Pharmacist Objectives

- Recognize the scope and impacts of unintended pregnancy
- Explain laws from Oregon and California that permit pharmacists to prescribe certain forms of contraceptives in those states and the possible implications in Michigan
- Explain how to apply the U.S. Medical Eligibility Criteria (MEC) for contraceptive use to individual patient care for hormonal contraceptives
- Discuss how to deliver effective medication counseling to patients seeking contraceptives

Pharmacy Technician Objectives

- Recognize the scope and impacts of unintended pregnancy
- Explain laws from Oregon and California that permit pharmacists to prescribe certain forms of contraceptives in those states and the possible implications in Michigan
- Describe the difference between common contraceptive pharmacologic agents

Additional Topics

- Safety concerns of hormonal contraceptives
  - Risk vs. Benefits
  - Physician association opinions
- Patient self-screening
  - Medical literature
- Pharmacist prescribed contraceptives business case
  - Out-of-pocket
  - Insurance
  - MTM billing

Early Population and Fertility Research

- Research on concern for decreasing birth rates during the 1920s and Great Depression

- Most early research was based on birth and death certificates
- Higher fertility rates were noticed in families of lower income as early as the 1920s
- Research leaders at the time theorized that the harshness of life among the poor created psychological differences leading to higher fertility
- The importance of unwanted pregnancies was not well understood
Advancement in Fertility Studies

- The study of Social and Psychological Factors Affecting Fertility 1941
- Better known as the Indianapolis Study
- First systematic, stratified random sample survey
- Only included white females who were married and had children

Better known as the Indianapolis Study

First systematic, stratified random sample survey

Only included white females who were married and had children

Advancement in Fertility Studies

Studies in 1965 and 1970 had important changes:

- Contraceptive pill became available in 1960
- Included African American women
- Shifted away from the married couple’s fertility history to each individual birth or pregnancy
- Introduced the distinction between excess fertility (number failure) and timing failure (mistimed pregnancy)

National Survey of Family Growth

- 6 studies between 1973 and 2001
- Supported by the National Center for Health Statistis
- No longer limited to only married women
- 1995 study evaluated perceived impact of timing errors
  - 33% of women with mistimed pregnancies were unhappy
  - 66% of women with unwanted pregnancies were unhappy

Unintended Pregnancy

Unintended pregnancy contains two components:

- Unwanted Pregnancy: pregnancy/birth that is unwanted at any time by the mother
- Mistimed Pregnancy: pregnancy/birth that is unwanted at the time the pregnancy occurred


- Coker AL. Does Physical Intimate Partner Violence Affect Sexual Health? A Systematic Review. Trauma, Violence & Abuse. 2007;8:2

Unintended Pregnancy: Demographic Disparities

- Income
- All Women
- <100% Poverty
- 100-199% Poverty
- >200% Poverty

- Age
- All Women
- <100% Poverty
- 100-199% Poverty
- >200% Poverty

- Education
- Strong inverse correlation between education attainment and rate of unintended pregnancy

- Marriage
- Unmarried women more likely to have unintended pregnancy than married women

- Intimate Partner Violence (IPV)
- Associated with inconsistent contraceptive use
- Associated with adolescent and unwanted pregnancy
The Great Recession: 2009 Guttmacher Institute Survey

- Almost half of all women surveyed stated they wanted fewer children, to delay pregnancy or did not want any more children due to the economy
- Family planning centers saw increased demand for services and smaller budgets: appointment wait times
- Inconsistent use of contraceptives

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Health Outcomes

Delayed Access to Prenatal Care

Child Health Risk:
- Premature birth
- Low birth weight
- Fetal exposure to alcohol and tobacco
- Infant death in the first year
- Behavioral and developmental problems

Mother Health Risks:
- Depression
- Physical Abuse

---

Unintended Pregnancy: Economics

- Estimated direct healthcare costs unintended pregnancy $5 Billion USD 2002
- The study assumed unintended births have the same cost as average birth
- Unintended births have more complications (and likely higher costs)
- Did not factor indirect costs

- Direct healthcare cost savings with contraception $19 billion USD 2002
- Intrauterine devices were found to be the most cost-effective form of contraceptive
- Using other forms of contraceptives are still more cost-effective then using no method at all
- Delay in contraceptive refill may significantly reduce efficacy and is a common reason for contraceptive failure

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Cost-effectiveness

- Direct healthcare cost savings with contraception $19 billion USD 2002
- Intrauterine devices were found to be the most cost-effective form of contraceptive
- Using other forms of contraceptives are still more cost-effective than using no method at all
- Delay in contraceptive refill may significantly reduce efficacy and is a common reason for contraceptive failure

---

Access to Contraceptives

- Shortage of primary care physicians and midlevel practitioners
- Physician appointment wait times as long as 66 days
- Primary Care Health Professional Shortage Areas (HPSPA) are based on a physician to population ratio of 1:3,500
- In Medically Underserved Areas/Populations (MUA/P) residents have a shortage of personal health services

---

Health

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" - WHO
Increasing Contraceptive Access

- Pharmacists are among the most accessible and most trusted healthcare professionals

![Map showing increasing contraceptive access](image)

Concerns

Should patients get pelvic exam, Pap tests and STI screening first?

- The World Health Organization (WHO) and the American College of Obstetricians & Gynecologists (ACOG) both support unbundling of screening from invitation of contraception

Concerns

Should patients get pelvic exam, Pap tests and STI screening first?

- Oral contraceptives (OCs) are not teratogenic
- Use of OC is not linked to cervical cancer or infections
- Consensus developed during the last decade supports a change in practice; hormonal contraception can safely be provided based on careful review of medical history and blood pressure measurement

Concerns

Hormonal contraceptives increase risk of Venous Thromboembolism (VTE)

- VTE is comprised of:
  - Deep vein thrombosis (DVT) and pulmonary embolism (PE)
- Estrogen containing contraceptives can increase blood clotting factors II, VII, X, XII, factor VIII, and fibrinogen, leading to VTE
Concerns
Hormonal contraceptives increase risk of Venous Thromboembolism (VTE)
- Women 15-45 not using OC’s VTE risk: 4-5/10,000
- Women 15-45 using OC’s VTE risk: 8-10/10,000
- Women during pregnancy VTE risk: 29/10,000
- Women during postpartum VET risk: 300-400/10,000


Concerns
How do we know medical histories will be accurate?
- Research suggests female patients are able to self-select for safe contraceptive use
- One study found 96% of patient completed medical questionnaires were in overall agreement with health provider assessment
- Another study found only 6.6% of patients incorrectly assessed eligibility for OC. This was mostly due to unrecognized hypertension.
- Roughly 6% of OC users have contraindications with physician Rx


Concerns
How do we know this will work in pharmacies?
Gardner, Miller, Downing et all (2008), Seattle, Washington
- Protocol based collaborative practice agreements
- Patient self-screening 20 item questionnaire
- 26 community pharmacists trained
- 214 women screened
- 91% eligible and prescribed contraceptives
- 9% found not to be eligible
- 70% of responded continuing contraceptives at 12 months


Laws in Oregon and California
California Senate Bill (SB) 493
- Major overhaul of pharmacy practice in California
- Advanced Practice Pharmacists
- Provider status
- Prescribing for hormonal contraception, nicotine replacement and travel medications
- Other issues

Oregon House Bill (HB) 2879
- Issue specific legislation on hormonal contraception
- Provider status-like bill passed around the same time

Bill Comparison
<table>
<thead>
<tr>
<th>Oregon HB 2879</th>
<th>California SB 493</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed into law</td>
<td>July 2015</td>
</tr>
<tr>
<td>Administrative Rules complete</td>
<td>January 2016</td>
</tr>
<tr>
<td>Contraceptives forms</td>
<td>Contraceptive patches &amp; oral hormonal contraceptives</td>
</tr>
<tr>
<td>Patient Age</td>
<td>No restrictions 18+ yrs Evidence of previous Rx under 18 yrs</td>
</tr>
<tr>
<td>Training program</td>
<td>Required</td>
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<tr>
<td>Insurance coverage</td>
<td>Yes</td>
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### Bill Comparison

<table>
<thead>
<tr>
<th></th>
<th>Oregon HB 2879</th>
<th>California SB 493</th>
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</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>Developed by multidisciplinary state boards</td>
<td>Developed by multidisciplinary state boards</td>
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<td>Screening-tool</td>
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<td>Required</td>
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<tr>
<td>PCP referral</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PCP notification</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient appointment</td>
<td>Prohibited from requiring</td>
<td>Admin rules incomplete</td>
</tr>
<tr>
<td>Women’s Health Visit</td>
<td>Required every 3 years from first prescription</td>
<td>Admin rules incomplete</td>
</tr>
</tbody>
</table>

### Oregon HB 2879

As of March 2016, roughly 250 pharmacists in Oregon underwent training and are now able to prescribe contraceptives; goal of 1200 trained by July 2016

- Can only prescribe oral and transdermal hormonal contraceptives
- Protocols and self-screening
  - Similar to studies referenced in previous slides
  - Based on United States Medical Eligibility Criteria (MEC) for Contraceptive Use 2010

### Contraceptives

- **Contraceptive Use**
  - Pill: 17%
  - Female Sterilization: 10%
  - Condom: 17%
  - Other Contraceptives: 18%
  - No Contraception: 38%

### Review

- **Hormonal Contraceptive Mechanism of Action**
  - **Estrogen (Ethinyl estradiol or Mestranol)**
    - Suppress FSH and prevents follicle development
    - Stabilizes endometrial lining, controlling bleeding
  - **Progestins (Synthetic progesterone - multiple available)**
    - Cervical mucous thickening acting as barrier to sperm
    - Prevents LH surge and ovulation
    - Thins endometrium reducing ability of implantation
Hormonal Contraceptives

Progestins vary in activity

<table>
<thead>
<tr>
<th>Generation</th>
<th>Progestin</th>
<th>Estrogenic</th>
<th>Progestinal</th>
<th>Androgenic</th>
<th>Antialdosterone</th>
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</thead>
<tbody>
<tr>
<td>First</td>
<td>Northindrone</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Ethynodiol diacetate</td>
<td>++</td>
<td>+++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Norethynordrel</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Second</td>
<td>Levonorgestrel</td>
<td>-</td>
<td>+++</td>
<td>++++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Norgestrel</td>
<td>-</td>
<td>+++</td>
<td>++++</td>
<td>-</td>
</tr>
<tr>
<td>Third</td>
<td>Desogestrel</td>
<td>+/-</td>
<td>+++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Norgestimate</td>
<td>-</td>
<td>+++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Norelgestromin</td>
<td>+/−</td>
<td>+++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>Fourth</td>
<td>Drospirenone</td>
<td>-</td>
<td>+/-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Dienogest</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Hormonal Contraceptives

Combined Oral Contraceptives (COC)
- Contains both estrogen and progestin
- Disrupt ovulation - originally designed for 28 day regimen
- Mono-phasic: Contain same amount of estrogen and progestin for 21 days followed by 7 day placebo
- Multi-phasic: contain variable amounts of estrogen and progestin over 21 days then 7 days of placebo. No data proving mono or multi-phase is superior

Progestin Only Pill (POP)
- Contains only progestin
- Also known as the “Mini-pill”
- Not as effective as COCs

Contraceptive Hormonal Transdermal Patch
- Only brand available, Ortho Evra
- Contains
  - Ethinyl estradiol 35 mcg/day
  - Norelgestromin 200 mcg/day

U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Category 1
- “A condition for which there is no restriction for the use of the contraceptive method.”

Category 2
- “A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.”

Category 3
- “A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.”

Category 4
- “A condition that represents an unacceptable health risk if the contraceptive method is used.”

Category 4: Unacceptable Health Risk (Contraindicated)
- Breastfeeding or non-breastfeeding <21 days postpartum
- Current breast cancer
- Severe (decompensated) cirrhosis
- History/risk of or current deep venous thrombosis/pulmonary embolism (not on anticoagulant therapy); thrombogenic mutations
- Major surgery with prolonged immobilization
- Migraines with aura, any age
- Systolic blood pressure ≥160 mm Hg or diastolic ≥100 mm Hg
- Current and history of ischemic heart disease
- Benign hepatocellular adenoma or malignant liver tumor
- Moderately or severely impaired cardiac function; normal or mildly impaired cardiac function >6 months
- Smoking ≥15 cigarettes per day and age ≥35
- Complicated solid organ transplantation
- History of cerebrovascular accident
- SLE; positive or unknown antiphospholipid antibodies
- Complicated valvular heart disease
Category 3: Unacceptable Health Risk (Contraindicated)
- Breastfeeding 21–30 days postpartum with or without risk factors for VTE Breastfeeding
- 30–42 days postpartum with other risk factors for VTE Non-breastfeeding
- Breastfeeding 21–42 days postpartum with other risk factors for VTE (Post breast cancer prior to 5 years History of DVT/PE)
- Smoking <15 cigarettes per day and age ≥35
- Use of rifampicin or rifabutin therapy
- Diabetes mellitus (Type 1 or type 2)
- Gallbladder disease, symptomatic and treated by cholecystectomy or asymptomatic
- Use of certain anticonvulsants (Phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and lamotrigine)
- Diabetes with vascular disease or >20 years duration (possibly category 4 depending upon severity)
- Multiple risk factors for arterial cardiovascular disease (older age, smoking, diabetes, and hypertension) (possibly category 4 depending on category and severity)

Category 1: No restriction
- Thalassemia, iron deficiency anemia
- Malignant hemochromatosis
- Minor surgery without immobilization
- Depression
- Gestational diabetes mellitus
- Endometrial cancer/hyperplasia, endometriosis
- Epilepsy
- Gestational trophoblastic disease
- Non-migrainous headaches
- History of bariatric surgery: restrictive procedures
- History of pelvic surgery
- HIV infected or high risk
- Malaria
- Ovarian cancer
- PID
- Post-abortion
- Non-breastfeeding >42 days postpartum
- Severe dysmenorrhea
- Sexually transmitted infections
- Varicose veins
- Thrombocytopenia
- Tuberculosis
- Uterine fibroids
- Use of nucleoside reverse transcriptase inhibitors
- Use of broad-spectrum antibiotics, antifungal, and anti-parasitic
- Past ectopic pregnancy

Category 2: Advantages generally outweigh theoretical or proven risks
- Age ≥40 (in the absence of other comorbid conditions that increase CVD risk)
- Sickle cell disease
- Undiagnosed breast mass
- Cervical cancer and awaiting treatment; cervical intraepithelial neoplasia Family history of DVT/PE
- Major surgery without prolonged immobilization
- Diabetes mellitus (Type 1 or type 2)
- Gallbladder disease; symptomatic and treated by cholecystectomy or asymptomatic
- Migraines without aura, age <35
- History of pregnancy related cholestasis
- History of high blood pressure during pregnancy
- Benign liver tumors
- Breastfeeding >42 days postpartum
- Use of non-nucleoside reverse transcriptase inhibitors
- Hyperlipidemia
- Use of broad-spectrum antibiotics, antifungal, and antiparasitic
- Unexplained vaginal bleeding or dysmenorrhea
- Unexplained testicular pain
- Uncomplicated valvular heart disease

You will need three forms
1. Oregon Self-Screening Risk Assessment Questionnaire
2. Summary of US Medical Eligibility Criteria for Contraceptive Use (Corresponding to Oregon Questionnaire)
3. Standard Procedures Algorithm for Oregon RPh Prescribing of Contraceptives

Oregon Questionnaire
Background Information
DOB, age, weight, medication allergies, insurance

1. Do you think you might be pregnant now?
2. What was the first day of your last menstrual period?
3. Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?
4. Have you ever been told by a medical professional not to take hormones?
5. Do you smoke cigarettes?
Oregon Questionnaire

1. Health and History Screen
   Review Hormonal Contraceptives Self-Screen Questionnaire.
   To Evaluate Health and history, refer to US MEC.
   1 or 2 (green boxes) proceed to next step
   3 or 4 (red boxes) contraindication: Refer

2. Pregnancy Screen
   a. Did you have a baby less than 6 months ago, are you fully or nearly fully breast feeding, and have you had no menstrual period since the delivery?
   b. Have you had a baby in the last 4 weeks?
   c. Did you have a miscarriage or abortion in the last 7 days?
   d. Did your last menstrual period start within the past 7 days?
   e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
   f. Have you been using a reliable contraceptive method consistently and correctly?
   If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step
   If No to ALL of these questions, pregnancy cannot be ruled out: Refer

3. Medication Screen (Questionnaire #19 & 20)
   Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturates, herbs & supplements, including:
   carbamazepine, oxcarbazepine, rifampin, rifabutin, felbamate
   ritonavir, griseofulvin, St. John's Wort, phenytoin
   primadone, topiramate, lamotrigine, phenobarbital

4. Blood Pressure Screen
   Is blood pressure < 140/90?
   Note: RPh may choose to take a second reading if initial reading is high.
   BP < 140/90
   Continue to Step 5
   BP > 140/90
   Refer
Oregon Standard Procedures Algorithm

Step 5: Evaluate patient history, preference and current therapy for selection of treatment
- Based on patient preference/history of use

Step 6: Discuss strategy for initiation or changing therapy
- Counseling on initiation, side effects, adherence and explanations

Step 7: Discuss, provide referral and provide visit summary to patient
- Encourage routine health screenings, STI prevention and notification to care provider

Which Contraceptive to Start?

Women without medical conditions, mono-phasic pill 35 mcg or less of EE, and less than 0.5 mg of norethidrone, is a reasonable first choice
- Evidence that complications and side effects result from excessive hormone content

The transdermal patch is less effective in women weighing 200 lbs or more and not a good first line option for that population.

Women under 110 lbs, women older than 35 years, and perimenopausal women may have fewer side effects with lower dose EE (20-25 mcg of EE)

ACOG suggests progestin-only hormonal contraception for obese women over the age of 35 years.

Initiation Counseling

1. Initiated on the first day of bleeding during cycle
2. Initiated on the first Sunday after the menstrual cycle
3. Quick Start - patient takes pill on the first day prescribed
   - Must use backup contraception method or abstain for the first 7 days of initiation
   - Most side effects will dissipate after 2 to 3 cycles

Side Effect Counseling

Hormonal Side Effect | Comments
--- | ---
Nausea and vomiting | Typically improves in 2-3 cycles
Breast tenderness | Consider changing to lower estrogenic content if problem does not resolve
Weight gain | 
Acne/oily skin | Consider changing to lower androgenic progestin
Depression and fatigue | 
Breakthrough bleeding/spotting | Consider changing to higher estrogenic content if problem does not resolve

Missed Dose Counseling

COC and POP

<table>
<thead>
<tr>
<th>Missed Pills</th>
<th>When to Take Missed Pills</th>
<th>Backup Contraception</th>
<th>Emergency Contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missed or Late Combined Oral Contraceptives (28-day packs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 pill</td>
<td>Take 1 pill soon as remembered</td>
<td>Not needed</td>
<td>Consider if missed other dose(s) in month</td>
</tr>
<tr>
<td>2 pills in a row</td>
<td>Take 2 pills (on the same day) as soon as remembered. Continue taking rest of pack</td>
<td>Yes, for 7 days</td>
<td>Consider if missed during first week of cycle</td>
</tr>
</tbody>
</table>

Missed Progestin-Only Oral Contraceptives

| 3 hours late | As soon as remembered | Yes, for 48 hours | Consider if > 3 hours |

Transdermal Patch

Management of a Missed Patch

<table>
<thead>
<tr>
<th>Interruption of Patch</th>
<th>Management</th>
<th>Backup Contraception</th>
<th>Emergency Contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed application of patch falls off &lt;48hr</td>
<td>Apply a new patch as soon as possible</td>
<td>Not needed</td>
<td>Consider if had delay in patch change or detachment earlier in the month</td>
</tr>
<tr>
<td>Delayed application of patch falls off &gt;48hr</td>
<td>Apply new patch ASAP. Keep same patch change day. If in 3rd week, skip hormone free week and start new patch OR use backup</td>
<td>1 week, 7 days</td>
<td>Consider if had delay in patch change or detachment earlier in the month</td>
</tr>
</tbody>
</table>
Concerns: Business Case

Gardner, Miller, Downing et al (2008), Seattle, Washington

- Collaborative practice agreements (can also be done in Michigan)
- One local third-party payer was reimbursing pharmacists at a rate the same as other non-physician providers
- 80% of eligible patients paid out-of-pocket for services
- Service cash price was $25 in this study that took place 2003-2005

References
