**PHARMACIST PRESCRIBED HORMONAL CONTRACEPTIVES: LEGAL AND CLINICAL UPDATE**

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**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

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**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 v Benefits
  - Physician association opinions
- Patient self-screening
  - Medical literature
- Pharmacist prescribed contraceptives business case
  - Out-of-pocket
  - Insurance
  - MTM billing

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**Early Population and Fertility Research**

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

![Number of Children per Woman](chart.png)

- 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

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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

Advancement in Fertility Studies

• Growth of American Families Study 1955

• Influenced by rise in fertility post World War II

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 Statists
- 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

![Unintended Pregnancy Rates 1981-2011](image-url)

Percentage of Unintended Pregnancy 1987-2011

Unintended Pregnancies per 1,000 Women age 15-40

Unintended Pregnancy: Demographic Disparities Income
Unintended Pregnancy: Demographic Disparities

- 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
**Unintended Pregnancy: Economics**

- 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

**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

**Health**

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" - WHO
U.S. Healthcare Costs

- 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

Source: J Contraception. 2007;75:3

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

Source: J Contraception. 2009;79:1

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 (HPSA) 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

Source: HRSA.gov

Increasing Contraceptive Access

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

- 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
Hormonal contraceptives increase risk of Venous Thromboembolism (VTE)

- Most DVTs can be treated successfully
- In the event of PE, death is about 1 in 100
- PE death from contraceptive use
  - Assuming every VTE incident is PE
    - 10 VTE/10,000 x 1 PE Death/100 PE = 1/100,000
  - Death during pregnancy estimated around 8/100,000


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 California & Oregon

- 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

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<th>California SB 493</th>
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<td>July 2015</td>
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<td>January 2016</td>
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<td>Patient Age</td>
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Bill Comparison

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<tr>
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<tr>
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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
Contraceptive Use

- Pill 17%
- Female Sterilization 17%
- Condom 10%
- 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

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<td>++</td>
<td>++</td>
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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


Hormonal Contraceptives

• 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

- Created in close collaboration with WHO
- Decision-making tool for healthcare practitioners
- Does not consider use of contraceptives for treatment of medical conditions
- Four categories for contraceptive use based on patient disease states and conditions

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 anti-phospholipid antibodies
- Complicated valvular heart disease
### Category 3: Unacceptable Health Risk (Contraindicated)

- Breastfeeding 21–30 days postpartum with or without risk factors for VTE
- 30–42 days postpartum with other risk factors for VTE
- Breastfeeding
- 21–42 days postpartum with other risk factors for VTE
- Breast cancer and no evidence of disease 5 years History of DVT/PE (not on anticoagulant therapy)
- Migraines without aura, age ≥ 35
- History of bariatric surgery, History of cholestasis
- SBP 140–159 mm Hg or DBP 90–99 mm Hg
- Normal or mildly impaired cardiac function ≥ 6 months
- Postpartum 21 to 42 days with other risk factors for VTE
- Smoking <15 cigarettes per day and age ≥ 35
- Use of ritonavir boosted protease inhibitors
- Use of certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and lamotrigine)
- Use of rifampicin or rifabutin therapy
- 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 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 21–42 days postpartum without risk factors for VTE
- Breastfeeding ≥42 days postpartum
- Non-breastfeeding 21–42 days postpartum without risk factors for VTE
- Rheumatoid arthritis on or off immunosuppressive therapy
- Smoking and <35 years old
- Uncomplicated solid organ transplantation
- Superficial thrombophlebitis
- SLE and severe thrombocytopenia or immunosuppressive treatment
- Unexplained vaginal bleeding before evaluation
- Use of non-nucleoside reverse transcriptase inhibitors
- Hyperlipidemia

### Category 1: No restriction

- Thalassemia, iron deficiency anemia
- Mild compensated cirrhosis
- 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
- Thyroid disorders
- Tuberculosis
- Urethral infections
- Use of nucleoside reverse transcriptase inhibitors
- Use of broad-spectrum antibiotics, anti-fungal, and anti-parasitic
- Past ectopic pregnancy
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

Hormonal Contraceptive Self-Screening Questionnaire

Name ____________________________  Health Care Provider’s Name ____________________________  Date ______

Date of Birth __________  Age ______  Weight ______  Do you have health insurance? Yes / No ____________________________

What was the date of your last women’s health clinical visit?

Background Information:

1. Do you think you might be pregnant now? Yes / No ____________________________
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? Yes / No ____________________________
   Did you ever experience a bad reaction to using hormonal birth control? Yes / No ____________________________
   - If yes, what kind of reaction occurred? ____________________________
4. Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection? Yes / No ____________________________
   - If yes, which one do you use? ____________________________
5. Have you ever been told by a medical professional not to take hormones? Yes / No ____________________________
6. Do you smoke cigarettes? Yes / No ____________________________

Medical History:

6. Have you given birth within the past 6 weeks? Yes / No ____________________________
7. Are you currently breastfeeding? Yes / No ____________________________
8. Do you have diabetes? Yes / No ____________________________
9. Do you get migraines headaches? If so, have you ever had these kinds of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts? Yes / No ____________________________
10. Do you have high blood pressure, hypertension, or high cholesterol? Yes / No ____________________________
11. Have you ever had a heart attack or stroke, or been told you had any heart disease? Yes / No ____________________________

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

6. Have you given birth in the last 6 weeks?
7. Are you currently breast feeding?
8. Do you have diabetes?
9. Do you get migraine headaches?
10. Do you have high blood pressure, HTN or high cholesterol?
11. Have you ever had a heart attack or stroke, or been told you had any heart disease?
12. Have you ever had a blood clot?
13. Have you ever been told that you are at risk of developing a blood clot?

Oregon Questionnaire

14. Have you had recent surgery or are you planning to have surgery in the next 4 weeks?
15. Have you had bariatric surgery or stomach reduction surgery?
16. Do you have, or have you ever had, breast cancer?
17. Do you have, or have you ever had, hepatitis, liver disease, liver cancer, or gall bladder disease?
18. Do you have lupus, rheumatoid arthritis, or any blood disorders?
19. Do you take medication for seizures, tuberculosis (TB), fungal infections, or HIV?
20. Do you have any other medical problems or take any medications, including herbs supplements?

Oregon Standard Procedures Algorithm

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

   Continue to Step 2
Summary of US Medical Eligibility Criteria for Contraceptive Use

Oregon Standard Procedures Algorithm

2. Pregnancy Screen

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If No to ALL of these questions, pregnancy can NOT be ruled out: Refer

Continue to Step 3

3. Medication Screen (Questionnaire #19 & 20)

Caution: anticonvulsants, antiretrovirals, antibiotics, barbiturates, herbs & supplements, including:
- carbamazepine
- oxcarbazepine
- rifampin/rifabutin
- valproic acid
- St. John’s Wort
- topiramate
- lamotrigine
- phenobarbital

No contraindicating Medication(s)

Continue to Step 4
Oregon Standard Procedures Algorithm

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

Refer

BP <140/90

Continue to Step 5

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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

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Which Contraceptive to Start?

- Women without medical conditions, mono-phasic pill 35 mcg or less of EE, and less than 0.5 mg of norethindrone, 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
<table>
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<th>Hormonal Side Effect</th>
<th>Comments</th>
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<tr>
<td>Nausea and vomiting</td>
<td>Typically improves in 2-3 cycles Consider changing to lower estrogenic content if problem does not resolve</td>
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<tr>
<td>Breast tenderness</td>
<td></td>
</tr>
<tr>
<td>Weight gain</td>
<td></td>
</tr>
<tr>
<td>Acne/oily skin</td>
<td>Consider changing to lower androgenic progestin</td>
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<tr>
<td>Depression and fatigue</td>
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<tr>
<td>Breakthrough bleeding/spotting</td>
<td>Consider changing to higher estrogenic content if problem does not resolve</td>
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Missed Dose Counseling
COC and POP

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<th>When to Take Missed Pills</th>
<th>Backup Contraception</th>
<th>Emergency Contraception</th>
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<tbody>
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<td>1 pill</td>
<td>1 pill soon as remembered</td>
<td>Not needed</td>
<td>Consider if missed other dose(s) in month</td>
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<tr>
<td>2 pills in a row</td>
<td>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>
<tr>
<td>&gt;3 hours late</td>
<td>As soon as remembered</td>
<td>Yes, for 48 hours</td>
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Missed Dose Counseling
COC and POP

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<tr>
<td>Delayed application or patch falls off ≥48hr</td>
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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

Concerns: Business Case

- From what information is available in Oregon, insurers are reimbursing pharmacists at a rate the same as other non-physician providers
- Many patients who do not have coverage are willing to pay for the service out-of-pocket
- Other options for additional reimbursement to export may be through using MTM billing for initiating new therapy
Summary

- Unintended Pregnancy is a persistent and common problem in the US
- Access to PCP and OBGYN can be difficult or delayed and present a barrier to contraceptive adherence
- Hormonal contraceptives come with risks and benefits; care should be individualized but protocol based
- The WHO, ACOG and other organizations support unbundling of contraceptive prescribing from annual pelvic exams
- Pharmacists are uniquely positioned and trained to increase safe access to care, and it is already being done in other states

**References**

- Blythe MJ, Diaz A. Contraception and Adolescents. *Committee on Adolescence.* *Pediatrics.* 2007;120:1135
- HRSA.gov
Slide 71

DM22 I think this would look better if you added some color. You also need to update your title to include PSI especially since they are paying your salary.

Dianne Malburg, 4/7/2016

Slide 72

DM20 As long as all slides have references you don't need these pages. Okay to leave just don't show cause audience won't be able to read.

Dianne Malburg, 4/7/2016
References

- Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013. Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use. 2nd Edition. MMWR 2013;62(No. 5)
- Oregon Self-Screening Risk Assessment Questionnaire. Oregon Board of Pharmacy. Available at: https://www.oregon.gov/pharmacy/Pages/ContraceptivePrescribing.aspx
- Summary of US Medical Eligibility Criteria for Contraceptive Use. Available at: https://www.oregon.gov/pharmacy/Pages/ContraceptivePrescribing.aspx