# ROADMAP TO SUCCESSFUL PHARMACIST PRESCRIBING OF HORMONAL CONTRACEPTION

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June 26, 2021

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## FINANCIAL DISCLOSURES

None

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## LEARNING OBJECTIVES

**Pharmacists and pharmacy technicians:**

- Explain the current landscape of pharmacist prescribing in the US
- Describe facilitators and barriers to successful provision of hormonal contraception
- Describe common challenging scenarios and approaches for provision of hormonal contraception and referral

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## ROADMAP

Background of Pharmacist Prescribing → Current Research on Pharmacist Prescribing

Challenging Clinical Scenario

- Hypertension
- Migraine Headaches
- Obesity

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# BACKGROUND

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## ACCESS TO CONTRACEPTION

- 1/3 of women report barriers to obtaining prescription for hormonal contraception
  - Few clinician appointments
  - Inconvenient clinic locations
  - Provider requirements for pelvic examination prior to prescribing
- Barriers increase inconsistent use and unintended pregnancies

Grindlay K et al. *J Womens Health.* 2016
ACOG CO 788 *Obs Gynecol.* 2012

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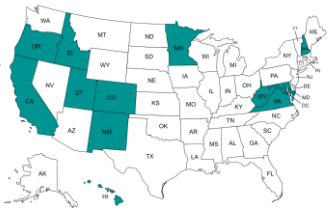
## PHARMACIST PRESCRIBING

12 U.S. states and the District of Columbia have authorized pharmacist prescriptive authority for hormonal contraception




[1] https://ncsp.us/resource/contraceptives/#:~:text=Currently%2C%20there%20are%2013%20U.S.,%2C%20Virginia%2C%20and%20West%20Virginia

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## UPTAKE OF PHARMACIST PRESCRIBING

- Reported percentage of pharmacies:
  - 11% of pharmacies in California, but 68% charged a fee
  - 42% of pharmacies in Oregon
- 10% of Oregon Medicaid prescriptions written by pharmacists
- 65% of pharmacists nationwide report interest in prescribing contraception

Gomez AM. *JAMA*. 2017
Rodriguez MI et al. *Contraception*. 2020
Anderson L et al. *Obstet Gynecol*. 2019
Rafie et al. *J Pharm Pract*. 2019

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## BARRIERS

- Pharmacist reported barriers:
  - Need for additional staff
  - Training/education
  - Liability
  - Reimbursement process
  - Billing structure

Rodriguez MI et al. *Contraception*. 2020
Kooner M et al. *J Am Pharm Assoc*. 2020

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## NEW MEXICO

- 2001 – Pharmacist Prescriptive Authority Act
- 2017 – Act amended to include hormonal contraception
  - pill, patch, ring, depo-medroxyprogesterone acetate
- 2019 – New Mexico HB89
  - 6-month supply of contraception
- 2020 – New Mexico HB42
  - Reimbursement of pharmacists at same rate as physicians

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## NEW MEXICO


Contraception
journal homepage: www.elsevier.com/locate/con

Brief Research Article

Availability of pharmacist prescription of contraception in rural areas of Oregon and New Mexico

Maria I. Rodriguez *, Bharti Garg, Shannon M. Williams, Jessica Souphanavong, Kaitlin Schmitz, Blair G. Darney

- 19% of New Mexico pharmacies report prescribing contraception
- Similar proportion of rural pharmacies offer prescriptions as urban pharmacies
- Majority of pharmacies billed women directly and not insurance

Rodriguez MI et al. *Contraception*. 2020

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## NEW MEXICO


Journal of the American Pharmacists Association

RESEARCH NOTES

Perspectives on prescribing hormonal contraception among rural New Mexican pharmacists

Alexandra Herman, Grace McCauley, Lauren Thaxton, Matthew Borrego, Andrew L. Sussman, Eve Espey

- Positive perspectives towards prescribing
- Barriers:
  - training needs, reimbursement and liability
- Facilitators:
  - availability of private areas within pharmacies, pharmacists' role as knowledgeable health care team member and pharmacist accessibility without appointments

Herman A et al. *J Am Pharm Assoc*. 2020

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## NEW MEXICO

Journal of the American Pharmacists Association (01) (2021) e140–e144
Contents lists available at ScienceDirect
Journal of the American Pharmacists Association
journal homepage: www.japha.org
RESEARCH NOTES

Pharmacists' perspectives and experience prescribing hormonal contraception in rural and urban New Mexico

Maria I. Rodriguez*, Alexandra M. Herman, Eve Espey, Alyssa R. Hersh, Amy M. Bachyrycz

- 27% of urban vs 23.5% of rural pharmacists reported prescribing contraception
- No differences between urban and rural pharmacists in prescribing hormonal contraception (adjusted OR 1.22 [95% CI 0.56-2.68])

[15]Rodriguez MI et al. *J Am Pharm Assoc.* 2021

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## NEW MEXICO

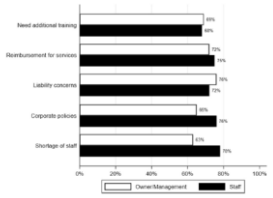


**Figure 1.** Top 5 barriers to prescribing hormonal contraception stratified by working as the owner/manager versus staff. All *P* values > 0.05

[15]Rodriguez MI et al. *J Am Pharm Assoc.* 2021

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# CURRENT RESEARCH "Implementation of Pharmacy Access to Hormonal contraception"

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## OBJECTIVES

- Understand implementation of pharmacy access to hormonal contraception at the state level
- **Primary Objective:**
  - Understand steps taken to enable pharmacist prescription
- **Secondary Objectives:**
  - Compare perceived challenges and their reported solutions
  - Explore determinants of successful program implementation

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## METHODS

- Qualitative study
- Semi-structured interviews with stakeholders from the 12 U.S. states and District of Columbia -
  - Pharmacist Association
  - Medicaid offices
  - Community pharmacists

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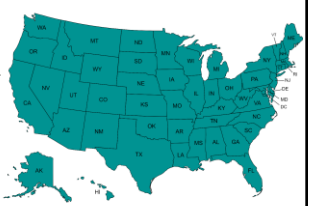
## POTENTIAL IMPACT

- Improve access to hormonal contraception
- Foster further conversations of pharmacist prescribing



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# CLINICAL SCENARIO

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## MARINA

- 32 y/o G3P3 who presents to the pharmacy for a refill of combined hormonal contraceptives. Six months ago, you prescribed her an LNG/EE combination pill for 3 months with 1 refill. You had discussed this interval as she had not had a Pap smear in 7 years.
- She returns today for a refill; she complains of a headache
- Medical history unremarkable; Marina has not yet gotten an appointment for a Pap smear
- BMI 43, BP today 143/88

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## 7 MINUTES TO DISCUSS

- What do you think about her headache and BP?
- What about the Pap smear?
- What about her BMI?
- Would you refill?

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## DO CHCS CAUSE HYPERTENSION?

- Small but significant increases in BP with CHCs
  - Increased arterial stiffness
  - Renin-angiotensin system stimulation
  - Salt and water retention
- Risk increases with age, smoking, obesity and longer duration of use
- Rapid reversal with discontinuation

- Wenger et al, Hypertension across a woman's life cycle, Journal of the American College of Cardiology, 2018
- Hoge et al, Hypertension in Women, Kidney international supplements 2013

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ELSEVIER
Contraception 73 (2006) 179–188
Contraception

Review article

Combined oral contraceptive use among women with hypertension: a systematic review

Kathryn M. Curtis[a,*], Anshu P. Mohllajee[a], Summer L. Martins[a], Herbert B. Peterson[b,c]

Overall, these studies showed that hypertensive COC users were at higher risk for stroke and acute myocardial infarction (AMI) than hypertensive non-COC users, but that they were not at higher risk for venous thromboembolism (VTE)

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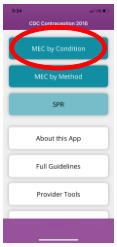
## CHCS IN THE SETTING OF HYPERTENSION

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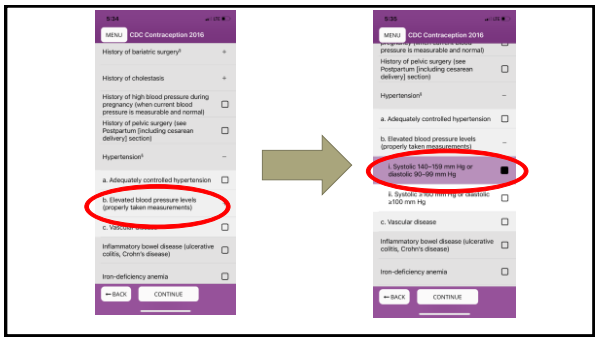


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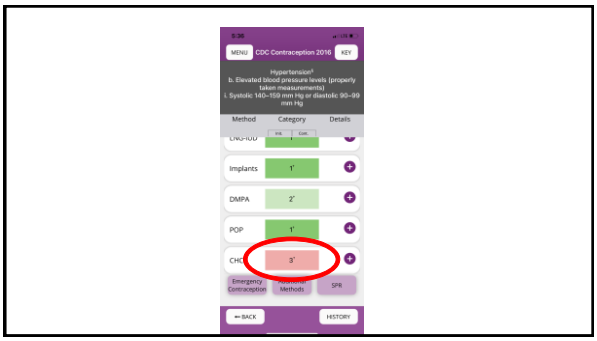


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## DOES PHARMACY ACCESS IMPACT PREVENTIVE CARE?

- Concern for non-screening in patients who access pills from a clinician vs. Pharmacy access/OTC
- Prospective cohort study
  - 532 – clinic access
  - 514 – OTC access in Mexico
- Pap smear screening, STIs, breast exam

Hopkins et al., 2012

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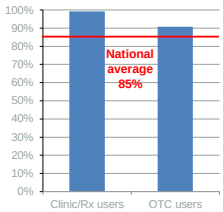
## CERVICAL CANCER SCREENING




**Reasons for not having a Pap in last 3 years**

- Too expensive
- Too inconvenient
- Keep putting it off
- Don't know where to get it

Hopkins et al., 2012

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## WEIGHT AND CHCS

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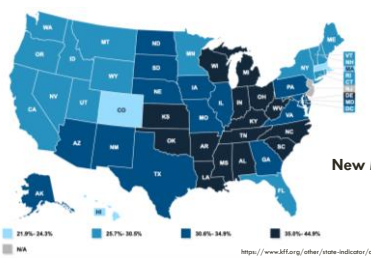
## OBESITY IN ADULT WOMEN BY STATE 2019




**New Mexico – 32.5%**

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## RESEARCH ON OBESITY - CONTRACEPTION

- Overweight/obese women traditionally excluded from trials
- Over 130% of ideal body weight
- Pharmacokinetics may not tell the whole story
- Higher quality studies are reassuring
- Pregnancy risks
  - Gestational hypertension, pre-eclampsia
  - Diabetes
  - Anesthesia complications
  - Worsening obesity

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## EFFECTIVENESS OF ORAL CONTRACEPTIVES

- Most studies show no differences between obese/non-obese
  - Limitations in studies showing difference
    - Self reported weight remote from study
    - No differentiation between PK factors and behavioral factors (adherence)
- Dosing strategy
  - Reducing hormone free interval may improve effectiveness in obese women (e.g., 28-0 or 24-4 vs. 21-7)
- Needed research
  - Effectiveness by progestin formulation
  - No data in the highest weight categories

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## EFFECTIVENESS OF PATCH AND RING

- Patch may be less effective in obese women
  - Limited evidence:
    - Pooled analysis of early trials 3319 women – more contraceptive failures in obese women
    - Data submitted to FDA of 1523 women – high risk of pregnancy
  - Absolute risk of pregnancy low in both groups – better than barriers
- Ring may be as effective in obese woman
  - Single study of contraceptive failure – no difference in obese vs. non-obese

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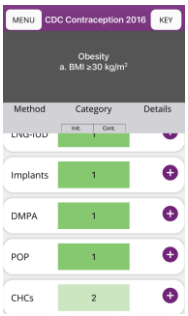


nonusers ... evidence suggests that effectiveness ... some COC formulations might decrease with increasing BMI, however the observed reductions in effectiveness are minimal and evidence is conflicting. Effectiveness of the patch ... might be reduced in women > 90 kg. Limited

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## DO PILLS CAUSE WEIGHT GAIN?


Combination contraceptives: effects on weight

- Cochrane review 2014
- 49 trials: RCTs, at least 3 treatment cycles, compared a COC to placebo or another COC
- 4 trials with placebo group or a non-intervention group – no differences in weight
- Overall conclusions
  - Available evidence insufficient to determine the effect of COCs on weight
  - No large effect noted
  - Future trials need placebo or non-intervention groups

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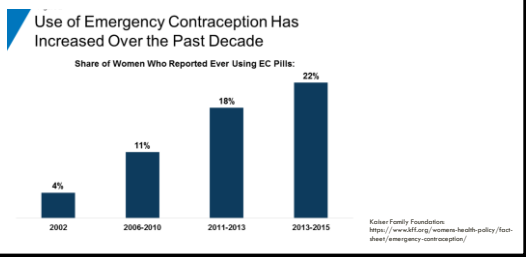
## EMERGENCY CONTRACEPTION

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## ORAL EC AND OBESITY

**Levonorgestrel (LNG)**

- Data limited, poor quality
- Study results inconsistent
- Higher risk of pregnancy up to 4.4 x rate for normal weight women
- Rates increase dramatically after 75-80 kg

**Ulipristal acetate (Ella)**

- Data limited, poor quality
- Study results inconsistent
- Possible higher risk, up to 2 x rate
  - Wide confidence intervals

Jatlaoui and Curtis, Safety and effectiveness data for emergency contraceptive pills among women with obesity: A systematic review. Contraception, 2016

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Encourage EC use regardless of weight!

Copper IUD > Ulipristal acetate > LNG

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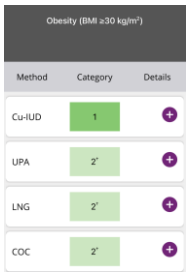


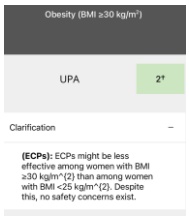


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## HEADACHES AND CHCS

- Oral contraceptives and migraines common in young women
- Oral contraceptives increase the risk of ischemic stroke in women with migraine with aura
- Consider use of a tool to diagnose migraine with aura

Sacco et al, Hormonal contraception and risk of ischemic stroke in women with migraine: A consensus statement from the European Headache Federation and the European Society of contraception and reproductive health, Journal of Headache and Pain, 2017

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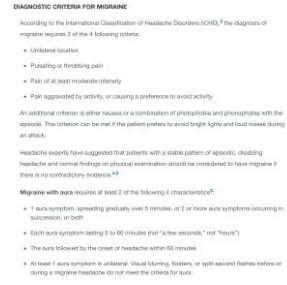

**DIAGNOSTIC CRITERIA FOR MIGRAINE**

According to the International Classification of Headache Disorders (ICHD),[3] the diagnosis of migraine requires 2 of the 4 following criteria:

- Unilateral location
- Pulsating or throbbing pain
- Pain of at least moderate intensity
- Pain aggravated by activity, or causing a preference to avoid activity

An additional criterion is either nausea or a combination of photophobia and phonophobia with the episode. This criterion can be met if the patient prefers to avoid bright lights and loud noises during an attack.

Headache experts have suggested that patients with a stable pattern of episodic, disabling headache and normal findings on physical examination should be considered to have migraine if there is no contradictory evidence.[4,5]

**Migraine with aura** requires at least 2 of the following 4 characteristics[3]:

- 1 aura symptom, spreading gradually over 5 minutes, or 2 or more aura symptoms occurring in succession, or both
- Each aura symptom lasting 5 to 60 minutes (not "a few seconds," not "hours")
- The aura followed by the onset of headache within 60 minutes
- At least 1 aura symptom is unilateral. Visual blurring, flashes, or split-second flashes before or during a migraine headache do not meet the criteria for aura.

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## DIAGNOSIS OF MIGRAINE

**TABLE 3 Visual Aura Rating Scale (VARS) for the diagnosis of aura[4]**

| Visual symptom characteristic | Risk score |
|---|---|
| Duration of visual symptom of 5 to 60 minutes | 3 |
| Visual symptom develops gradually over ≥ 5 minutes | 2 |
| Scotoma symptom | 2 |
| Zig-zag line (fortification) | 2 |
| Unilateral (homonymous) | 1 |
| Migraine with aura diagnosis | Summed score ≥ 5 |

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## IF DIAGNOSIS OF MIGRAINE WITH AURA IS UNCLEAR

- Consider referral
- Consequences of label of migraine with aura

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## 6 MONTH PRESCRIBING AUTHORITY

- As of January, 2021, 6-month prescription for contraceptives is New Mexico law
- ACLU conversation:
  - "Understand that when the carrier comes back and says we're not going to approve it – we have a role in pushing back"

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## PREGNANCY IS DANGEROUS!

Significantly higher than most of the dangers of contraindications


The American College of Obstetricians and Gynecologists
Communications Office
Washington, DC
202-484-3321
communications@acog.org acog.org

**Half of Women Unaware that Pregnancy Is More Dangerous Than Contraception**

May 7, 2013

*New Orleans, LA* — About half of pregnant women incorrectly believe that hormonal contraception is more dangerous than pregnancy, according to new research presented

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