Evolving roles of pharmacists: are hormonal contraceptives next on the list?

PAIGE KOSKINEN, PHARM.D.
Pgy1 community pharmacy resident
H-E-B pharmacy/the university of texas at austin
Disclosures

No conflicts of interest to disclose
Objectives

At the conclusion of this activity, the learner should be better able to:

• Describe the relevant pathophysiology of a woman’s menstrual cycle
• Educate patients and other health care providers on the impact of pharmacist-prescribed oral contraceptives
• Evaluate and utilize an oral contraceptive protocol for pharmacists
Audience Poll
Do you know a pharmacist that can prescribe hormonal contraceptive?

Yes

NO
Do you think pharmacists have the appropriate knowledge to prescribe hormonal contraceptives?

- Yes
- No
If you answered yes: WHY?
If you answered no: WHY?
Background
History of Oral Contraceptives

1960
1st Oral Contraceptive Approved

1965
6.5 million American women were “on the pill”

2012
62% of women who are reproductive age
Menstruation

https://www.menstrupedia.com/articles/physiology/whats-menstruation
Menstrual Cycle

- First day of your period  ➔  First day of your next period
# Hormone Effects on the Body

<table>
<thead>
<tr>
<th>Estrogen</th>
<th>Progestin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess</td>
<td>Deficiency</td>
</tr>
<tr>
<td>Nausea</td>
<td>Early/mid-cyle breakthrough bleeding</td>
</tr>
<tr>
<td>Bloating/Edema</td>
<td>Increased spotting</td>
</tr>
<tr>
<td>Polyposis</td>
<td>Hypomenorrhea</td>
</tr>
<tr>
<td>Melasma</td>
<td>Acne</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Oily scalp</td>
</tr>
<tr>
<td>Migraine</td>
<td>Depression</td>
</tr>
</tbody>
</table>
The Journey

1: period
1-5: follicles develop on ovaries

5-7: one follicle grows & estrogen rises

8: high estrogen & follicle grows bleeding stops

8: high estrogen uterus grows & thickens - rich in blood & nutrients

12: estrogen peaks & sharp rise in LH

14: LH causes follicle to release egg from ovary = ovulation

15-24: egg moves from ovary to uterus

14: LH causes follicle to release egg from ovary = ovulation

estrogen is highest before ovulation

uterine lining thickens

follicle on ovary increases progesterone

15-24: egg moves from ovary to uterus

if not fertilized = breaks apart = not pregnant = estrogen & progesterone levels drop

drop in hormones = mood changes

unfertilized egg leaves the body with uterine lining

sperm + egg in fallopian tube = fertilization

fertilized egg attaches to uterus & pregnancy begins
Types of Oral Contraception

- Monophasic
- Biphasic
- Triphasic
Recommended Actions After Late or Missed Combined Oral Contraceptives

- If one hormonal pill is late: (<24 hours since a pill should have been taken)
  - Take the late or missed pill as soon as possible.
  - Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day).
  - No additional contraceptive protection is needed.
  - Emergency contraception is not usually needed but can be considered if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle.

- If one hormonal pill has been missed: (24 to <48 hours since a pill should have been taken)
  - Take the most recent missed pill as soon as possible (any other missed pills should be discarded).
  - Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day).
  - Use back-up contraception (e.g., condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days.
  - If pills were missed in the last week of hormonal pills (e.g., days 15-21 for 28-day pill packs):
    - Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
    - If unable to start a new pack immediately, use back-up contraception (e.g., condoms) or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days.
  - Emergency contraception should be considered if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days.
  - Emergency contraception may also be considered at other times as appropriate.

- If two or more consecutive hormonal pills have been missed: (≥48 hours since a pill should have been taken)

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https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/248124_fig_2_3_4_final_tag508.pdf
Why?
Audience – POLL
How could pharmacist prescribed hormonal contraceptive affect healthcare?
Why is this important?

• Strategy to improve access to contraception and reduce unintended pregnancy
  • 4 million
  • Shortage of primary care providers
• Pharmacists are highly trained clinical professionals
  • Scope of practice
• Improved patient relationships
• Multiple barriers exist today
  • Cost
  • Access
Different Approaches
Key Differences

• Covered contraceptive methods
• Age
• State wide procedures vs. Collaborative practice agreements
• Insurance
  • Service
  • Medication
Workflow
A “typical” day in the pharmacy

Pharmacy Technician

Pharmacist

Fee + Copay

Counseling
Example Patient Questionnaire
SEE APPENDIX

Hormonal Contraceptive Self-Screening Questionnaire (updated 2017)

Name: __________________________ Health Care Provider's Name: __________________________
Date of Birth: __________________________ Age*: __________________________
Weight: __________________________ Do you have health insurance? Yes / No

Any Allergies to Medications? Yes / No If yes, list them here:

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 injection? Yes ☐ No ☐
   - Have you previously had contraceptives prescribed to you by a pharmacist? 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 21 days? If yes, how long ago? Yes ☐ No ☐
7. Are you currently breastfeeding? Yes ☐ No ☐
8. Do you have diabetes? Yes ☐ No ☐
9. Do you get migraine headaches? If so, have you ever had the kind 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? (Please indicate yes, even if it is controlled by medication) Yes ☐ No ☐
11. Have you ever had a heart attack or stroke, or been told you had any heart disease? Yes ☐ No ☐
12. Have you ever had a blood clot? Yes ☐ No ☐
13. Have you ever been told by a medical professional that you are at risk of developing a blood clot? Yes ☐ No ☐
14. Have you had recent major surgery or are you planning to have surgery in the next 4 weeks? Yes ☐ No ☐
15. Have you had bariatric surgery or stomach reduction surgery? Yes ☐ No ☐
16. Do you have or have you ever had breast cancer? Yes ☐ No ☐
17. Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)? Yes ☐ No ☐
18. Do you have lupus, rheumatoid arthritis, or any blood disorders? Yes ☐ No ☐
19. Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?
   - If yes, list them here: __________________________
20. Do you have any other medical problems or take any medications, including herbs or supplements? Yes ☐ No ☐
   - If yes, list them here: __________________________
21. Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.) Yes ☐ No ☐

Do you have a preferred method of birth control that you would like to use?
☐ A pill you take each day ☐ A patch that you change weekly ☐ Other (ring, injectable, implant, or IUD)

At the care of only ☐ verified ID* with valid photo ID ☐ IP Reading /
Pharmacist Name: __________________________ Pharmacist Signature: __________________________
Drug Prescribed: __________________________ Rx: __________________________
Sign: __________________________ (Pharmacy Phone Address)
Notes: __________________________

Where is it happening now?
Audience Poll
Where do you think pharmacists are prescribing hormonal contraceptive?
State Policies Expanding Access To Oral Contraception

Expansion of pharmacists’ authority — 8 states + D.C.
- oral contraception only: TN, WA
- oral and transdermal (i.e. the patch) contraception: CO, OR
- All self-administered hormonal contraception (i.e. the pill, the patch, the ring, and injection): CA, D.C., HI, MD**, NM

Expansion of insurance coverage for contraception
- Insurers must cover 12 month supply — 12 states + DC: CA, CO**, DC, HI, IL, ME, NM*, NY, NV*, OR, VA*, VT, WA*
- Insurers must cover at least one contraceptive of all prescription methods without cost-sharing** — 8 states: CA, IL, MD*, ME, NV*, OR, VT
- Insurers must cover over the counter and prescription contraception equally — 8 states: IL, MD*, OR**

NOTES: *Effective in 2018 (MD’s contraceptive equity law, NV, NM, VA, WA). **Effective in 2019 (CO, MD’s pharmacist-prescribing law, OR’s Contraceptive Coverage Requirement).

* Insurers may apply cost-sharing for drugs or devices that are therapeutically equivalent to another contraceptive drug or device that is already covered under the same policy.

“The bill changed the scope of practice so there was no question [payers] had to [reimburse],” said Aliyah Horton, CAE, executive director of the Maryland Pharmacists Association (MPhA).
What is happening in Texas?

Ensure that pharmacists are properly reimbursed by the insurance company for services provided if a similar service provided by a doctor, physician assistant, or advanced practice nurse that falls within pharmacy’s scope of practice is reimbursed by the insurance company.

Clarify language in current legislation to allow a physician to delegate to any qualified and trained pharmacist in any practice setting.
What is happening in Texas? (continued)

Allow pharmacists to “furnish” medications when there is a positive CLIA-waived test for flu and strep (ie test and treat); pharmacists can already test, but cannot treat.

Allow pharmacists to “furnish” non-diagnostic medications like tobacco cessation products, oral hormonal contraceptives, travel medications, prenatal vitamins, and vitamin D supplements.
Literature Review
Pharmacists’ experience with prescribing hormonal contraception in Oregon
Rodriguez et al.

<table>
<thead>
<tr>
<th>Title</th>
<th>Pharmacists’ experience with prescribing hormonal contraception in Oregon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion</td>
<td>Pharmacists who responded to the initial survey at 6 months were eligible to take the survey at 12 months.</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Pharmacists not currently practicing in Oregon. Pharmacists with incorrect email addresses. Pharmacists who did not complete the state-mandated contraceptive training.</td>
</tr>
</tbody>
</table>
| Methods     | Hormonal Contraceptive Training → Survey  
Survey: anonymous with a unique identifier  
- Sent electronically  
- Reminders were sent  
- No incentives to participation |
Pharmacist Prescribing of Hormonal Contraception

JANUARY 1, 2016
Rodriguez et al.

802

- 732 Included
- 70 Excluded

6 months survey
- 121
- Did not complete 6 month survey
- 611

12 month survey
- 62
Rodriguez et al.

Pharmacists certified to prescribe contraception

6 mo.
19.4% of all OR zip codes

12 mo.
63% of all OR zip codes
THE SURVEY

26 QUESTIONS

AGE
GENDER
YEARS IN PRACTICE
CURRENT POSITION

Rodriguez et al.
Rodriguez et al.

Position
• Manager: 38.8%
• Staff: 53.7%

Practice Site
• 76.9% chain community pharmacy

Years in Practice
• License Year > 2010: 29.8%
Results: Rodriguez et al.

<table>
<thead>
<tr>
<th>Variable</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of time prescribing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3 months</td>
<td>42.2</td>
<td>16.1</td>
</tr>
<tr>
<td>&gt; 3 months</td>
<td>41.3</td>
<td>69.9</td>
</tr>
<tr>
<td># of prescriptions written monthly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>76</td>
<td>84.1</td>
</tr>
<tr>
<td>10-20</td>
<td>2.3</td>
<td>0</td>
</tr>
<tr>
<td>&gt;20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Comfortable counseling and prescribing all methods (yes)</td>
<td>87.6</td>
<td>90.4</td>
</tr>
</tbody>
</table>
Results continued: Rodriguez et al.

Motivators of Pharmacists to Provide Hormonal Contraception

- Increased access to contraception
- Reduce unintended pregnancy
- Increased job satisfaction
- Increased scope of practice
- Strengthen collaboration between pharmacists and health team

6 Months vs 12 Months
Results continued: Rodriguez et al.

Pharmacist Attitudes Regarding Provision of Contraception
Pharmacists’ comfort level and knowledge about prescribing hormonal contraception in a supermarket chain pharmacy
Lio et al.

<table>
<thead>
<tr>
<th>Title</th>
<th>Pharmacists’ comfort level and knowledge about prescribing hormonal contraception in a supermarket chain pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion</td>
<td>Kroger pharmacist in the Mid-Atlantic Division</td>
</tr>
<tr>
<td>Exclusion</td>
<td>If you did not complete the pre-survey you were excluded from the post-survey</td>
</tr>
<tr>
<td>Methods</td>
<td>Pre-post survey-based study</td>
</tr>
</tbody>
</table>
Lio et al.

118 Pharmacies → 350 Pharmacists → Pre & Post 78 Pharmacists
Lio et al.

THE SURVEY

- Comfort
- Knowledge
- Perceptions of barriers & resources needed to prescribe hormonal contraception
- Demographics

- State of Practice
- Gender
- Years in Practice
- Current Position
Lio et al.

Position
- Manager: 44.9%
- Staff: 23.1%
- Floater: 19.2%
### Results: Lio et al.

**Pharmacist comfort levels prescribing by contraceptive type**

<table>
<thead>
<tr>
<th>Contraceptive type</th>
<th>Pre/Post</th>
<th>EC</th>
<th>SC</th>
<th>N</th>
<th>SUC</th>
<th>EUC</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Pre</td>
<td>8</td>
<td>26</td>
<td>10</td>
<td>20</td>
<td>14</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>14</td>
<td>36</td>
<td>10</td>
<td>12</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Transdermal</td>
<td>Pre</td>
<td>5</td>
<td>23</td>
<td>11</td>
<td>22</td>
<td>17</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>13</td>
<td>30</td>
<td>13</td>
<td>14</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Injection</td>
<td>Pre</td>
<td>5</td>
<td>16</td>
<td>13</td>
<td>26</td>
<td>18</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>12</td>
<td>21</td>
<td>15</td>
<td>22</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Intravaginal</td>
<td>Pre</td>
<td>7</td>
<td>21</td>
<td>12</td>
<td>22</td>
<td>16</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>12</td>
<td>25</td>
<td>19</td>
<td>13</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

Pre and post refer to survey responses before and after training session. Numbers represent the absolute number of pharmacists based on each category of the Likert-type scale. *P* values derived with the use of Wilcoxon signed rank test comparing pre-post difference in comfort levels following the training program. Abbreviations used: EC, extremely comfortable; SC, somewhat comfortable; N, neither; SUC, somewhat uncomfortable; EUC, extremely uncomfortable.
Results continued: Lio et al.

Comfortable in prescribing at baseline:
- Protocol: 45.5%
- Collaborative Practice Agreement: 64.9%
- Knowing when to refer to a physician: 63.3%
- Increased after training
Results continued: Lio et al.

Contraceptive knowledge after training increased:

• Comfort level concerning knowledge on contraceptive dosing
• Different concentrations of estrogen and progestin in each hormonal contraceptive
• Choice of therapy as related to medical conditions

• All 3: p value < 0.001
<table>
<thead>
<tr>
<th>Pharmacist Identified Barriers</th>
<th>Liability 31.8%</th>
<th>Workflow Disturbances 27%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gaps in Contraceptive Knowledge 24.3%</td>
<td>Not wanting to neglect women’s health care aspects 16.9%</td>
</tr>
</tbody>
</table>
Example Protocol

See Appendix
Audience Poll
How could pharmacist prescribed hormonal contraceptive affect healthcare?
Do you think pharmacists have the appropriate knowledge to prescribe hormonal contraceptives?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Conclusion

• Pharmacist Education, Knowledge, Expertise

• Protocols

• Training Program

• Reimbursement
Acknowledgements

Nathan Pope, PharmD, BCACP, FACA
Jennifer Wilbanks, PharmD
Ashley Garling, PharmD
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QUESTIONS?
References


**Hormonal Contraceptive Self-Screening Questionnaire**  
*(updated 2017)*

<table>
<thead>
<tr>
<th><strong>Name________________________</strong></th>
<th><strong>Health Care Provider’s Name________________________</strong></th>
<th><strong>Date________________________</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of Birth________________</strong>****</td>
<td><strong>Age________________</strong>****</td>
<td><strong>Weight________________</strong>****</td>
</tr>
<tr>
<td><strong>What was the date of your last women’s health clinical visit? __________________</strong></td>
<td><strong>Any Allergies to Medications? Yes / No</strong></td>
<td><strong>If yes, list them here: __________________</strong></td>
</tr>
<tr>
<td>1. Do you think you might be pregnant now?</td>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td>2. What was the first day of your last menstrual period?</td>
<td></td>
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<tr>
<td>3. Have you ever taken birth control pills, or used a birth control patch, ring, or injection?</td>
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<tr>
<td>4. Did you ever experience a bad reaction to using hormonal birth control?</td>
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<tr>
<td><strong>If yes, what kind of reaction occurred?</strong></td>
<td><strong>If yes, which one do you use?</strong></td>
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<tr>
<td>5. Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?</td>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td><strong>If yes, which one do you use?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medical History:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Have you given birth within the past 21 days? If yes, how long ago?</td>
<td>Yes □ No □</td>
<td></td>
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<tr>
<td>7. Are you currently breastfeeding?</td>
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<td>21. Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)</td>
<td>Yes □ No □</td>
<td></td>
</tr>
</tbody>
</table>

**Do you have a preferred method of birth control that you would like to use?**

- [ ] **A pill you take each day**
- [ ] **A patch that you change weekly**
- [ ] **Other (ring, injectable, implant, or IUD)**

---

**Internal use only**

[ ] verified DOB* with valid photo ID

[ ] BP Reading _______/______

**Pharmacist Name ____________________________**

**Pharmacist Signature ____________________________**

[ ] Drug Prescribed ____________________________

Rx# ______________ -or- [ ] Patient Referred-circle reason(s)

Sig: ____________________________

(Pharmacy Phone ______________ Address ____________________________)

---

Notes:__________________________________________

---

STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF CONTRACEPTIVES (excluding DMPA)

1) Health and History Screen
Review Hormonal Contraceptive Self-Screening Questionnaire.
To evaluate health and history, refer to USMEC or Oregon MEC.
1 or 2 (green boxes) - Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) - Hormonal contraception is contraindicated --> 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 can NOT be ruled out --> Refer

3) Medication Screen (Questionnaire #24 + med list) (Corticosteroids - refer to DMPA algorithm)
Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturates, herbs & supplements, including:
carbamazepine
lumacaftor/ivacaftor
primidone
(*PLEASE ALWAYS REFER TO CURRENT MEC*)
felbamate
oxcarbazepine
rifampin / rifabutin
griseofulvin
phenobarbital
topiramate
lamotrigine
phenytoin
fosamprenavir (when not combined with ritonavir)

4) Blood Pressure Screen:
Take and document patient’s current blood pressure. Is BP <140/90?
Note: RPH may choose to take a second reading, if initial is high.


5a) Choose Contraception
Initiate contraception based on patient preferences, adherence, and history for new therapy
-Prescribe up to 12 months of desired contraception and dispense product
(quantity based on professional judgment and patient preference)

5b) Choose Contraception
Continue current form of pills or patch, if no change is necessary
-or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate
-Prescribe up to 12 months of desired contraception and dispense product. (quantity based on professional judgment and patient preference)

6) Discuss Initiation Strategy for Initial Treatment/Change in Treatment (as applicable)
a) Counseling - Quick start - Instruct patient she can begin contraceptive today; use backup method for 7 days.
b) Counseling - Discuss the management and expectations of side effects (bleeding irregularities, etc.)
c) Counseling - Discuss adherence and expectations for follow-up visits

7) Discuss and Provide Referral / Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to care provider