - Patients not likely to return for follow-up

or

- * Four weeks to avoid risk of thromboembolism

Hormonal Influence on Breastfeeding

- * Estrogens inhibit prolactin leading to decreased milk production and protein content
- * Progestins do not affect production
 - Depo-Provera® has been noted to increase milk quantity and protein content

Return of Fertility

Dependent on . . .

- * Recovery of pituitary function leading to release of FSH and LH
- * Return of ovarian function
- * Endometrial restoration

Long-acting Combination Hormonal Contraceptives

- * Weekly patch
- * Vaginal ring
- * Monthly injection

Contraceptive Patch "Ortho Evra"

- * Combination transdermal contraceptive
- * Ethinyl estradiol- 0.20 mg/d
- * Norelgestromin- 0.150 mg/d
- * Less effective \geq 198 lbs
- * Changed weekly
 - Three weeks on medication
 - One week off



Contraceptive Patch "Ortho Evra"

- * Detached < 24hrs, apply new patch and no backup method needed
- * Late in applying new cycle, need backup method for 7 days
- * Late in midcycle
 - <48hrs no backup
 - >48 hrs backup method for 7 days

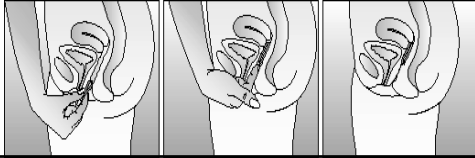
Vaginal Ring- "NuvaRing"

- * Non-biodegradable, flexible ring
- * Ethinyl estradiol- 0.015mg-d
- * Etonogestrel- 0.120 mg-d



Vaginal Ring- "NuvaRing"

- * Remains in place three weeks
- * Withdrawal bleeding during week out
- * If expelled, wash and replace within 3 hours
- * 90% couple satisfaction



Monthly Injectable Contraception

- * 25mg medroxyprogesterone acetate and 5mg estradiol cypionate (MPA/E2C)
- Lunelle
- * 0.5ml volume for deep IM injection
?self-injection in anterior thigh

MPA/E2C Pros & Cons

- * Estrogens contributes to bleeding pattern
- * No risk of congenital abnormalities
- * Not a procoagulant
- * BP neutral
- * Bone density stable
- * Quicker return of fertility

Progestin Only Contraception Potential Candidates

- * CVD
- * Liver disease
- * >35 yo and smokes
- * Increased risk of thromboembolism
- * Hx of CVA
- * Uncontrolled HTN or Ischemic HTN Dx
- * Migraine influenced by estrogen
- * Estrogen-dependent cancer
- * Breastfeeding

Contraindications to Progestin Only Contraception

- * Pregnancy/ undiagnosed vaginal bleeding
- * Active thromboembolic disease
- * History of cerebrovascular disease
- * Liver tumors
- * Breast Cancer

Progestin Only Contraception

- * Oral
- * Injectable
- * Implantable

Progestin Only Pill

- * 0.35 mg norethindrone
- * 0.075 mg norgestrel

Progestin-Only Mini-Pill

- * Effectiveness more sensitive to variations
- * Must take same time every day
- * May result in more irregular bleeding or amenorrhea
- * Must use back-up method if pill is missed

Mini-Pill Adverse Reactions

- * Menstrual irregularities
- * Breast tenderness
- * Headache
- * Nausea
- * Dizziness
- * Poor prevention for ectopic pregnancy
- * Contraindications: breast cancer, liver tumors, pregnancy

Depo - Provera®



- * Long-acting medroxyprogesterone acetate

Dose

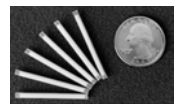
- * 150mg IM every 3 months
- * Begin during first 5 days of cycle
- * Use back-up method first 2 weeks

Depo-Provera Pros & Cons

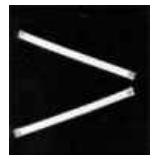
- * Amenorrhea
- * Weight gain
- * Return of fertility averages 10 months
- * Slight risk to pregnancy of increased infant mortality
- * Decreased bone mass
 - Bone mass increases when stopped
 - May not return to full bone mass
 - 1200 mg of calcium per day

Progestin-only Subdermal Implants

- * Levonorgestrel
 - 20-30mcg/day
 - 5 years
 - Insert in first 5-7 days of cycle
 - Not currently marketed in the US

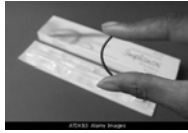


Nonplant implants, which are inserted into the upper arm, can provide up to 5 years of contraception.



Progestin-only Subdermal Implant

- * Etonogestrel (Implanon)
 - 68 mg/day
 - Single 40mm X 2mm rod
 - 3 years then remove
 - \$523.00
 - Metabolized by CYP3A



Documentation

- * Discussion about risks and benefits of all contraceptive methods
- * A plan for follow-up
- * All patient interactions (including phone calls)



Patient Follow-up

- * Provide a contact in case questions arise
- * Aids compliance

In 3 Months:

- * Blood pressure
- * Patient concerns

Yearly:

- * Health changes
- * Pap and breast exams

Available IUDs



- * **TCu-380A (Para Gard®):** Copper approved for 10 years
- * **Progestasert®:** 65mcg Progesterone per day for approximately 1 year then must be replaced
- * **Mirena®:** 20mcg levonorgestrel per day good for 5 years

Intrauterine Device (IUD)



Mechanism

- * Spermicidal activity
- * Mild inflammatory tissue reaction
- * Copper or Progesterone effects
- * Best inserted in first 5-7 days of cycle

IUD Pros & Cons

- * Can use during lactation or if estrogen is contraindicated
- * Highest approval rating among users
- * Most common and cost-effective reversible method worldwide
- * 54% of females afraid of this method

IUD Pros & Cons

- * Increased risk of PID in first month
- * Place in parous women in monogamous relationships
- * Increased bleeding and cramping with copper IUD
- * Decreased bleeding and cramping with progesterone IUD
- * Perforation of the uterus

Contraindications to IUD

- * Pregnancy/ undiagnosed vaginal bleeding
- * Unresolved abnormal Pap
- * Active genital infection or high risk of STDs
- * Immunocompromised
- * Distorted uterine cavity
- * Wilson's disease or copper allergy

Barrier Methods

- * **Over-the-Counter**
 - Condom
 - Sponge
 - Vaginal Spermicide
- * **Prescription**
 - Diaphragm
 - Cervical Cap

Barrier Methods Pros & Cons

- * Use of more than one method increases efficacy
- * All are relatively inexpensive
- * Only the diaphragm and cervical cap require a physician
- * Failure rate 2-25% and all are dependent on the users
- * Diaphragm increases incidence of UTI
- * Cervical cap increases incidence of cervical dysplasia

Condoms



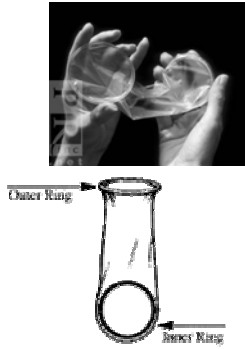
- * Use latex condoms
- * Additional spermicide
- * Correct & Consistent Use:
Avoid oil-based lubricants

Condom Pros & Cons

- * STD protection
- * Prevent premature ejaculation and sperm allergy
- * Reduced sensitivity, interruption of activity, latex allergy, embarrassment, breakage
- * Non-latex available- decreased STD protection

Female Condom- Reality

- * Long, thin polyurethane sheath
- * Inner ring like diaphragm
- * Outer ring covers external genitalia
- * Improved STD protection
- * Expensive if used often
- * Not aesthetically pleasing

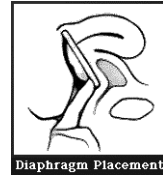


Diaphragms

- * Prescription item fitted in an office setting
- * Wide range of sizes (50-105mm diameter)

4 Types: Ease of use and fit vary among women

- Flat Spring
- Arcing Spring
- Coil Spring
- Wide seal rim



Diaphragm Pros & Cons

- * Requires initial fitting
- * User dependent so increased failure rates
- * Repeat application of spermicide for multiple uses
- * Increased risk of UTI
- * Relatively inexpensive
- * Few contraindications to use
- * Protects against STDs

Use & Care of Diaphragms

- * Insert with 1 teaspoon spermicide in dome no more than 6 hours prior to intercourse
- * Add spermicide before each intercourse
- * Leave in place at least 6 hours post-coitus (Max of 24 Hours)
- * Wash with soapy water, dry & store in cool, dry location
- * Assess fit yearly at time of annual exam

Cervical Cap



- * Prescription item fitted in an office setting
- * Range of 3 sizes (more difficult to fit)
- * Requires precise insertion over cervix
- * May remain in place 48 hours
- * Use with spermicide
- * Remove 6 hours or more after coitus

Return of the Sponge



Spermicides

Nonoxynol-9

Mechanism

- Surface active agents that damage sperm cell membranes

Efficacy & Correct Use

- Does **NOT** offer protection against STDs
- Jelly/Cream/Foam/Film/Suppository/Tablet: Effective up to 8hr
- Tabs/Supp: Effective approx. 1hr
- Apply 10-30 min prior to intercourse

Pros & Cons

Periodic Abstinence

- * Method keyed to the observation of natural signs of the fertile phase of the cycle.

Examples:

- Rhythm or Calendar
- Cervical Mucus
- Basal Body Temperature
- * Referrals to community programs

Sterilization

- * Consider procedures **permanent**
- * Less effective than originally believed
- * Failures frequently result in ectopics

Sterilization

- * Male: Vasectomy
 - Can be done in office
 - Can "check" results
- Female: Bilateral Tubal Ligation
 - Intra-abdominal procedure requiring anesthesia
 - Essure- coil embedded with mesh inserted through a hysteroscope

Contraceptive Failure Rates

Typical Use% / Perfect Use%

Sterilization	0.5-2.0/0
Copper IUD	0.8/0.6
Mirena®	0.1/0.1
Progesterone IUD	2.0/1.5
Norplant®	0.05/0.05
Depo-Provera®	0.3/0.3
Lunelle®	3/0.05
NuvaRing®	8/0.3
Evra Patch®	8/0.3
Sponge	24/15

Contraceptive Failure Rates

Typical Use% / Perfect Use%

* Combo OCP	8/0.3
* Progestin OCP	8/0.3
* Condoms	
male	15/2
female	21/5
* Diaphragm	16/6
* Cervical Cap	
nulliparous	20/9
parous	40/26
* Spermicide	29/18
* Chance	85/85

Postcoital Contraception-Hormonal



- * **Mechanism:** High dose hormones may prevent implantation, may delay ovulation, ?
- * **Contraindications:** Pregnancy, (relative: current migraine, H/O thromboembolism)
- * **Side effects:** N/V, breast tenderness, cycle disturbances

Emergency Contraception

- * Yuzpe method
 - 100mg EE and 0.5mg levonorgestrel X2
 - First dose within 72 hours repeat dose in 12 hours
- * 75%- 89% effective
- * Nausea- take with food, premedicate with meclizine or Dramamine

Emergency Contraception

- * Combination OCPs
 - Ovral 50mcg EE/25mg levonorgestrel
- * Dedicated Products
 - Preven 50mcg EE/25mg levonorgestrel
 - Plan B 0.75 levonorgestrel

Emergency Contraception

Copper Containing IUD

Insert within 5 days
Not FDA approved

Single dose 600mg mifepristone (RU-486)

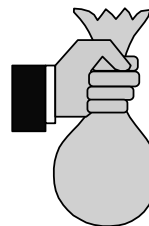
Used overseas
Not FDA approved

Emergency Contraception

Ongoing contraception

- No evidence for decreased contraceptive use
- May delay menses and hence start of hormonal contraception
- Continue OCP's for 13 days then start new pack with Sunday start
- IUD provide 10yrs of ongoing contraception

Cost Comparison



- * OTC Barrier Methods
 - Male- \$.50 Female- \$2.50
 - Sponge- \$1.25-\$2.50
 - Cream or jelly- \$.25 per use
- * Prescription Barrier Methods
 - Diaphragm/Cap- \$35.00
 - Fitting- \$129.00
- * IUDs
 - Progesterone-\$100.00
 - Copper-\$300.00
 - Insertion- \$191.00
 - Removal- \$126.00

Cost Comparison

- * Long-Acting Hormonal Methods
 - Depo-Provera- \$50.00/\$15.00
 - Implanon
 - Kit- \$523.00
 - Insertion- \$191.00
 - Removal- \$336.00
- * Oral Contraceptives
 - Generic- \$20.00/pack
 - Trade name- \$35.00/pack

Cost Comparison

- * Evra Patch- \$30.00 per month
- * Nuva Ring- \$35.00 - \$45.00 per month
- * Mirena IUD- \$300- \$400 plus insertion

New Methods of Contraception

- * New Delivery Systems
 - Patches
 - Newer Implants
 - IUDs
 - Vaginal Ring (progesterone only)
- * New Steroids
- * New Barrier Methods

New Methods of Contraception

- * Vaccines
- * Tubal Occlusion
- * Male Methods
 - Hormonal
 - Gonadal Toxins
 - Surgical methods

HPV Vaccine Gardasil[®]

- * Quadrivalent vaccine
 - Types 16 and 18- 70% of cervical cancer
 - Types 6 and 11- 90% of genital warts
- * Girls age 9 to 26
- * Given at time 0, 2 mos, and 6 mos
- * Cost- approximately \$120 per dose
 - Insurance coverage is variable

Case 1

45 yo nonsmoker, Caucasian female on Norinyl comes in for her yearly exam. She is G1P1, married, attorney and is in generally good health. Her family history is positive for her grandmother dying at age 45 of an MI. She has had "several" aunts conceive and bear children in their late 40's and early 50's. She likes her current method of birth control and does NOT want to become pregnant. BP 120/80.

Case 1

- * Is the patient an appropriate candidate to continue OCPs?
- * What additional information might be helpful in making a contraceptive choice?
- * What other contraceptive options might be appropriate for this patient?
- * When can she stop using contraception safely?

Case 2

36 yo nonsmoker, Caucasian, G0 on Tri-Phasil. Patient is here for her annual exam. She complains of frequent migraines. Her family history is (+) for CHD. She does NOT want to become pregnant but admits her husband is interested in having a child. In previous discussions the patient has been adamant about continuing her OCPs. BP 120/80.

Case 2

- * Is the patient an appropriate candidate to continue her OCPs?
- * Is her current OC formulation the best choice for her?
- * What other contraceptive choices might be considered in this patient?
- * What other issues need to be explored with this patient?

Case 3

15yo G1P0Tab1 is brought in by her mother for contraceptive counseling. The patient has been treated once for chlamydia. She has irregular menses with moderate to heavy cramping some months. She says she doesn't want to be pregnant but is not interested in using birth control.

Case 3

Is this patient an appropriate candidate for contraception?
What contraceptive methods might be the most appropriate in this setting?
What additional issues need to be addressed?
Is it legal to prescribe contraception to a minor without parental consent
How would you handle this situation?

Case 3

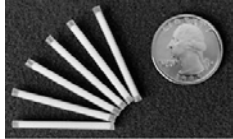
- * If you decide to begin the patient on an OCPs, which would you choose and why?
- * How would you write the prescription?
- * What instructions would you give the patient?

Norplant®

- * Subdermal levonorgestrel

Dose

- * Minor surgical procedure in which 6 capsules are implanted under the skin
- * 20-30mcg/day for 5 years
- * Insert in first 5-7
- * days of cycle



Norplant implants, which are inserted into the upper arm, can provide up to 5 years of contraception.