ROADMAP TO SUCCESSFUL PHARMACIST PRESCRIBING OF HORMONAL CONTRACEPTION

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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

ROADMAP

Background of Pharmacist Prescribing

Current Research on Pharmacist Prescribing

Challenging Clinical Scenario
- Hypertension
- Migraine Headaches
- Obesity

BACKGROUND

ACCESS TO CONTRACEPTION

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

FINANCIAL DISCLOSURES

None
12 U.S. states and the District of Columbia have authorized pharmacist prescriptive authority for hormonal contraception


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

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

Pharmacist Prescriptive Authority Act
- 2001 – Pharmacists granted prescriptive authority
- 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

NEW MEXICO

- 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

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
NEW MEXICO

- 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])

Rodriguez MI et al. J Am Pharm Assoc. 2021

CURRENT RESEARCH

“Implementation of Pharmacy Access to Hormonal contraception”

METHODS

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

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

POTENTIAL IMPACT

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

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

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?

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

CHCS IN THE SETTING OF HYPERTENSION

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)
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

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

Clinic/Rx users
OTC users
National average

Hopkins et al., 2012

WEIGHT AND CHCS

OBESITY IN ADULT WOMEN BY STATE 2019

New Mexico – 32.5%

https://www.kff.org/other/state-indicator/adult-obesity-bysex/
**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

**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

**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 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

**DO PILLS CAUSE WEIGHT GAIN?**
- 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
- General conclusions
  - Available evidence insufficient to determine the effect of COCs on weight
  - No large effect noted
  - Future trials need placebo or non-intervention groups

**EMERGENCY CONTRACEPTION**
- Use of Emergency Contraception Has Increased Over the Past Decade
- Share of Women Who Reported Ever Using EC Pills
  - 2000: 4%
  - 2001-2011: 15%
  - 2012-1016: 18%
  - 2016: 12%
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

Encourage EC use regardless of weight!
Copper IUD > Ulipristal acetate > LNG

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

DIAGNOSIS OF MIGRAINE

| TABLE 3 Visual Aura Rating Scale (VARS) for the diagnosis of aura |
|---------------------------------|-------------------|
| Visual symptom characteristics   | Risk score |
| Duration of visual symptom of 5 to 60 minutes | 3 |
| Visual symptom develops gradually over ≥ 5 minutes | 2 |
| Scintoma symptom                  | 2 |
| Zig-zag line (furluration)        | 2 |
| Unilateral (homonymous)           | 1 |
| Migraine with aura diagnosis      | Summed score ≥ 5 |

IF DIAGNOSIS OF MIGRAINE WITH AURA IS UNCLEAR
- Consider referral
- Consequences of label of migraine with aura

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”

PREGNANCY IS DANGEROUS!
Significantly higher than most of the dangers of contraindications