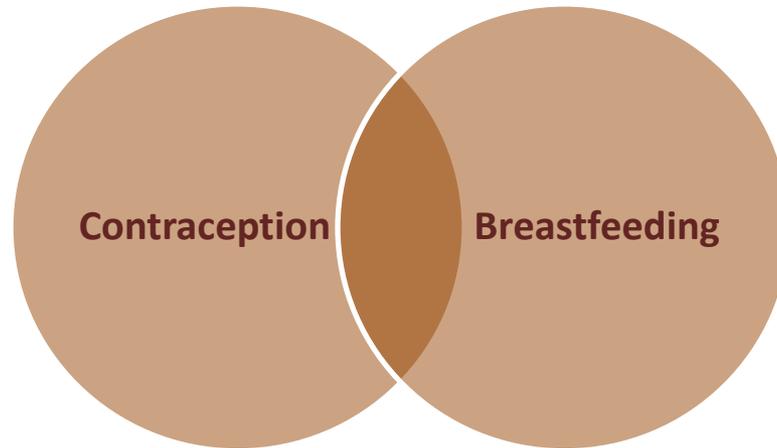


Family Planning for the Breastfeeding Woman



Virginia E. Robertson, MD, MScPH, CLC
Bureau of Maternal, Infant and Reproductive Health

September 16, 2015 Webinar

**For Audio, please call in using this conference line:
1-866-285-7780 Access Code: 5428417**

88%* of New York City Moms start breastfeeding...



*NYC Pregnancy Risk Assessment Monitoring System (PRAMS) data 2012

...And many will need/want
contraception ...during breastfeeding



Goal: Exclusive breastfeeding for 6 months and continuing to at least to one year after introducing other foods...

Promoting Health of the Family

- Inter-pregnancy spacing
- Prevention of maternal illness
- Promotion/protection of infant and child health



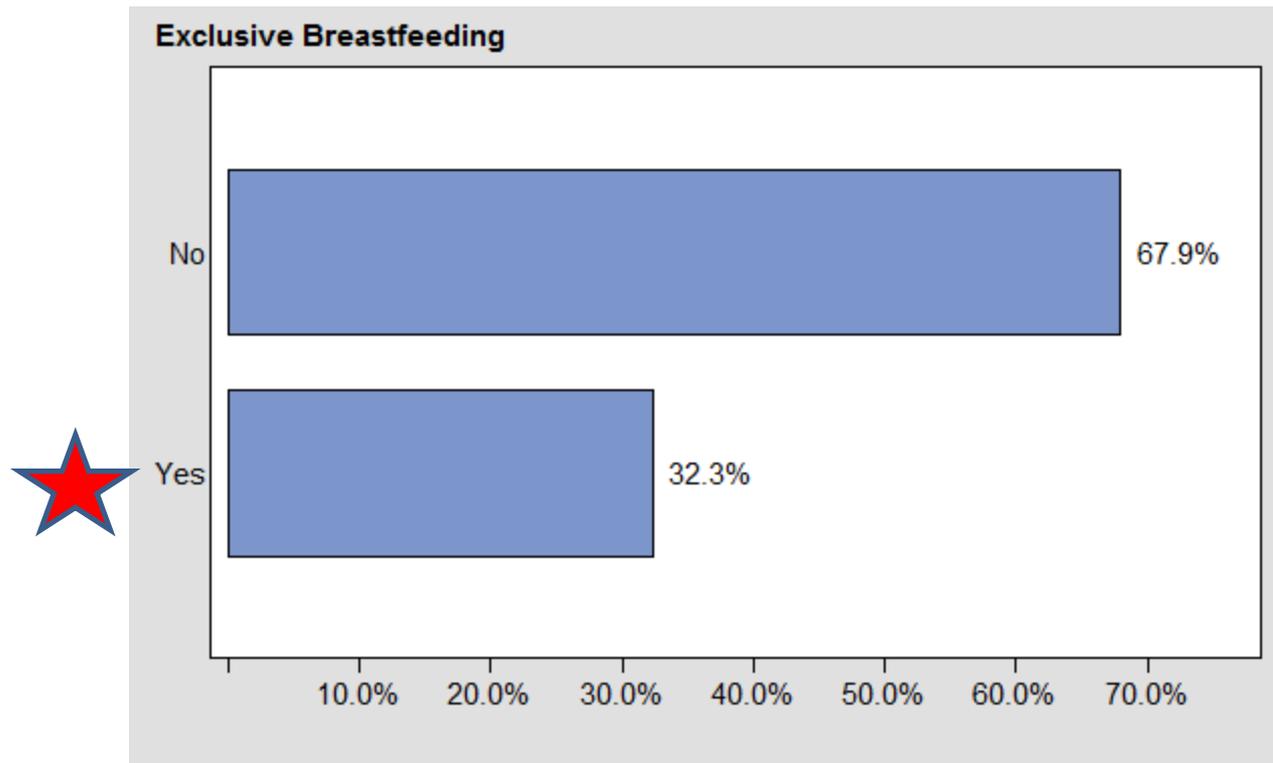
Objectives

- Be able to:
 - Be familiar with evidence about hormonal contraception during lactation
 - Understand current guidelines on contraception for lactating women
 - Discuss realistic contraception options with breastfeeding mothers

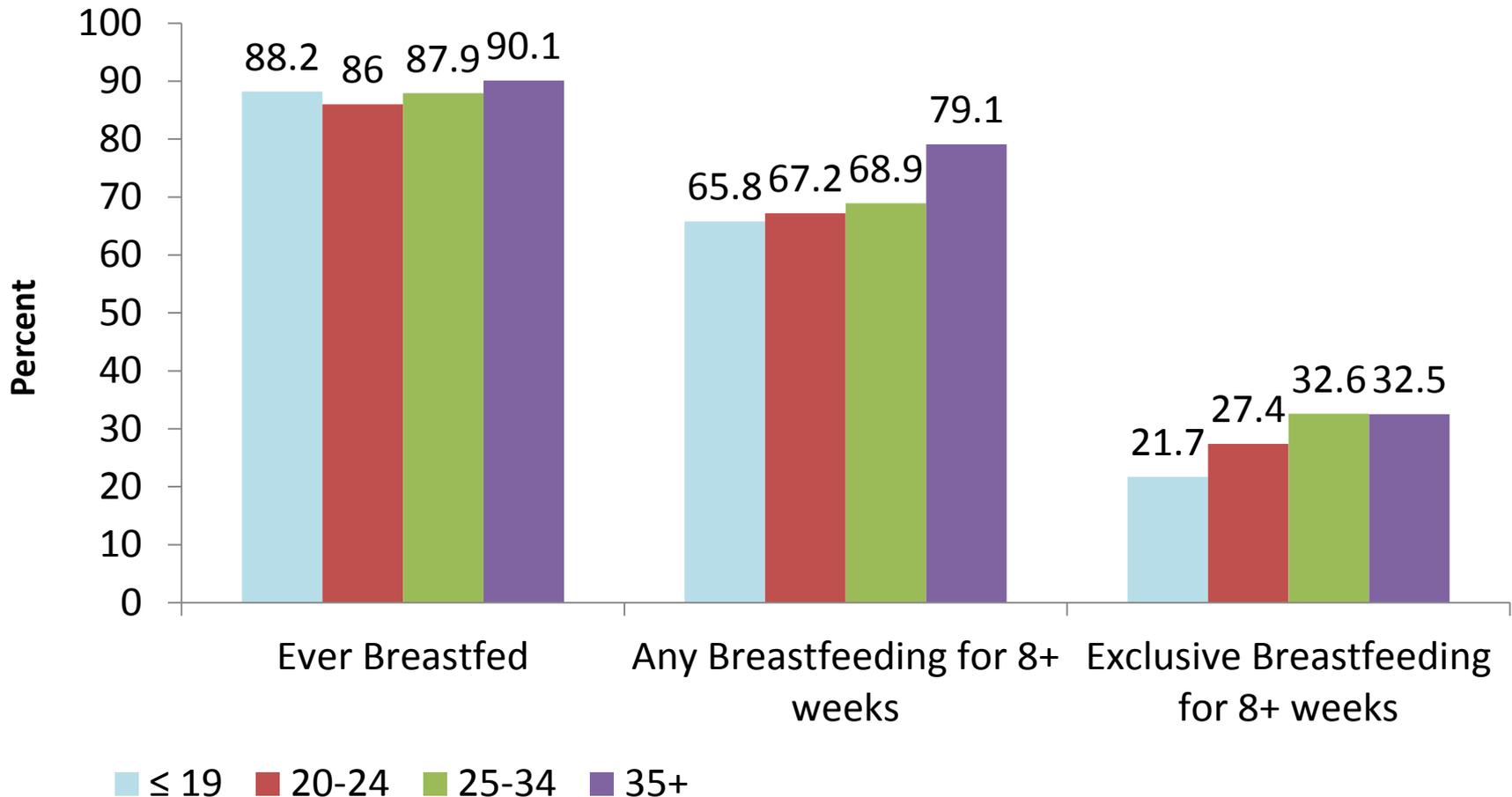
Disclaimers

- I have no commercial interests in any of the products mentioned.
- **Not a full-on primer on contraception**
- **Not a primer on Lactational Amenorrhea Method (LAM)**

NYC 2013: 120, 457 live births, Breastfeeding at Hospital Discharge

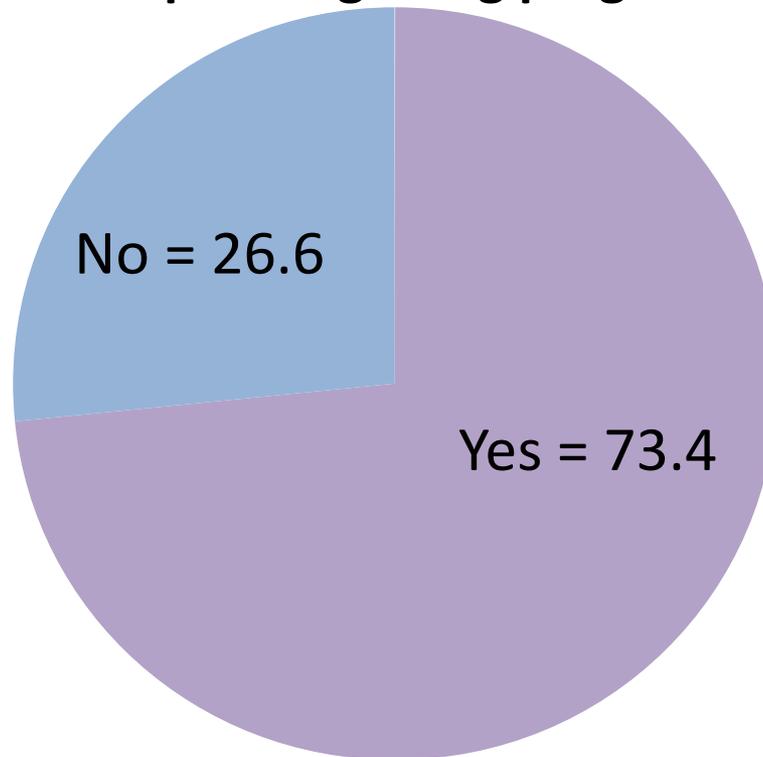


Breastfeeding Initiation and Any and Exclusive Breastfeeding for 8+ weeks by Maternal Age, NYC 2012



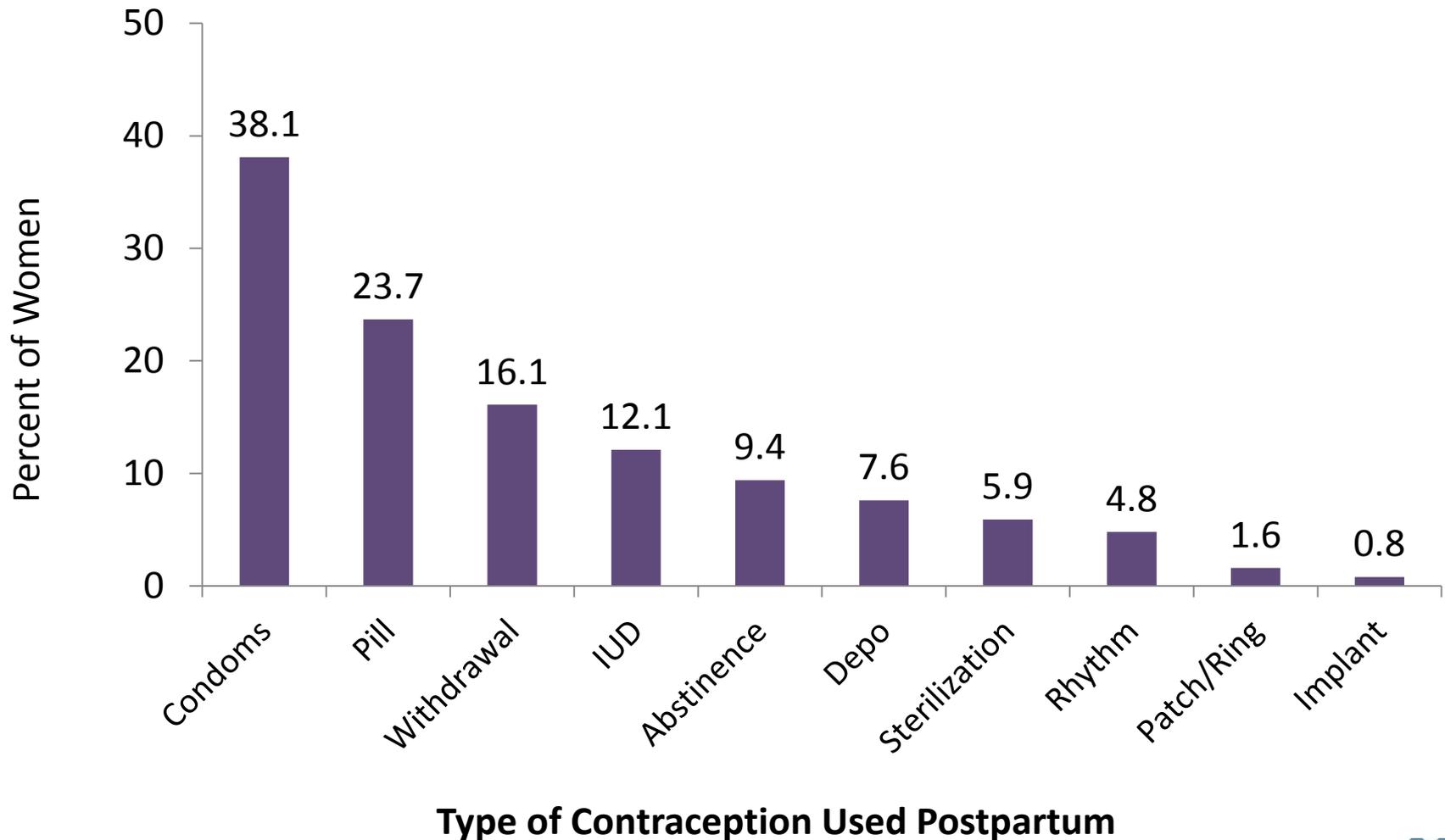
Postpartum contraception among women with a recent live birth, 2012

**Are you or your husband/partner doing anything now*
to keep from getting pregnant?**

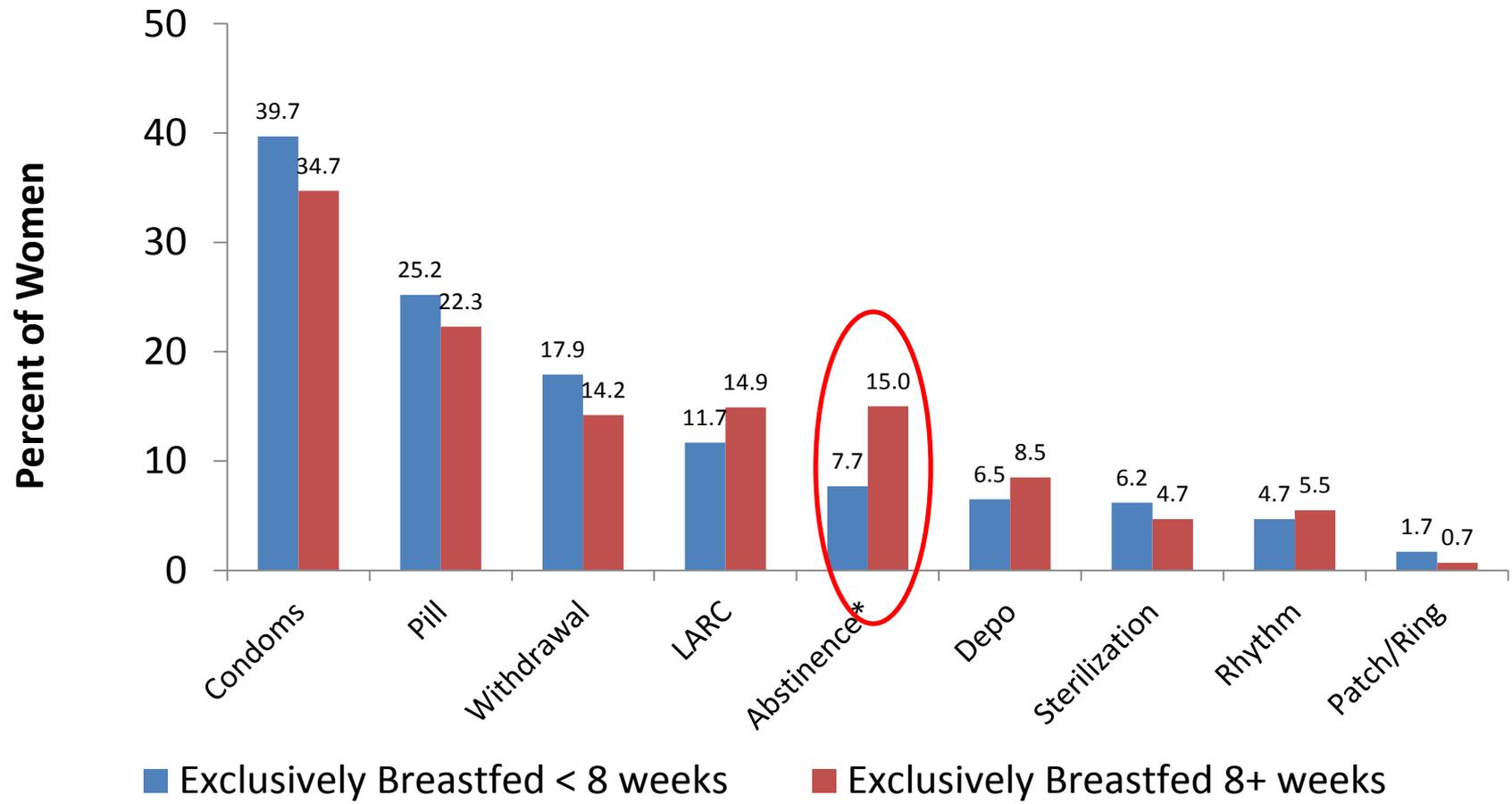


*Survey received back 9 wks - 8 months post-partum; median 4 months.
Source: NYC PRAMS 2012

Type of Contraception Used Postpartum Among Women Trying To Prevent Pregnancy, 2012



Type of Contraception Used Postpartum Among Women Trying To Prevent Pregnancy by Exclusive Breastfeeding for 8+ weeks, NYC 2012



Source: NYC PRAMS 2012 *significant difference ($p < 0.05$) between groups

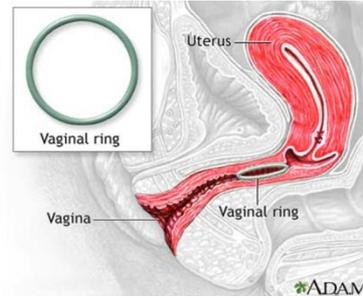
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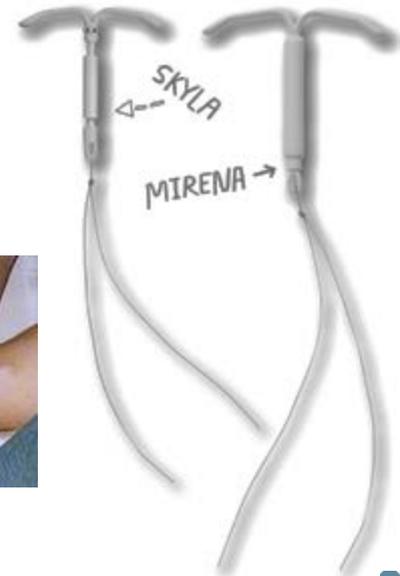
Questions about Hormonal Contraception and BrFdg

- Any impact on...
 - Breastmilk composition and production?
 - Breastfeeding duration?
 - Infant growth and development?
- Does timing of introduction affect above?
 - For women who want early contraception, what is the evidence?
- Is there a “best” method?

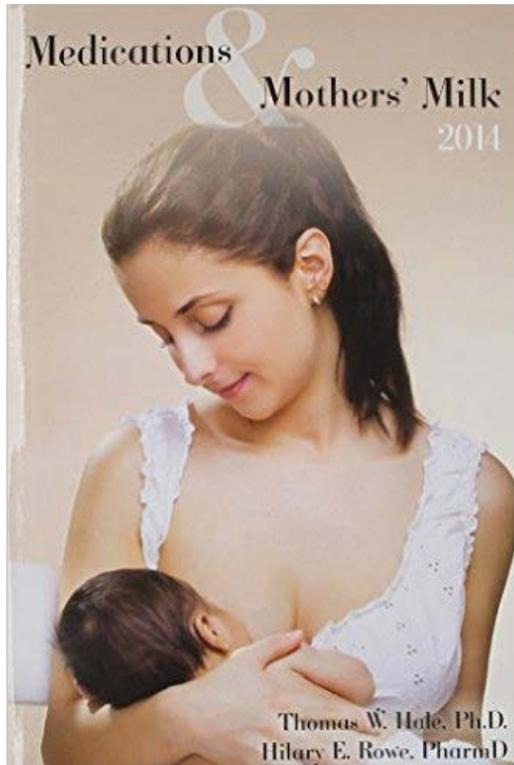
Combined hormonal methods (estrogen plus progestin)



Progestin-only methods



Usual Clinical References



- Combined oral contraceptives (COC) rated L3 = Moderately safe
 - “Tend to decrease the volume of milk produced”
 - Reduced fat content?
 - Earlier started, more likely suppression
 - However, not just a phenomenon in early lactation
 - Low transfer into milk...”minimal or no effect on sexual development in infants”



LactMed Database

- Ethinyl estradiol in COC
 - “COCs probably do not affect” milk composition
 - “seems likely that doses of 30 mcg daily or greater can suppress lactation”
 - Low levels get into milk... case reports of breast engorgement in infants
 - Little evidence on low-estrogen COCs, in pre-emies or ill infants
- Norethindone as POP
 - “poor to fair quality evidence...does not adversely effect the composition of milk, the growth and development of the infant or the milk supply”
 - “May be prudent to avoid...until lactation is well-established”

LactMed

- Levonorgestel (LNG)
 - “No clinically important negative effect on the quality of breastmilk and results in either no effect or an increase in the milk supply and duration of lactation”
 - Based on several LNG only methods, including Norplant studies (method no longer available)
 - Cites studies with delayed insertions (after 6 wks)
- DMPA
 - “Fair quality evidence” suggests “no effect on composition of milk, the growth and development of the infant, or the milk supply” ...but notes that there are low quality studies on initiation before 6 wks

Let's go to the literature....

- ***Focus on*** early use of contraceptives in lactation
- Of note:
 - Most are small studies
 - Often one or 2 studies per contraceptive method (if that) are found
 - Breastfeeding outcomes variable
 - Randomized, placebo-controlled studies not appropriate...multiple methods

COC vs POP, 2005-8

- New Mexico, breastfeeding moms 15 -45 yrs, healthy term infants, N = 127
 - Wanted to start oral contraception by 2 wks
 - No contraindications by usual standards
- Double-blind randomization:
 - 63 received progestin-only pill (NE)
 - 64 received combined pill (NE/EE 35 mcg)
- Survey, phone follow-up, in-person visits over 2-6 months

COC vs POP: Participants

- At 2 week start-up:
 - 63% of women in each group were exclusively breastfeeding
 - 22% in each group perceived inadequate milk supply
 - Women in COC group more like to have used oral contraception in past
 - Women in POP group more likely to have breastfed before
- Participant retention at 8 wks: Only 40 in each group were still in the study, breastfeeding, AND using contraceptive

No Differences in Infant Growth

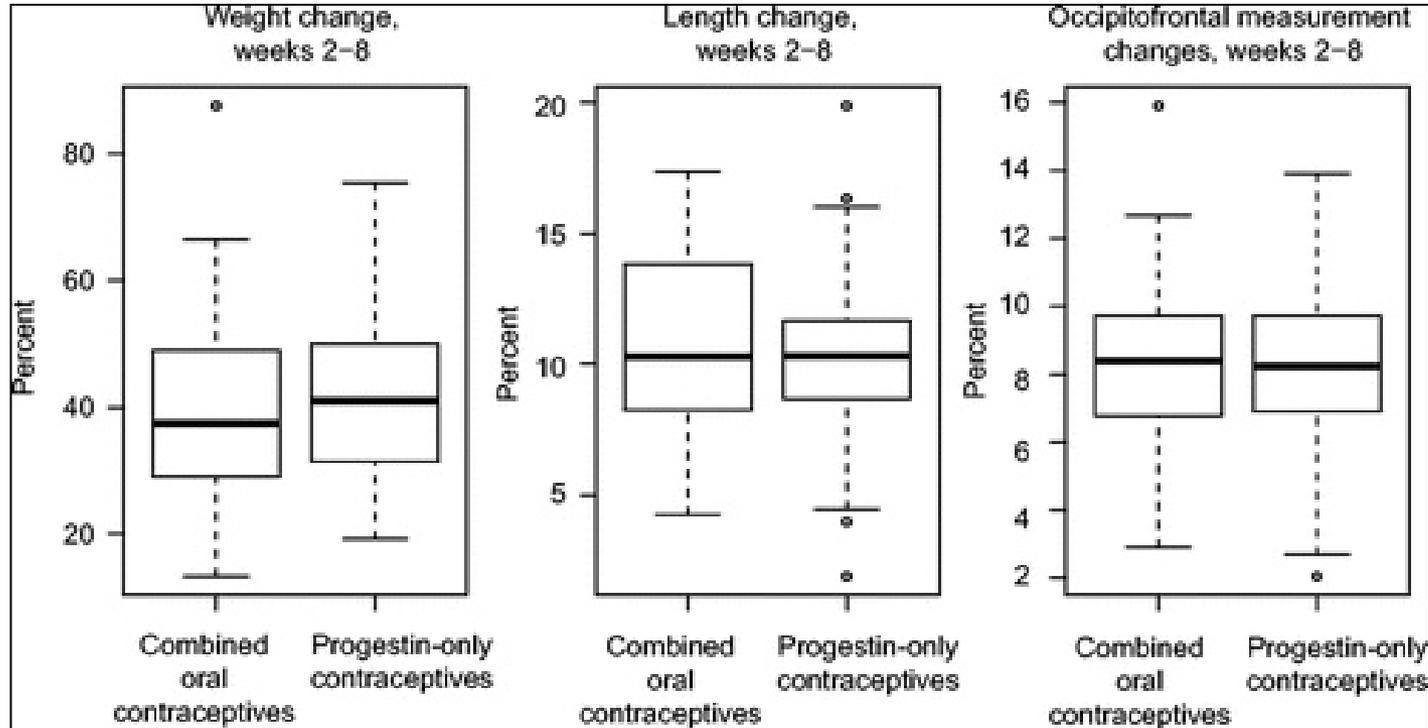
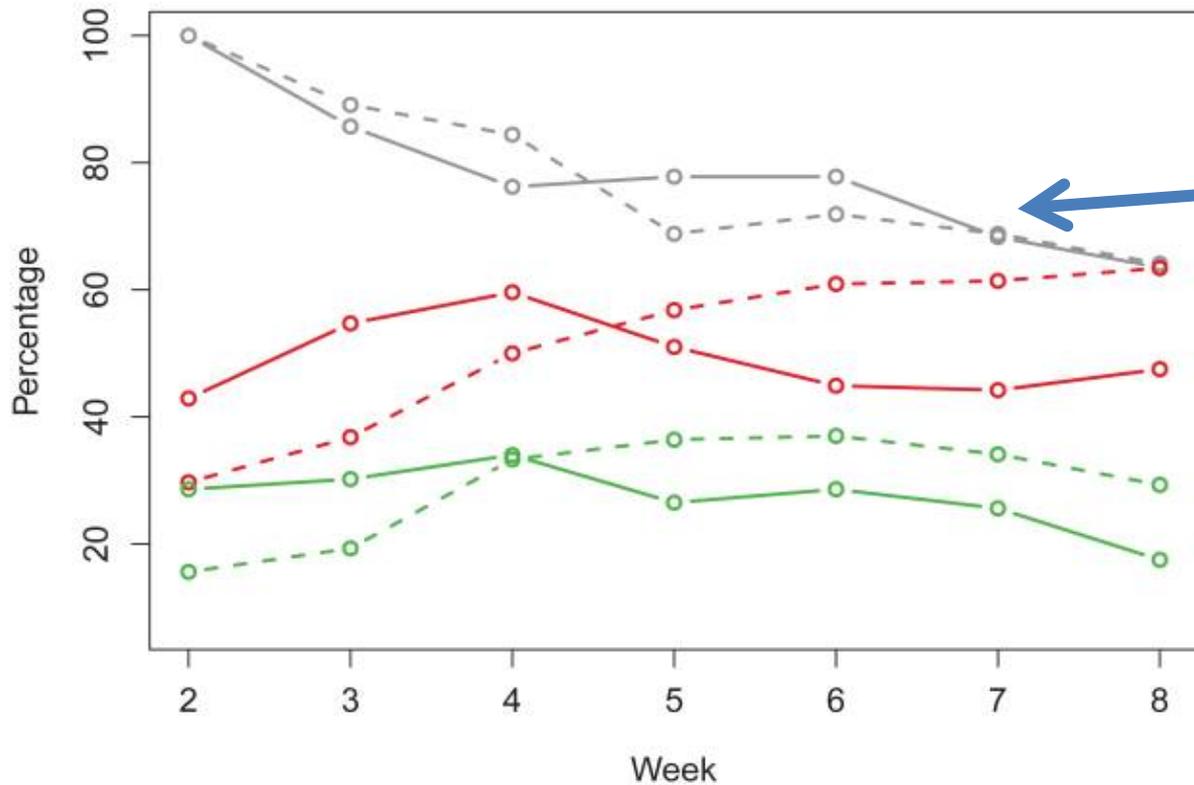


Fig. 4 . Infant growth. Changes in weight, length, and occipito-frontal measurements in infants of women using combined oral contraceptive compared with those using progestin-only pills between weeks 2 and 8. n was 41 and 40, respectively, for infants in the combined oral contraceptive and progestin-only pills with weight and length. For occipito-frontal measurement, the respective n was 40 and 38.

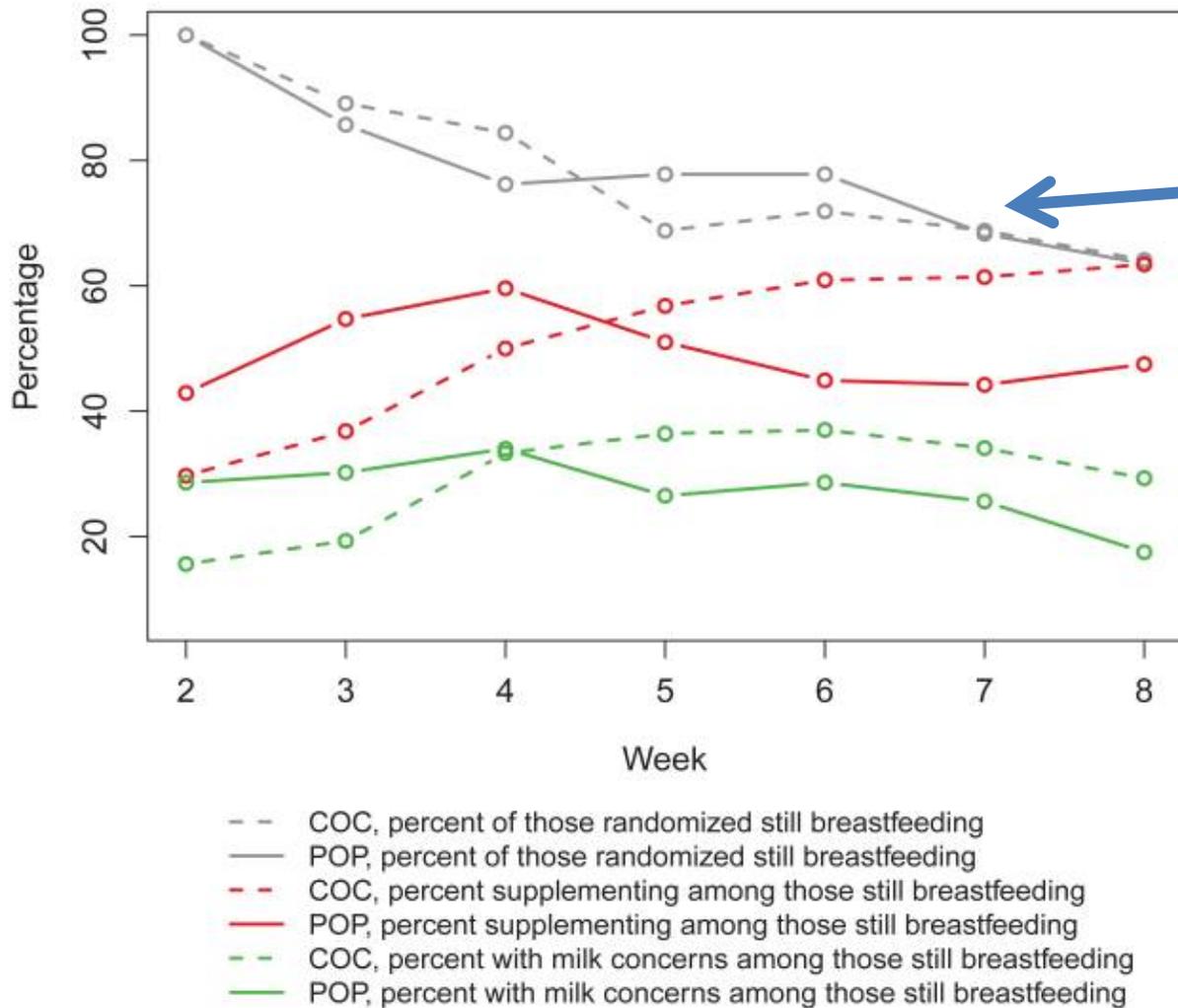


Primary endpoint = still brfdg at 8 wks:

COC 64.1%, POP 63.5%
(p = ns)

- COC, percent of those randomized still breastfeeding
- POP, percent of those randomized still breastfeeding
- COC, percent supplementing among those still breastfeeding
- POP, percent supplementing among those still breastfeeding
- COC, percent with milk concerns among those still breastfeeding
- POP, percent with milk concerns among those still breastfeeding

Fig. 3 . Breastfeeding outcomes at 8 weeks. Continued breastfeeding in combined pills (n=64) compared with progestin-only pill (n=63) groups. Percentage still breastfeeding for a group is the percentage still breastfeeding of the number originally randomized to the group. Percentage supplementing or with milk concerns for a group is the percentage supplementing or with milk concerns of those who still are breastfeeding within the group. *Obstetrics & Gynecology*. 119(1):5-13, January 2012. DOI: 10.1097/AOG.0b013e31823dc015

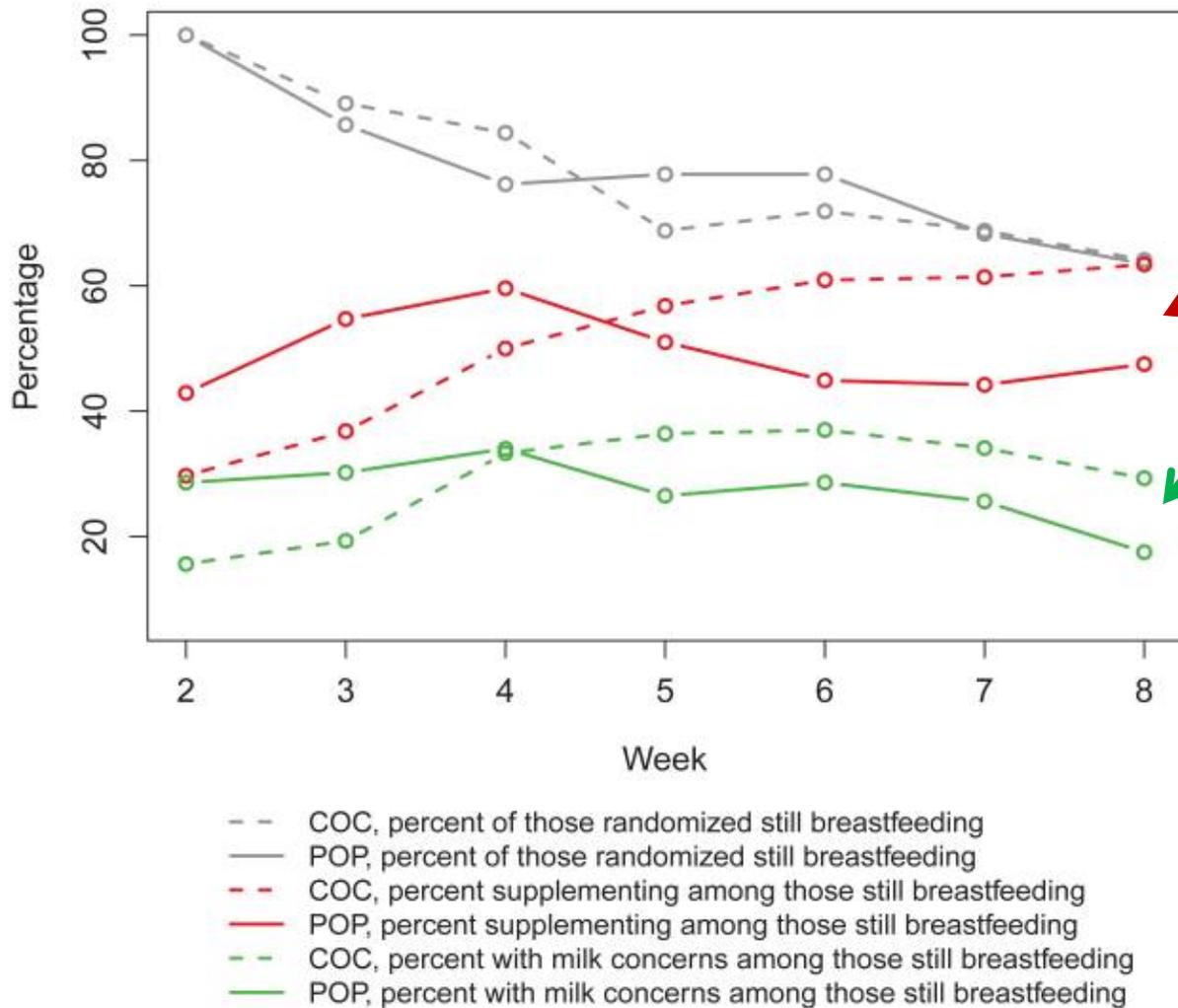


Primary endpoint—still brfdg at 8 wks: COC 64.1%, POP 63.5%

Conclusions:

- **No difference in breastfeeding duration or persistence...and relatively high dose COC**
- **No difference in satisfaction with breastfeeding or contraception** (data not shown)

Fig. 3 . Obstetrics & Gynecology. 119(1):5-13, January 2012. DOI: 10.1097/AOG.0b013e31823dc015



Not fully analyzed:

- Differences in supplementation
- Differences in concerns

Also, of women who stopped BrFdg:

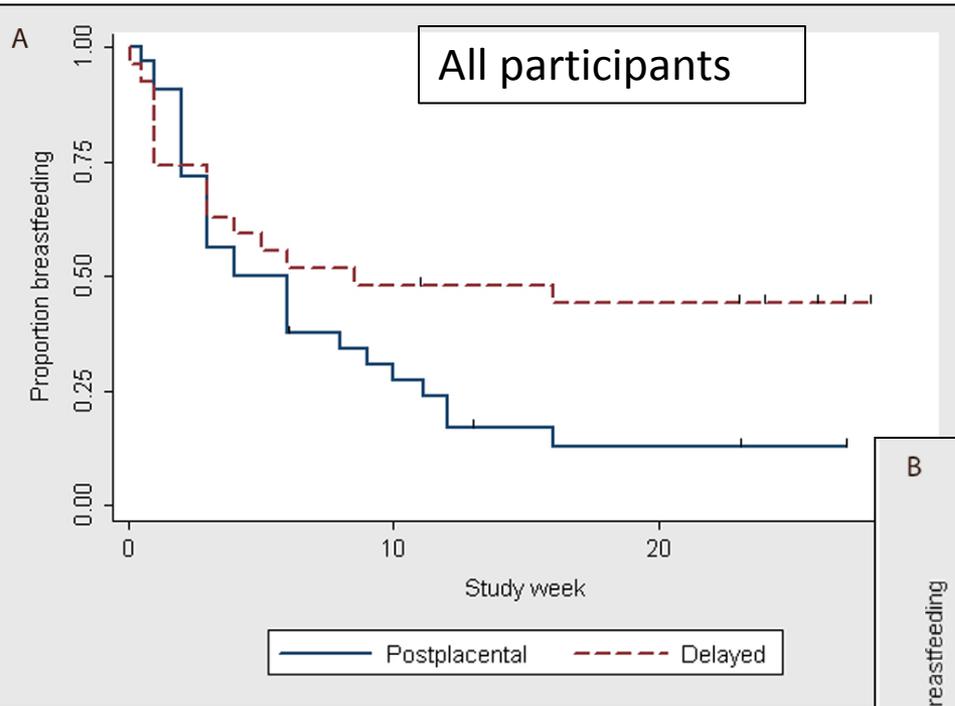
55% of COC stated perceived lack of milk supply vs 44% POP (p<.05)

Fig. 3 . Obstetrics & Gynecology. 119(1):5-13, January 2012. DOI: 10.1097/AOG.0b013e31823dc015

LNG IUD: Timing of Initiation, 2007-08

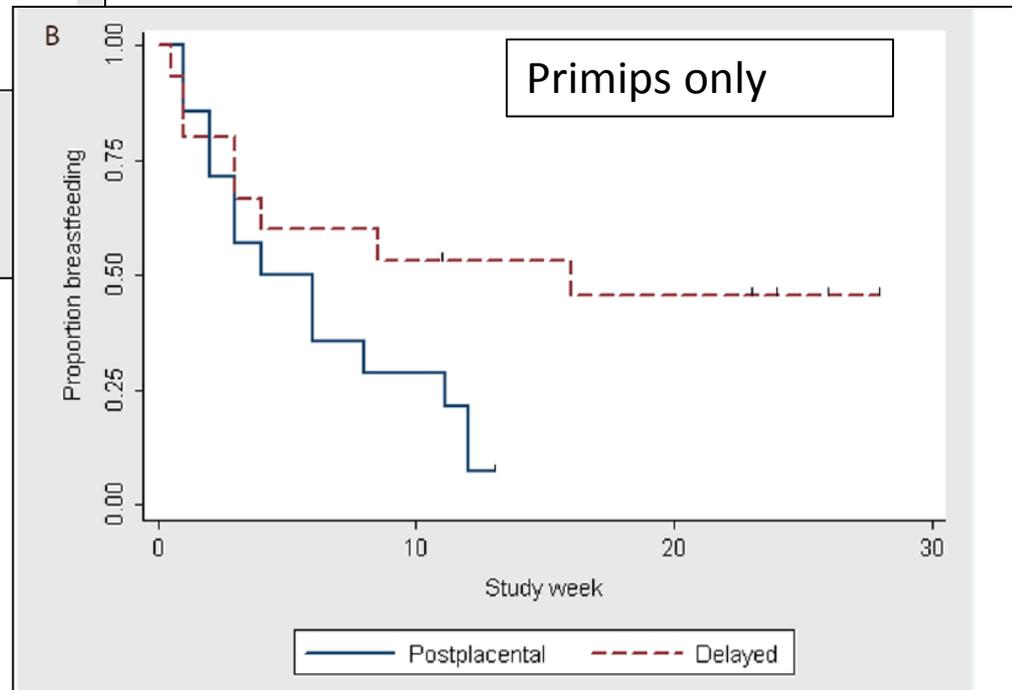
- Pittsburgh: Vaginal delivery, 18 yr and older, interested in IUD
- Blinded, randomized at labor to post-placental (n=50) or delayed insertion (n=46) at 6-8 wk
 - No significant difference in initiators between groups
 - 6 moms in delayed group got DMPA
- Follow-ups: 6 - 8 wk post partum, 3 and 6 months
- Primary outcome: Breastfeeding at 6 months

Early Placement Associated with Worse Breastfeeding Continuity

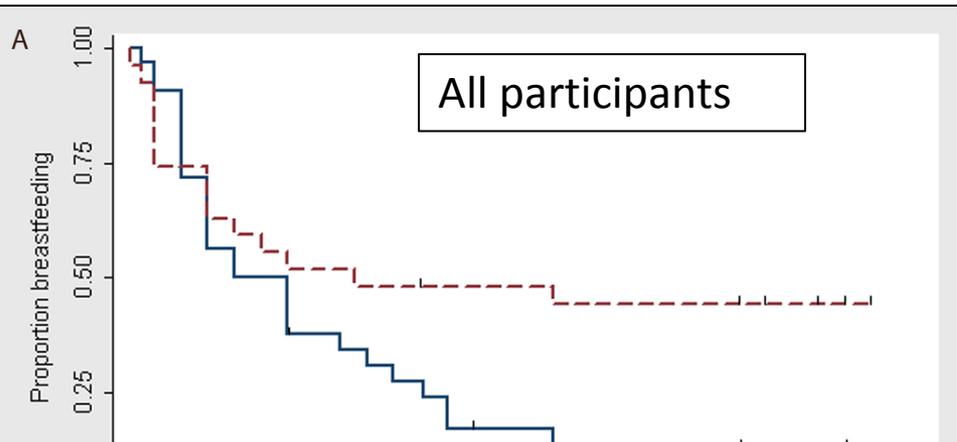


- No significant socio-demographic differences found after randomization

- Limited multivariate analysis showed delayed insertion and higher education associated with longer duration

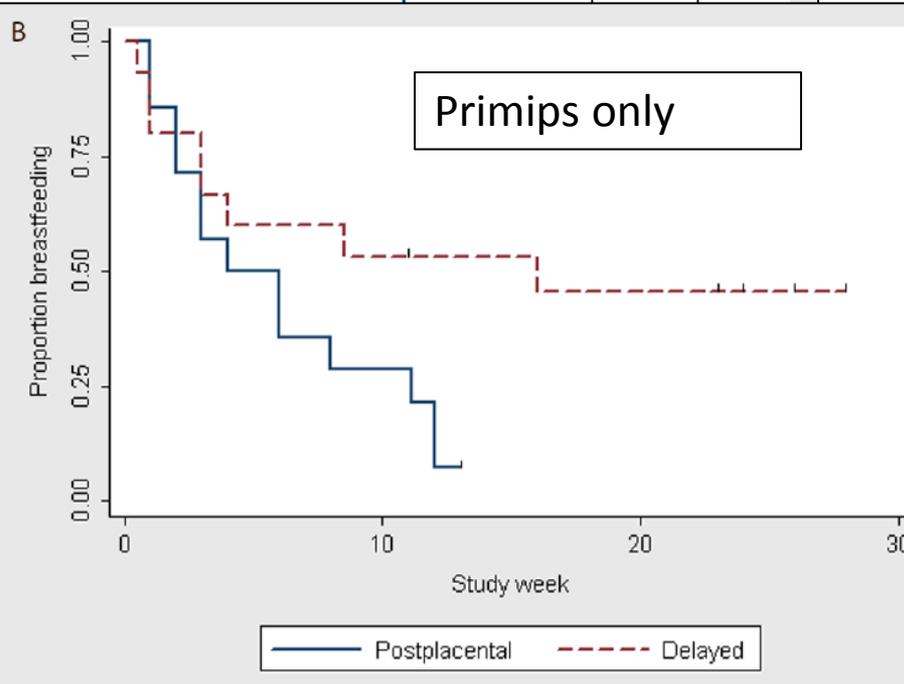


Early Placement Associated with Worse Breastfeeding Continuity



Author's Conclusion:

- Don't use early progestin??
- Biologic plausibility



However:

- Was a secondary analysis of an earlier study
- Just a single study
- Other studies needed

“Depo” Post-Partum: 2010-12

- Rochester, NY,, moms 18 yr and older with infants 1 yr or younger
- Retrospective cohort study
- 68 moms with DMPA prior to hospital discharge vs 115 moms who never had DMPA
- Outcome: Self-reported breastfeeding to 6 weeks

Brownwell EA et al, 2013. The effect of immediate postpartum DMPA on early breastfeeding cessation. *Contraception*, 87(6): 836-843.

No Significant Difference in Breastfeeding Drop-off

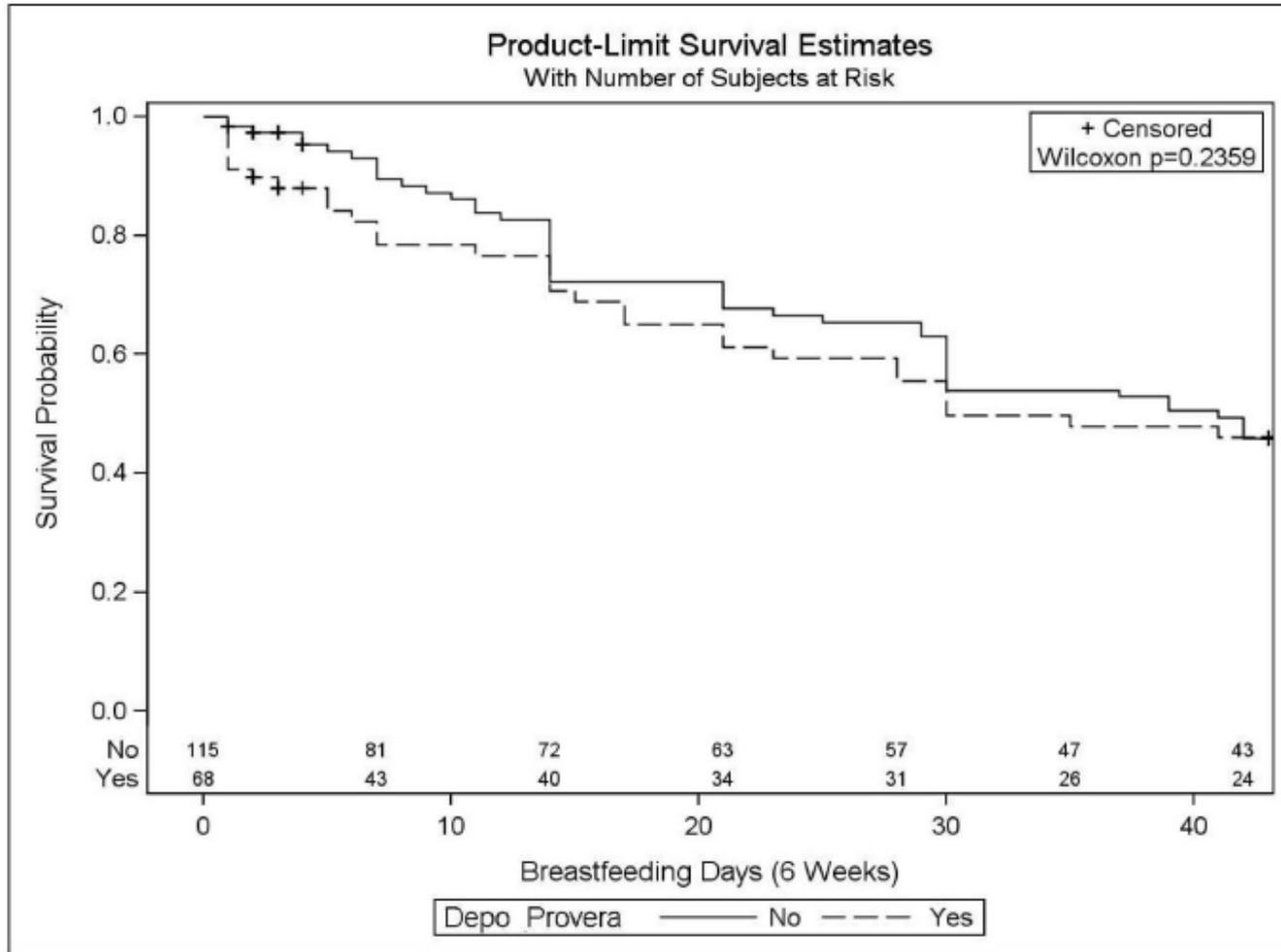
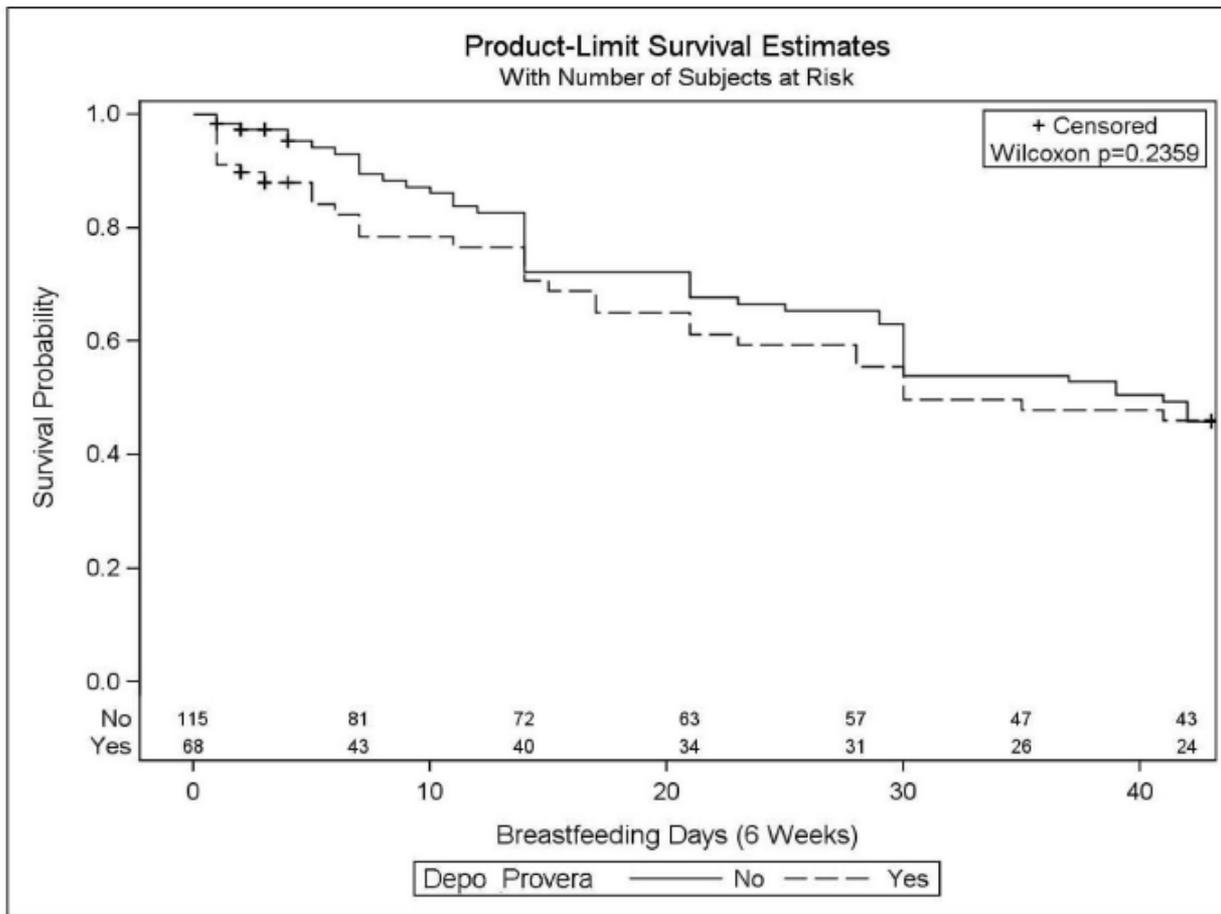


Figure 2.
Cessation of any breastfeeding within six weeks.

No Significant Difference in Breastfeeding Drop-off



- Power to detect < 20% difference was weak.
- Needs prospective study

Authors conclude:
“Given the state of the evidence, it is unclear whether a causal effect does or does not exist.”

Figure 2.
Cessation of any breastfeeding within six weeks.

Etonorgestel Implant, 2014

- Brazil, N = 24
- “Randomized” to implant within 48 hrs post-partum vs no contraception (=control)
- Deuterium assay to estimate milk intake
- Powered to detect 10% difference
- Outcome: Amount of breastmilk intake to 6 wks post partum
 - Also measured infant growth

Implant study: No Difference

- Frequency of breastfeeding was similar between groups during study period
- No significant difference found in:
 - Intake of breastmilk volume
 - Infant weight across 6 wk study period
 - Exclusive breastfeeding (92% implant, 80% control)
- Conclusion: Post placental implant appears safe for breastmilk volume and infant growth

Cochrane Review 2015

- “**Results were not consistent** across the 11 trials.
- The evidence was **limited** for any particular hormonal method. The **quality of evidence was moderate overall and low for three of four placebo-controlled trials of COCs or POPs**. The sensitivity analysis included six trials with moderate quality evidence and sufficient outcome data.
- Five trials indicated no significant difference between groups in breastfeeding duration (etonogestrel implant insertion times, COC versus POP, and LNG-IUS).
- For breast milk volume or composition, a COC study showed a negative effect, while an implant trial showed no significant difference.
- Of four trials that assessed infant growth, three indicated no significant difference between groups. One showed greater weight gain in the etonogestrel implant group versus no method but less versus DMPA.”

Objectives

- Be able to:
 - Be familiar with some of the evidence about hormonal contraception during lactation
 - **Understand current guidelines on contraception for lactating women**
 - Discuss realistic contraception options with breastfeeding mothers



MMWRTM

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Early Release

May 28, 2010 / Vol. 59

**U.S. Medical Eligibility Criteria for
Contraceptive Use, 2010**

Adapted from the World Health Organization
Medical Eligibility Criteria for Contraceptive Use, 4th edition

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 62 / No. 5

June 21, 2013

**U.S. Selected Practice Recommendations for
Contraceptive Use, 2013**

Adapted from the World Health Organization Selected Practice
Recommendations for Contraceptive Use, 2nd Edition

Guidelines: Medical Eligibility Criteria (MEC)

- “...guidance on the safety of contraceptive method use for women with specific characteristics and medical conditions”*
- Evidence-based

* <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>, accessed 7-8-15

BOX 2. Categories of medical eligibility criteria for contraceptive use

U.S. MEC 1 = A condition for which there is **no restriction** for the use of the contraceptive method.

MEC 1

U.S. MEC 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

MEC 2

U.S. MEC 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

MEC 3

U.S. MEC 4 = A condition that represents an **unacceptable** health risk if the contraceptive method is used.

MEC 4

Abbreviations: U.S. MEC – *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.*

Source: CDC. U.S. medical eligibility criteria for contraceptive use. *MMWR* 2010;59(No. RR-4).

2012 US-MEC Update

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		2*		2*					
	b) 1 month or more postpartum	2*		1*		1*		1*					
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		1					
	b) 21 days to 42 days												
	(i) with other risk factors for VTE	3*		1		1		1					
	(ii) without other risk factors for VTE	2		1		1		1					
	c) > 42 days	1		1		1		1					
Postpartum (in breastfeeding or non-breastfeeding women, including post-caesarean section)	a) < 10 minutes after delivery of the placenta									2		1	
	b) 10 minutes after delivery of the placenta to < 4 weeks									2		2	
	c) > 4 weeks									1		1	
	d) Puerperal sepsis									4		4	

* Indicates "Please see full MEC..."

Condition	Sub-condition	Combined pill, patch, ring	Progestin-only pill	Injection	Implant
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*	2*	2*	2*
	b) 1 month or more postpartum	2*	1*	1*	1*

- Progestin-only preferred
- Asterisk on ALL (*) due to concerns about potential breastfeeding effects
- Reversibility of some methods important

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a3.htm>

Condition	Sub-condition	Combined pill, patch, ring	Progestin-only pill	Injection	Implant
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*	2*	2*	2*
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“Postpartum women who are breastfeeding should not use combined hormonal contraceptives during the first 3 weeks after delivery (U.S. MEC 4) because of concerns about increased risk for venous thromboembolism and **generally should not use combined hormonal contraceptives during the fourth week postpartum (U.S. MEC 3) because of concerns about potential effects on breastfeeding performance.**”

Breastfeeding	MEC for COCs	
a. <1 mo postpartum	3	
b. 1 mo to <6 mos postpartum	2	
c. ≥6 mos postpartum	2	

Clarification: The U.S. Department of Health and Human Services recommends that infants be exclusively breastfed during the first 4--6 months of life, preferably for a full 6 months. Ideally, breastfeeding should continue through the first year of life (123).

Evidence: Clinical studies demonstrate **conflicting results about effects on milk volume in women exposed to COCs during lactation**; no consistent effect on infant weight has been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated (124--133). In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants. **Theoretical concerns about effects of CHCs on breast milk production are greater in the early postpartum period when milk flow is being established.**

		LNG-IUD		Copper-IUD	
		I	C	I	C
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) < 10 minutes after delivery of the placenta	2		1	
	b) 10 minutes after delivery of the placenta to < 4 weeks	2		2	
	c) ≥ 4 weeks	1		1	
	d) Puerperal sepsis	4		4	

- Copper preferred for post-placental insertion on basis of no concern for breastfeeding
- Both are acceptable in healthy women

World Health Organization MEC Differs on Timing of COCs

- Initiation of COCs within 6 weeks of delivery
MEC 4
- Initiation of COCs from 6 weeks to 6 months
in primarily breastfeeding women MEC 3
- International Planned Parenthood Federation:
similar to WHO

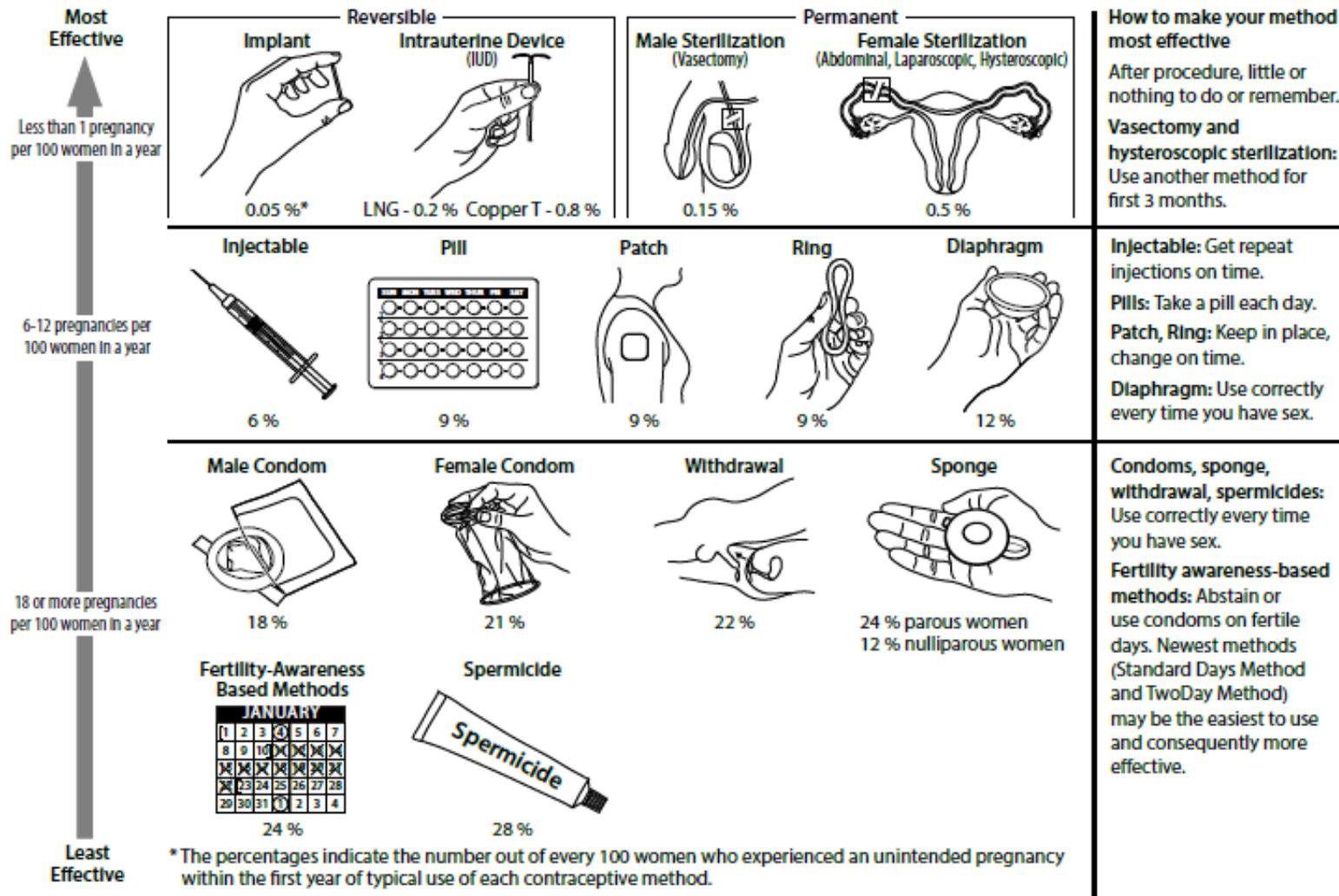
Academy of Breastfeeding Medicine Clinical Protocol #13

- Points out differences between US MEC and WHO MEC on hormonal methods
- Emphasis on exclusively breastfeeding women, with low risk of pregnancy in first 6 weeks
 - “In this setting...early initiation may derail a woman’s exclusive breastfeeding intentions...”

Non-hormonal methods: Less Concerns for Breastfeeding Effect

- Copper-T IUD
 - Barrier methods: Condoms, cervical cap, diaphragm
 - Sterilizations
 - Abstinence
 - Lactational Amenorrhea Method
-
- Effectiveness argument...

Effectiveness of Family Planning Methods



CS 242797



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397-404.



Lactational Amenorrhea Method (LAM)



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

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LAM: Requisites for Method Success

- Exclusive breastfeeding or “near-exclusive”
 - *At least* Q 4 hrs during days, Q 6 hrs nights
 - *Mostly at breast*
- Baby less than 6 months old
- No menses since delivery
- 1-2% risk of failure up to 6 months
 - Up to 5% seen in working mothers (pumping vs at-breast, perhaps less exclusivity)

What is a practicing clinician
to do?



What is a breastfeeding mother
to do?

Conversation and Counseling:

Prenatal...early postpartum...

postpartum visit



US-MEC as Basis

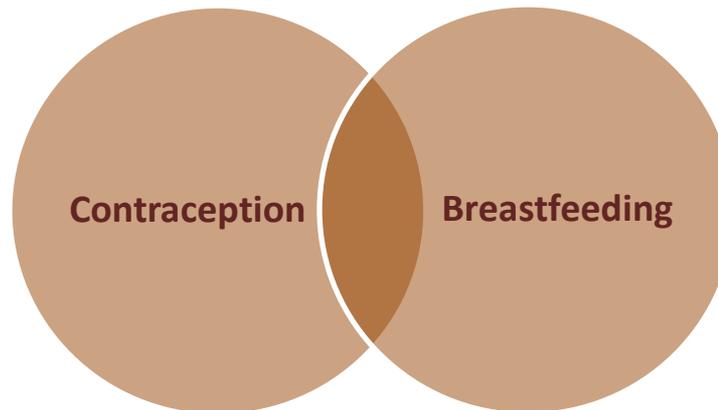
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	c) ≥ 4 weeks									1		1	
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Breastfeeding

- Intention
- Goals
- Previous successes (or not)
- Identifiable risk factors for not meeting goals
- Supports
- Likelihood of follow-up

Contraception

- Reproductive life planning
- Effectiveness/balance with breastfeeding
- Timing for initiation
- Confidentiality
- Ease of use for busy mom
- Likelihood of follow-up

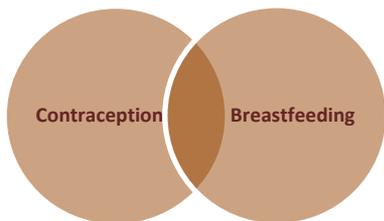


Cases

- **Multip Mom, previously breastfed with no problems, wants early reversible contraception**
- Primip teen with no other med issues
- Multip mom, GDM/obesity, poor breastfeeding experience last time
- Primip mom planning on return to work in 2 wks
- Mom post c/section

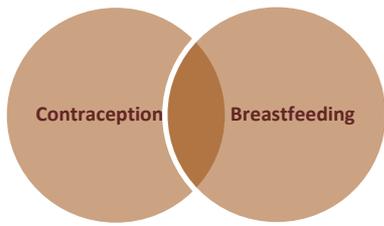
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- Multip Mom previously breastfed no problems
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- Primip mom planning on return to work in 2 wks
- Mom post c/section



Take-home messages

- Breastfeeding AND contraception both very important
- Many contraceptives are acceptable in lactation, some are preferred
- Shared decision-making can help in the “gray zones”
- More robust literature desirable
- Anticipate ongoing guideline revisions



Thank you!

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For credits, you must complete evaluation: Go to weblink

<https://www.surveymonkey.com/r/FamilyPlanning-Breastfeeding>

L-CERPs are pending approval by IBCLE.

This Live series activity, Bureau of Maternal, Infant and Reproductive Health Grand Rounds, from 07/16/2015 - 07/15/2016, has been reviewed and is acceptable for credit by the American Academy of Family Physicians. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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