Free the Pill: Expanding Access to Hormonal Contraceptives
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Learning Objectives
- Describe the burden of unintended pregnancy in the United States
- Review currently available hormonal contraceptive methods
- Differentiate between pharmacy access and over-the-counter access to hormonal contraceptives
- Identify state models for providing pharmacy access to hormonal contraceptives

Question
- What percent of pregnancies in the United States are considered to be unintended?
  a. 15%
  b. 25%
  c. 45%
  d. 85%

Unintended Pregnancy
- Estimates indicate 45% of all pregnancies in the U.S. are considered unintended
- Women who experience unintended pregnancy are:
  - More likely to have delayed or inadequate prenatal care
  - More likely to smoke and drink alcohol during pregnancy
  - At higher risk of having a premature or low birth weight baby
  - Less likely to breastfeed

Unintended Pregnancy
- Highest risk groups:
  - Poverty income
  - "Cohabiting"
  - Black women
  - No high school degree
  - Women 20-24 year of age
Unintended Pregnancy

- On average, women in the U.S. spend 3 years pregnant, postpartum, or trying to become pregnant and 3 decades of their life trying NOT to become pregnant.


41% Inconsistent Use
5% Consistent Use
43% Nonuse

Unintended Pregnancy and Consistency of Contraceptive Use

- “The best method is one that is medically appropriate and is used every time by someone happy with the method.”
- Perfect user
  - Never misses a dose, takes her dose at the same time every day, and never vomits or has diarrhea
- Typical user
  - Method not used consistently or correctly; takes human error into account

Contraceptive Efficacy

Contraceptive Efficacy

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Contraception in the U.S.

- Tina is a 27 year old female who presents to the pharmacy with questions about birth control options. She is unhappy with her current oral contraceptives because she often forgets to take her pill and thinks it may be causing acne. She is currently taking ethinyl estradiol 30 mcg/levonorgestrel 0.15 mg tablets.

- She denies any significant past medical history. Her blood pressure in the pharmacy today is 110/68 and weight is 135 pounds.

- Which hormonal contraceptives would be reasonable for this patient to use?
Hormonal Contraception

- Combination contraceptives
  - Contain both estrogen and progestin

- Progestin-only contraceptives
  - No estrogen

Combination contraceptives

- Estrogen + progestin
  - Ethinyl estradiol (EE) is the most common type of estrogen used in COCs
    - Pills typically contain 20-50 mcg of EE/dose
    - 30-35 mcg of EE = "low dose"
    - 20-25 mcg of EE = "very low dose"
    - 10 mcg of EE = "low-low dose"
  - Mestranol
    - Metabolized to EE before pharmacologically active (50 mcg of mestranol = 35 mcg of EE)
  - Estradiol valerate
    - Found in new four-phasic method
    - Rapidly metabolized to estradiol following ingestion

LEAST ANDROGENIC Progestins by Androgenic Properties

MOST ANDROGENIC

Newer formulations

- 3rd generation progestins = desogestrel and norgestimate
  - Less androgenic than levonorgestrel, especially when it comes to weight gain
  - May improve mild to moderate acne
- 4th generation = drospirenone
  - Analog of spironolactone
  - May help to decrease bloating and weight gain
  - Monitor for elevated serum potassium
- Dienogest (found in Natazia)
  - Similar anti-androgenic effects as drospirenone without elevating potassium

Oral Contraceptives

- Combination pills
  - Primary contraceptive effect through inhibiting ovulation
  - Monophasic, biphasic, triphasic, and four-phasic methods available
  - Advantages of decreasing placebo phase:
    - Improvements in irritability/depression
    - Decreased menstrual blood loss
    - Avoid resurgence of conditions exacerbated by placebo week
    - Asthma, migraine headaches, seizures, endometriosis, alterations in insulin requirements

- Progestin-only pill (aka minipill)
  - Norethindrone is currently only product on the market
  - Active pill taken daily
  - Timing of dose is critical to efficacy
  - Some women report taking late afternoon/early evening as thickening of cervical mucus happens approximately 2-4 hours after dose
  - If dose is > 3 hours late, must use backup or abstain for 48 hours
  - Irregular menses a usual common adverse effect
Transdermal Contraceptive

Ortho Evra patch (ethinyl estradiol/ norelgestromin)

- Transdermal patch applied once a week for 3 consecutive weeks; 4th week is patch-free
- Apply patch to lower abdomen, buttocks, upper outer arm or upper torso (excluding breasts)
- Patch contains enough hormone to last for 9 days

- Not recommended as 1st line in patients weighing >90 kg (198 lbs) = less effective
- Exposed to 60% more estrogen than a woman on an oral contraceptive containing 35 mcg of estrogen = increased risk of venous thromboembolism

Vaginal Ring

NuvaRing (ethinyl estradiol/etonogestrel)

- Vaginally-inserted ring that is left in place for 3 weeks and removed for 1 week
- May also be used as a continuous cycle method
  - Ring releases steady dose of hormones for 30-35 days
- Ring should not be removed for more than 3 hours
- Recommend women always have 2 rings on hand in case one is lost
- May be stored at room temperature for up to 4 months
- Reaches systemic concentrations same restrictions apply as with combination oral contraceptives

Patient Case #1 (again)

Tina is a 27 year old female who presents to the pharmacy with questions about birth control options. She is unhappy with her current oral contraceptives because she often forgets to take her pill and thinks it may be causing acne. She is currently taking ethinyl estradiol 30 mcg/levonorgestrel 0.15 mg tablets.

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Patient Case #2

A 32 year-old female presents to the pharmacy to pick up a prescription for a new oral combination contraceptive pill. She is wondering when she should begin the medication and would like to avoid using a back-up method if possible.

Which of the previously discussed initiation methods would be most appropriate for this patient?
Continuous-Cycle Regimens

- Currently women in America average 450-480 menstrual cycles per lifetime.
- “Periods” on combination oral contraceptives are truly a drug-withdrawal bleed.
- Inhibit ovulation, so there is actually no change in the endometrial lining.

Benefits of continuous cycle regimens:
- Improved efficacy due to more reliable ovulation suppression.
- Decrease:
  - Menorrhagia
  - Asthma exacerbations
  - Migraine headaches
  - Seizures
  - Symptomatic endometriosis
  - Alterations in insulin requirements.

Continuous-Cycle Regimens

- Monophasic pills are recommended if a continuous cycle is desired.
- Start new pack during 4th week when you would usually have a week of placebo pills.

- NuvaRing has also been studied as a continuous method.
  - Each ring is capable of releasing a constant amount of hormone for 42 days.
  - Continuous dosing studies changed ring every 21 days.

- Ortho Evra patch:
  - Studied as 84 days on/7 days off.
  - Linger ing concerns about increased exposure to estrogen.

- Extended/continuous cycle:
  - Adverse effects:
    - Data shows patients are not at an increased risk of developing venous thromboembolism, although most studies are 1 year in duration.
    - Endometrial biopsies performed up to a year after initiation indicate no increased risk of endometrial hyperplasia or cancer.
    - Frequency of breakthrough bleeding and spotting in the first 3-6 months of use has been shown to be higher than patients on cyclical methods.


Injectables

- Medroxyprogesterone acetate (Depo-Provera):
  - IM or sub-Q injection once every 3 months.
  - Excellent choice for women on anticonvulsant drugs or with sickle cell anemia.
  - Adverse effects:
    - 50% of women develop amenorrhea after 1 year; 80% after 5 years.
    - Significant weight gain can occur.
    - Black box warning for increased risk of osteoporosis.
    - Delayed return to baseline fertility.


Patient Case #3

- Gloria is a 26 year old female who presents to the pharmacy with questions about skipping her placebo week of birth control pills so she can avoid having periods. She is currently taking Ortho-Tri-Cyclen Lo (triphasic oral contraceptive).

What would you tell Gloria?

What risks/benefits are associated with continuous cycle regimens?
**Question**

- **True or False:**
  - Only women who have had children are eligible to use an intrauterine device (IUD) for ongoing contraception.

**'Get It and Forget It' Methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>Active Ingredient</th>
<th>Location</th>
<th>Duration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skyla, Liletta</td>
<td>Levonorgestrel</td>
<td>Intrauterine</td>
<td>3 years</td>
</tr>
<tr>
<td>Mirena</td>
<td>Levonorgestrel</td>
<td>Intrauterine</td>
<td>5 years</td>
</tr>
<tr>
<td>Paragard</td>
<td>Copper ions</td>
<td>Intrauterine</td>
<td>10 years</td>
</tr>
<tr>
<td>Nexplanon</td>
<td>Etonorgestrel (active metabolite of desogestrel)</td>
<td>Intradermal</td>
<td>3 years</td>
</tr>
</tbody>
</table>

**Considering Contraindications**

- **U.S. Medical Eligibility Criteria for Contraceptive Use (2016):**
  - **Grade Level Interpretation**
    - **Grade 1:** No restrictions.
    - **Grade 2:** Benefit usually outweighs risk.
    - **Grade 3:** Risk generally outweighs benefit.
    - **Grade 4:** Risk is unacceptable.

- **Progestin-only products have very few grade 3 or 4 ratings**
- **Combination hormonal contraceptives (regardless of route of delivery):**
  - Examples of grade 3/4 conditions
    - Postpartum women
    - Smoking (especially if 35 years of age or older)
    - Risk factors for cardiovascular disease (including hypertension)
    - History of or current venous thromboembolism
    - History of or current cerebrovascular disease
    - Migraine with aura
    - History of or current breast cancer

**Considering Contraindications**

- **What would be the most appropriate contraceptive for a woman with...**
  - An acute DVT currently on warfarin?
  - History of DVT from estrogen-containing contraceptive and no longer taking warfarin?
  - A 29-year-old woman who experiences migraine headaches with aura?
  - A 40-year-old smoker?

**Expanding Contraceptive Access**

- **American College of Obstetricians and Gynecologists, 2012 Committee Report:**
  - "Access and cost issues are common reasons why women either do not use contraception or have gaps in use."
  - "No drug or intervention is completely without risk..."
  - "Weighing the slimmer contraceptive benefits and currently available data, oral contraceptives should be available over-the-counter."
Expanding Contraceptive Access

- Organizational support:
  - American College of Obstetricians and Gynecologists
  - American Medical Association
  - American Academy of Family Physicians

Will pharmacy access to hormonal contraceptives decrease preventive health screenings?

- Study of U.S. resident women obtaining oral contraceptives through two routes:
  - Cohort 1: U.S. family planning clinic
  - Cohort 2: OTC from Mexico

- Measured self-report of screening for Pap smear, pelvic exam, breast exam, or sexually transmitted infections (STI)

- Results indicated >88% of women in both groups had a recent Pap smear, pelvic exam, and breast exam
- Rate of STI screening lower in both groups (87% vs. 72% for clinic and OTC users, respectively)


Expanding Contraceptive Access

<table>
<thead>
<tr>
<th>Pharmacy Access</th>
<th>OTC Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where is the product stored?</td>
<td>Behind pharmacy counter</td>
</tr>
<tr>
<td>Prescription required?</td>
<td>Yes</td>
</tr>
<tr>
<td>Age restrictions</td>
<td>Depends on state</td>
</tr>
<tr>
<td>Insurance coverage</td>
<td>Yes</td>
</tr>
<tr>
<td>Hours of availability</td>
<td>When pharmacist on duty</td>
</tr>
<tr>
<td>Religious objections may apply</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Hawaii Legislation passed

Oregon Contraceptive Prescribing

- Eligible patients must be either:
  - 18 years of age or older OR
  - If under 18, evidence of a previous prescription for a transdermal contraceptive patch or self-administered oral contraceptive

- Law allows pharmacist dispensing of:
  - Combination oral contraceptives
  - Transdermal combination patch

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California Contraceptive Prescribing

- No age limitation for initiation
- Requires completion of self-screening questionnaire and blood pressure measurement
- Law allows pharmacist dispensing of:
  - Oral contraceptives
  - Transdermal contraceptive patch
  - Vaginal ring
  - Depot injection

Treat or Refer?

- Lori is a 22-year-old female who presents to the pharmacy for consultation for initiation of a hormonal contraceptive. She denies any significant past medical history and her social history is negative for smoking or alcohol use.
  - Weight today = 185 pounds; blood pressure = 118/70

- Tanya is a 31-year-old woman who delivered her first baby approximately 4 weeks ago and is at the pharmacy to discuss contraceptive options. She is not currently breastfeeding. She is nervous about forgetting to take a pill everyday.
  - Weight today = 170 pounds; blood pressure = 108/74

- Marie is a 33-year-old female who wants to discuss her contraceptive options. She is married with 2 children and does not wish to have more children. Her medical history includes type 2 diabetes diagnosed 5 months ago, hypertension (today’s blood pressure = 165/90 mmHg), and seizure disorder.
  - Medications:
    - Metformin 1000 mg by mouth twice daily
    - Lisinopril 10 mg by mouth daily
    - Phenobarbital 300 mg by mouth twice daily

Treat or Refer?

- Sonya is a 35-year-old woman who delivered her first baby approximately 8 weeks ago and is at the pharmacy to discuss contraceptive options. She is not currently breastfeeding. She is nervous about forgetting to take a pill everyday.
  - Weight today = 170 pounds; blood pressure = 108/74
References