



# The Impact of Pack Supply on Oral Contraceptive Continuation

Katharine O'Connell White, MD, MPH

Columbia University

August 20, 2009

# Oral Contraceptive Use

- OCs are the most popular form of reversible contraception in the U.S.
- More than 18 million women use OCs
- As many as 2.7 million women cared for in Title X clinics
- 80% of women of reproductive age have used OCs at some point (average 5-6 yrs)

Rosenberg 1998; Forrest 1990; Dawson, 1990

# Oral Contraceptive MIS-use

- Discontinuation rates of 29% to 60% after the first 6 to 12 months of use
- High rates of non-return and subsequent discontinuation of contraception use
- Women who discontinue OCs are likely to not substitute another contraceptive or to adopt a less effective method

# OC Discontinuation

- Misuse of OCs results in ~ **1 million** unintentional pregnancies per year
- If the rate of premature OC discontinuation could be reduced by **10%**, unintended pregnancies would drop by 7%, leading to savings of up to **\$300 million**

# Reasons for OC Discontinuation

- Changes in need
- Side effects (or fear of them)
- User-related reasons
- **Logistical reasons**—lost prescription, lost Medicaid coverage, ran out of the method

# Conventional OC Dispensing

- Small initial supply (3 cycles)
  - No published guidelines
  - Concerns about hypertension
  - Concerns about incorrect OC use
- 
- The number of pill packs initially provided strongly correlates with the probability of method continuation

# “Six Pack”

- Enhanced OC provision
- Hypothesis: Women who receive more cycles will have higher continuation rates versus women who receive fewer cycles
- These women will have greater duration of total use of the method during the study period

# Study Design

- Randomized controlled trial
- New starts or restarts of OCs
- Baseline study questionnaire
- Routine clinic assessment
  - Relevant history, targeted physical exam
  - Urine pregnancy testing as needed
  - Plan B as needed
  - STI risk reduction education

# Follow-up

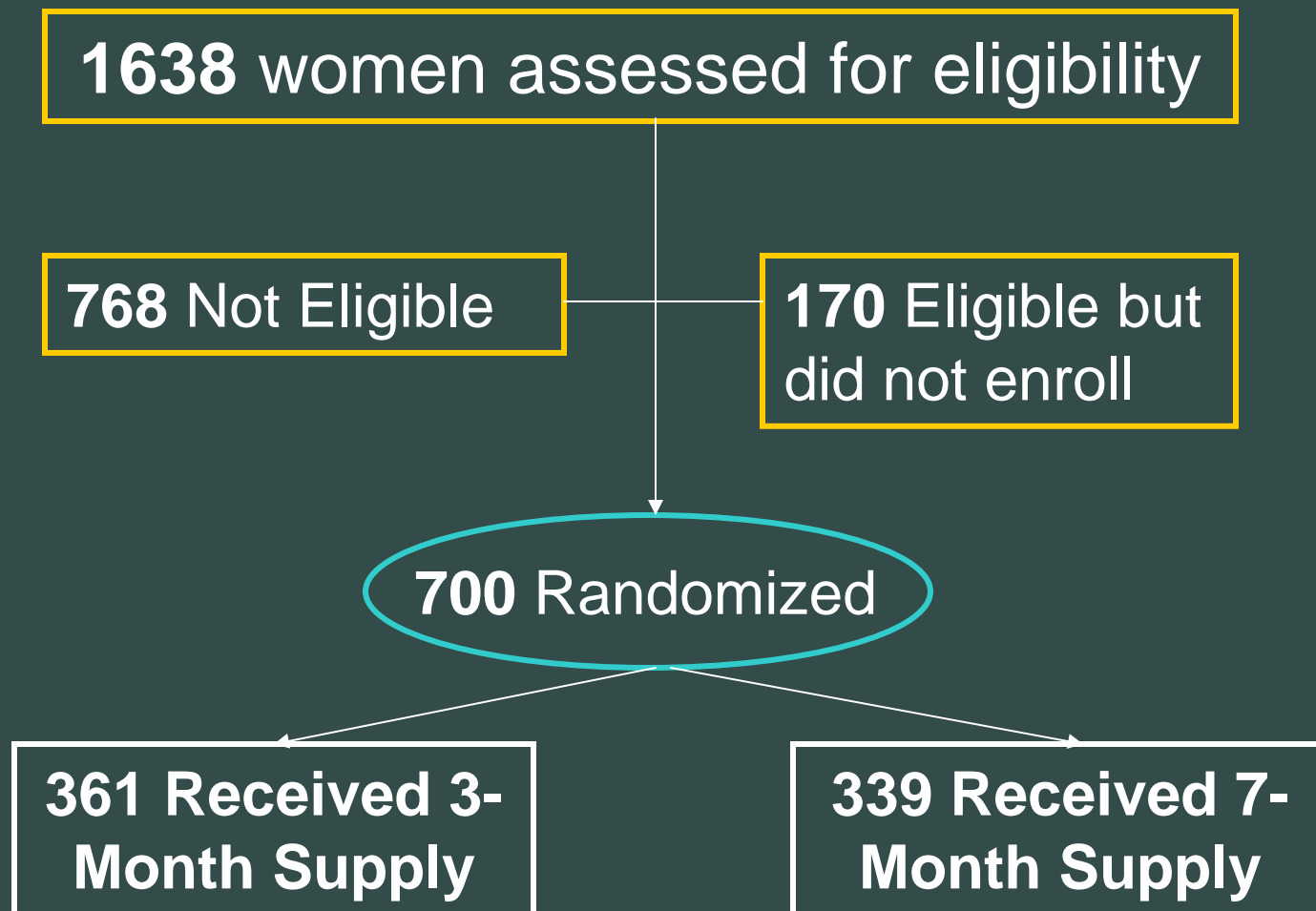
- Subjects receive pills at baseline:
  - 3 cycles (Conventional Supply)
  - 7 cycles (Enhanced Supply)
- Contacted at 6 months
- Primary outcome: 6-month OC continuation rate



# Family Planning Clinic (FPC)

- Columbia University
  - partly Title X-funded, community-based clinic
  - ~30,000 annual visits
  - 92% of patients are Latina or African-American
  - 96% report incomes below 100% of poverty level

# Results



# Results

## 3-Pack Group (361)

93 Discontinued Study  
16 Did not receive OCs  
72 Lost to follow-up  
5 Refused follow-up

43 have not yet completed follow-up

225 Subjects with follow-up information to date

## 7-Pack Group (338)

91 Discontinued Study  
22 Did not receive OCs  
66 Lost to follow-up  
3 Refused follow-up

37 have not yet completed follow-up

210 Subjects with follow-up information to date

# Safety (Adverse Events)

## ■ Conventional Supply

- Ectopic pregnancy
- Syncopal episode
- Infection
- Asthma
- Food poisoning
- Ulcerative colitis flare

## ■ Enhanced Supply

- Cholecystectomy
- Hemiplegic migraine
- Enteritis

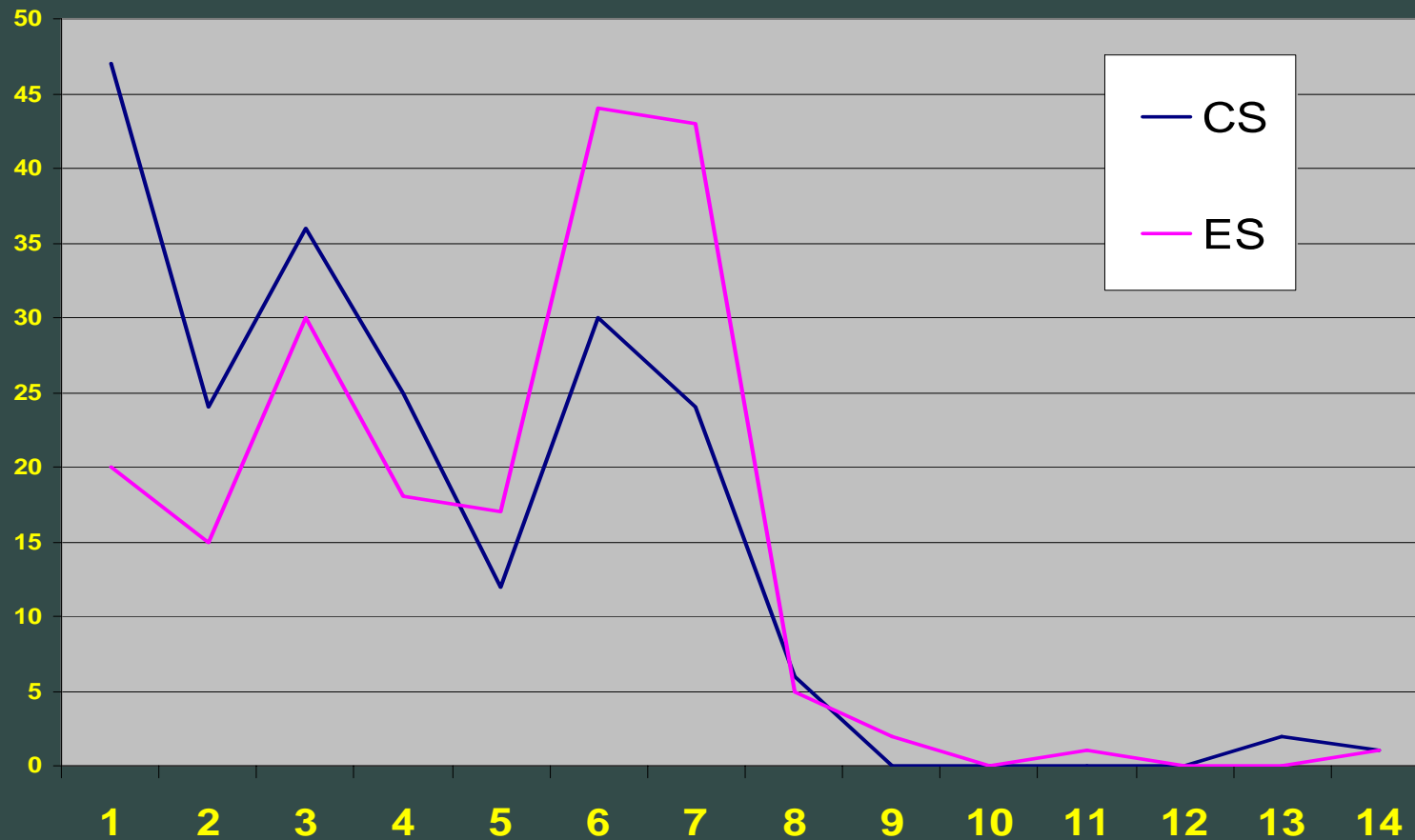
# Took a pill in the past 7 days

- Conventional supply: 30.7%
- Enhanced supply: 42.8%
  
- Chi-square: .008
- **OR 1.7** (95% CI 1.1 – 2.6) of 6 month continuation if given more pills

## *Best estimation of continuation*

- Conventional supply: 34.4%
- Enhanced supply: 51.7%
  
- Chi-square:  $<.001$
- **OR 2.08** (95% CI 1.4 – 3.1) of 6 month continuation if given more pills

# Number of Packs Started

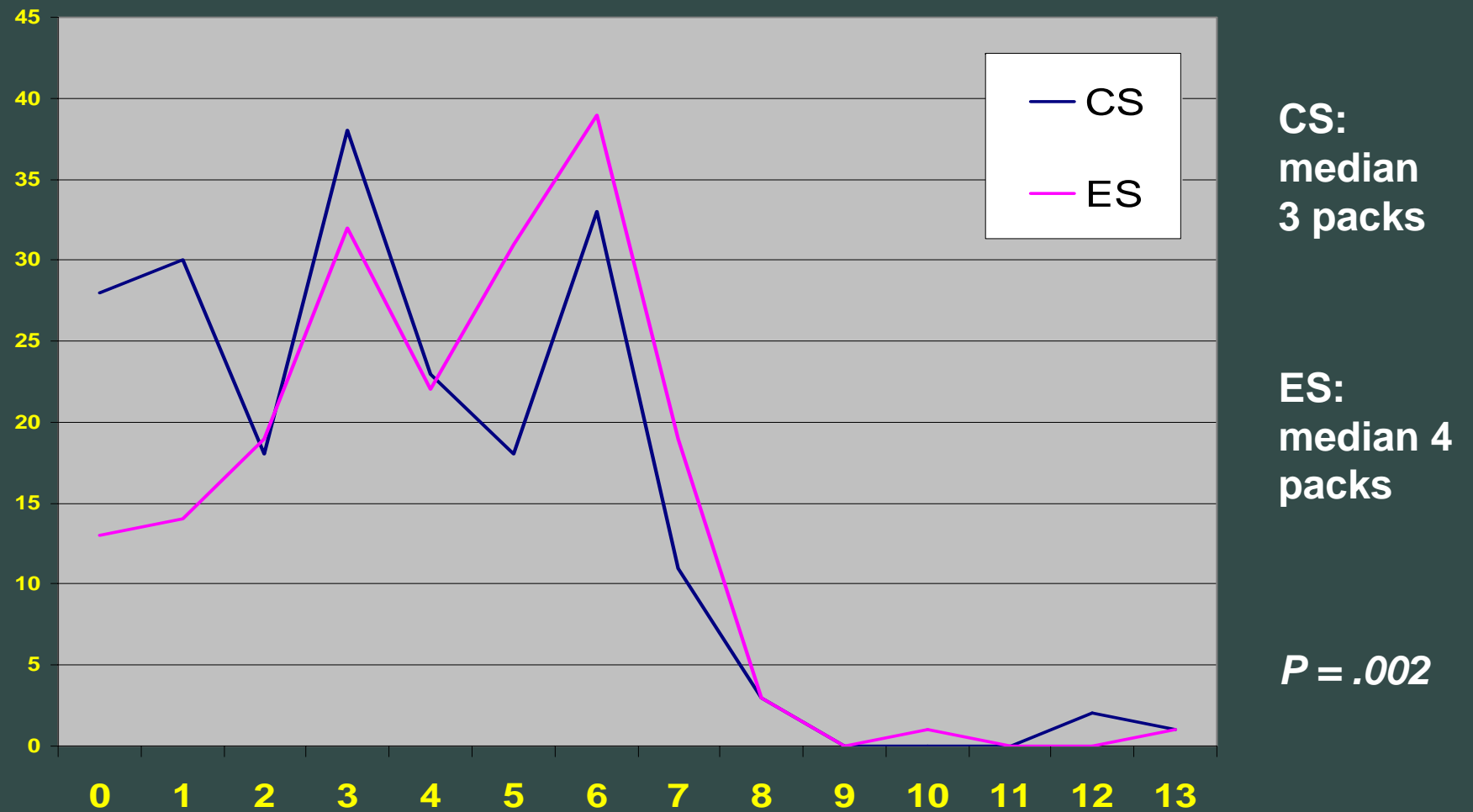


**CS:**  
median  
3 packs

**ES:**  
median  
5 packs

*P* < .001

# Number of Packs Finished



# Lost Packs of Pills

- Conventional Supply:
  - 8 subjects (3.7%)
  - Average number lost: 1.75
  - Range 1-3
- Enhanced Supply:
  - 13 subjects (6.5%)
  - Average number lost: 2.15
  - Range 1-5

# Pregnancies

- Conventional Supply group: 27 (7.5%)
- Enhanced Supply group: 19 (5.6%)
  
- Study not powered to detect a difference in pregnancy rates

# Implications for Service Provision

- Greater provision of pill packs at time of initiation is safe and effective
- Changes in service model
  - “Fast tracking” refills
  - Allows time to see more new clients
- Changes in budgeting
  - Prohibitive cost of OCs

# Thank You

- OPA grant 1 FPRPA 006025-01-00
- The staff at the Family Planning Clinic
- My collaborators
  - Carolyn Westhoff, MD
  - Claudia Roca, MPH
- The patients