

#1: Post-Partum Contraception

Background

- Historically, the postpartum visit was recommended at 6 weeks to allow for uterine involution and the “return of normal pelvic anatomy”
- Developed before modern contraceptive options were available
- National guidelines have not revisited this topic to update based upon new evidence and technology

2004 WHO Medical Eligibility Criteria Not breastfeeding

	OC	P/R	POP	DMPA	Implant	Cu-IUC	LN-IUC
< 48 hrs	3	3	1	1	1	2	3
2-21 days	3	3	1	1	1	3	3
3-4 weeks		1	1	1		3	3
> 4 weeks		1	1	1		1	1

Estrogen concerns

IUC expulsion concerns

2004 WHO Medical Eligibility Criteria Breastfeeding women

	OC	P/R	DMPA	Implant	Cu-IUC	LN-IUC
< 6 weeks	4	3	3	3	2	3
6 weeks-6 months	3	1	1	1	1	1
> 6 months	2	1	1	1	1	1

Lactation establishment

Milk volume concerns

Post-partum OC's: Effect on Lactation

- Quality (composition) of breast milk
 - No change, including iron and copper levels
- Quantity of breast milk
 - If started *before* establishment of lactation, high dose estrogen decreases quantity
 - If started *after* lactation is established, low dose OCs minimal effect on quantity
- POPs have no effect on quantity or content milk
- Women who use COCs have a lower incidence of breast feeding after the 6th pp month
 - Mean use: 3.7 mos with OCs vs. 4.6 mos controls

Post-partum OC's: Newborn Risk

- General rule: 1% of ingested drug secreted in milk
- Ethinyl estradiol dose reaching newborn is comparable to daily ovarian estradiol production
- Effect of OCs on breast-feeding infants
 - No short term differences vs. controls
 - A long term (5 year) study shows no effect on neurological development
- Newborn growth rates not affected by OC use
 - Any loss of milk volume compensated by increased suckling or food supplements

Post-partum OC's: Maternal Risk

- Changes in maternal clotting factors persist for 4 weeks after term delivery
 - Increased VTE risk up to 4 week post-partum
- Concern that coagulation effects from each of pregnancy *and* OC's may further increase risk of VTE
 - However, VTE rates have not been studied in postpartum low-dose OC users vs. controls
- Greater VTE risks not expected with POPs, since no change in clotting factors

Post-partum OC's: Clinical Guidelines

- **Non-nursing women**
 - COC starting 3-4 weeks postpartum
- **Nursing women**
 - **Conservative approach**
 - » First 3 months: avoid COCs; POPs acceptable
 - » ≥3 mo or weaned from breast: switch to COCs
 - **Liberal approach**
 - » COCs once lactation well established (≥ 3-4 wks)
- **If COCs used, use 20 mcg estrogen dose**
 - LoEstrin 1/20, Mircette, Alesse

Post-partum Long-acting Progestins

- **DMPA**
 - Mildly lactogenic; no change in milk composition
- **Implants (Implanon, Norplant studies)**
 - If inserted ≥ 4-6 wks post-partum, no effects on milk volume, content, or newborn growth rates
- **Administration before hospital discharge**
 - **Advantage**
 - » Protection if doesn't return for post-partum visit
 - **Disadvantages**
 - » Unnecessary for first 4 weeks
 - » May be difficult to differentiate anatomic bleeding from method "side effect" bleeding

2004 WHO MEC: Postpartum IUC Insertion

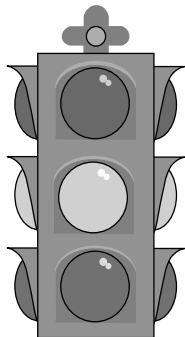
	Cu-IUD	LNG-IUD	Comment
< 48 hours	2	3	Evidence: There was some increase in expulsion rates with immediate insertion compared to delayed postpartum insertion and interval insertion.
48 hours to 4 weeks	3	3	
> 4 weeks	1	1	
Endometritis	4	4	

- Guidelines are identical in lactating and non-lactating women
- Insert IUC within 15 minutes of placental delivery
- Use sponge forceps on cervical lip; 2nd sponge forceps to insert
- Cut string flush with external cervical os

Lactational Amenorrhea Method (LAM)

- **Effectiveness**
 - Pregnancy rate: 1-2% by 6 months postpartum
 - 7% by 12 months; 13% by 24 months
- **Bellagio Conference Consensus (1989)**
 - Nurses "on demand" (≥ 5 feeds/day; > 65 min total)
 - Breast milk is only nutrition to newborn; no supplementary bottle feedings or other foods
 - No bleeding episode beyond 56 days from delivery
 - Nursing of newborn for less than 6 months

Lactational Amenorrhea Method



Beyond 6 months

10 weeks - 6 months

Delivery -10 weeks

The postpartum visit: it's time for a change in order to optimally initiate contraception

Leon Speroff^a, Daniel R. Mishell Jr.^{b,*}
Contraception 2008;78:90-98

- "The 6 week postpartum visit is an anachronism"
- At the 3 week visit, evaluate whether no, partial or full (and exclusive) breast feeding
- Apply "The Rule of 3's"
 - If no or partial breast-feeding, contraception should be initiated during the third postpartum week
 - If full breast-feeding, contraception should be started during the third postpartum month
- At the 3 month visit, initiate a method if breastfeeding or follow-up women who started a method at 3 weeks

#2 Contraception in Women with Gestational Diabetes Mellitus (GDM)

Background

- Older studies showed POPs (only if breast feeding) and DMPA may hasten diagnosis of type 2 DM
- GDMs who become frankly diabetic may continue combined or progestin-only contraceptives
- If GDM, both ADA and ACOG recommend
 - 75 gm 2-hour PGL test 6 weeks postpartum
 - Given >50% chance of Type 2 DM in next 10 years, repeat diabetes screening annually, irrespective of contraceptive method

WHO MEC 2004: Diabetes

- History of gestational diabetes: all are WHO-1
- DM *without* vascular disease (± insulin)
 - WHO-1: Cu-IUD
 - WHO-2: All others
- DM *with* vascular disease or DM > 20 years
 - WHO-3: OC, P/R, DMPA
 - WHO-2: POP, Implanon, LNG-IUD
 - WHO-1: Cu-IUD

ADA : Contraception After GDM

Damm P, Diabetes Care 2007; 30(S2):S236-241

Method	OC	P/R	POP BF	POP Not BF	DMPA, Implants	IUC	Bar- riers	Sterili- zation
“First choice”	√	√		√		√	√	√
“Not First choice”			√		√			

- POPs are “first line” in T1 diabetics, non-lactating GDMs
- DMPA, implants are first line if compliance with a daily method is a problem or methods with estrogen are contraindicated
- Avoid OC, patch, and ring if cardiovascular disease or risk factors

Summary: Contraception in GDMs

- WHO states that contraceptive options in women with gestational diabetes are identical to other women
- Concern regarding the use of POPs, DMPA, implants are based on weak retrospective studies and apply only to breast-feeding women
- Much more critical issues for GDMs are...
 - Effective use of contraception for birth spacing
 - Being screened for Type 2 diabetes with a glucose load test annually
 - If progression to T2DM, control of blood sugar before the beginning of subsequent pregnancies

#3 Emergency Contraceptive Products

- FDA changed the age threshold for OTC dispensing
 - Available without prescription if 17 y.o. or older
 - Prescription only for women under 17 y.o.
 - Pharmacist may require proof of age
- Plan B® One-Step (now Teva; previously Duramed)
 - Single dose tablet ; 1.5 mg levonorgestrel
 - Labeled for 72 hours from last intercourse
 - Plan B (2 tablet product) is no longer available
- Next Choice (generic/ Watson Pharma)
 - Same as the two tablet Plan B® product
 - Labeling: 1 tab Q12 hours; off label: 2 tablets at once

#4 Missed Hormonal Contraceptives

Background

- Instructions for missed contraceptive doses are complex; may not be understood by women
- Highest risk of ovulation when hormone free interval is longer than 7 days, either by delaying start or by missing hormone doses during the 1st week
- Ovulation rarely occurs after 7 consecutive days of combined oral contraceptive use

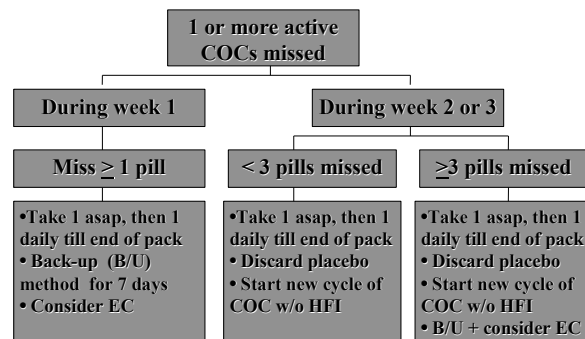
**Missed Hormonal Contraceptives:
New Recommendations**
Soc Ob GYN of Canada, JOGC 2008; 219:1050-62

- Reviewed contradictory instructions published by WHO, *Contraceptive Technology*, and ACOG
- Evaluated evidence regarding
 - Ovarian follicular development on sequential days that hormones are used (or not)
 - Pharmacokinetics of oral vs non-oral contraceptives
 - Studies of contraceptive efficacy
- Developed simple clear instructions to minimize pregnancy risk without using EC

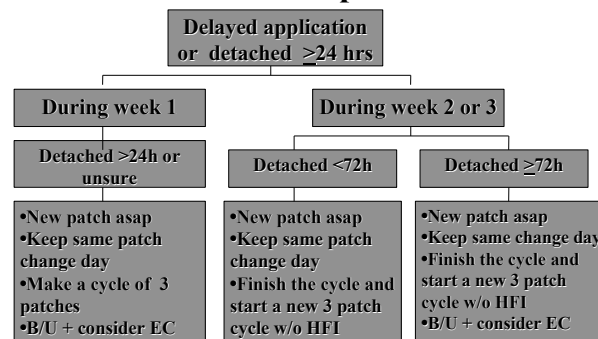
**Missed Hormonal Contraceptives:
New Recommendations**
Soc Ob GYN of Canada, JOGC 2008; 219:1050-62

- The hormone free interval (HFI) shouldn't exceed 7 days, as the risk of ovulation is greatest
- In the 1st week
 - Back-up should be used after ≥ 1 missed dose until 7 days of use occur. Consider EC
- In the 2nd and 3rd week
 - If < 3 days are missed, eliminate the next HFI
 - If ≥ 3 days are missed, back-up contraception and consideration of EC should be added

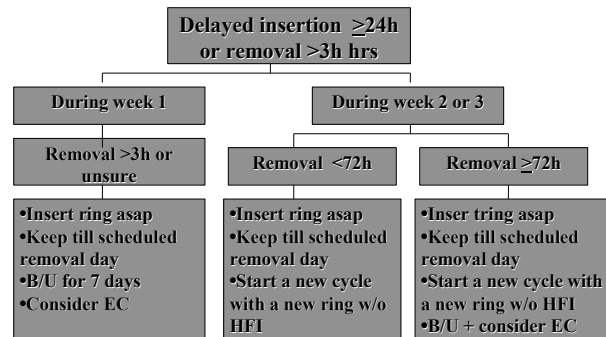
Missed Combined OCs



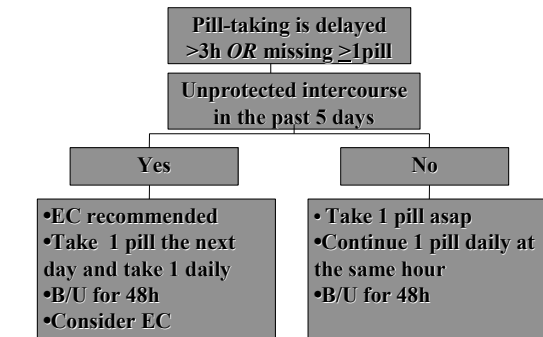
Missed Contraceptive Patch

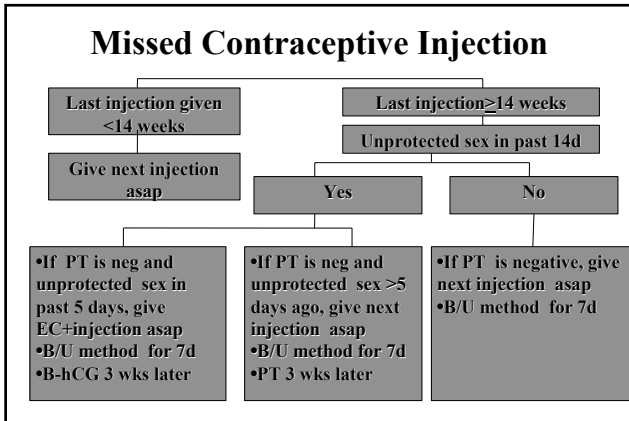


Missed Contraceptive Ring



Missed Progestin Only Pills





SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE

2008 update

▶ Grace period for a repeat injection of DMPA extended to 4 weeks

The following changes were made to address situations where a woman comes late for her repeat DMPA injection.

Question 6. When can a woman have repeat progestogen-only injectables (POIs) – depot-medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

Late for an injection

- The repeat injection of DMPA can be given up to 4 weeks late without requiring additional contraceptive protection.

Up to 16 weeks + 0 days without back-up

- ### #5: Body Weight and Contraception
- Four issues about body weight relate to each method
 - Will the method cause excess weight gain (compared to no method)?
 - Is the failure rate higher in obese women (compared to women of average weight)?
 - Are there medical risks attributable to the method in obese women (compared to women of average weight)?
 - What is the WHO-MEC category and why?
 - Pregnancy and childbirth among obese women are far more dangerous than are either contraception or sterilization

Body Weight and Contraception

	OC	Patch	DMP	Implant	IUC	Tubal
Weight gain	No	No	Yes*	No	No	No
↑ failure rate in obese women	No Δ	Yes #	No Δ	No Δ	No Δ	No Δ
Medical risk in obese women	DVT	No studies	None	None	Difficult insertion	Surgical complications
WHO-MEC	2	2	1	1	1	Not rated

*Mainly in obese adolescents and those who experience a ≥5% body weight increase within 6 months of DMPA initiation

In women who weigh ≥90 kg, increase of 2-4 failures/100 couples/year

- ### Body Weight and Oral Contraceptives
- Weight gain: no difference
 - Failure rate
 - Cochrane Review: “no evidence that obese women have a higher risk of OC failure, even with the lowest dose OCs
 - Grimes : “OCs may be less effective in heavy women, with an extra 2-4 pregnancies per 100 woman-years of OC use. Despite this effect, the effectiveness of OCs in clinical use remains high”
 - Medical risk in obese women
 - Obesity doubles risk for VTE vs. normal BMI
 - OC users with a BMI ≥35 have an increased risk of VTE compared with OC users of normal weight
 - WHO-2, because of VTE concerns

- ### Body Weight and OrthoEVRA
- Weight gain: no difference
 - Failure rate
 - Overall, 0.8 failures per 100 couples per year
 - Of 15 failures, 1/3 occurred in women weighing >90 kg
 - In patient package labeling, weight ≥ 90 kg is listed as a *precaution*, but not as a *contraindication*
 - Medical risk in obese women
 - No studies
 - WHO-2 , because of efficacy concerns
 - “Obese women should be counseled regarding this observation but reminded that the patch is still quite effective when used correctly and consistently”

Body Weight and DMPA

- **Weight gain**
 - Overweight or obese adolescent DMPA users gain more weight than normal weight DMPA users, although this effect was not seen in adults
 - DMPA users who experience a $\geq 5\%$ body weight increase within 6 months of DMPA initiation are most likely to gain excessive weight
- **Failure rate:** no effect
- **Medical risk in obese women :** none identified
- **WHO-1**

Body Weight and Contraceptive Implants

- **Weight gain**
 - In a comparative analysis, weight increase seen in 21% of women, but was drug-related in 6.4%
 - A comparative study found mean increase similar to that seen with non-medicated IUD
- **Failure rate:** no effect of obesity
- **Medical risk in obese women :** none identified
- **WHO-1**

Body Weight and IUCs

- **Weight gain:** no impact
- **Failure rate:** no effect of obesity
- **Medical risk in obese women**
 - Placement can be a challenge, since determining the size and direction of the uterus and visualization of the cervix can be difficult
 - IUCs are a good contraceptive choice for obese women given their high efficacy irrespective of weight and the ability of the Mirena IUS to prevent endometrial hyperplasia
- **WHO-1**

Body Weight and Sterilization

- **Weight gain:** no impact
- **Failure rate:** no effect of obesity
- **Medical risk in obese women**
 - Among women with laparoscopic sterilization, obesity increased the risk of surgical complications (RR 1.7)
 - Obesity linked with operative difficulties, technical failures, longer operating times and hospital stays
 - Because general anesthesia and abdominal entry are not necessary, Essure less likely to cause complications
 - Vasectomy for the partner of an obese woman is ideal
- **WHO-MEC:** unrated

#6 The Trend Toward a 4-Day Hormone-Free Interval (HFI)

- **No head-to-head studies of 24/4 regimens compared to 21/7 regimens**
- **What we want to know...**
 - Is a 24/4 regimen really more effective than 21/7?
 - Are bleeding patterns different between the two?
 - Are there fewer menstrual symptoms with a 4 day HFI compared to a 7 day HFI?
 - How much of the difference is marketing vs. real advantages?

4-Day Hormone-Free Interval (HFI) What We Do Know

- **Lower hormone doses are cleared more rapidly than with older (and higher dose) OCs**
- **Higher FSH levels with 7 day HFI than with 4 day HFI**
- **More follicle growth with 7 day HFI than with 4 day HFI**
- **24/4 cycles (compared to 21/7) *theoretically will ...***
 - Be more forgiving of late OC initiation
 - Will have marginally lower failure rates

24/4 OC Products

- **YAZ® (Bayer [Berlex]): 4/06**
 - EE 20 mcg + drospirenone 3 mg
- Vs. Yasmin*
 - EE 30 mcg / drospirenone 3 mg
 - Cycle: 21 days active, 7 days hormone free
- **Loestrin 24® (Warner Chilcott): 2/06**
 - EE 20 mcg + nor acetate 1 mg + Fe fumarate
 - 24 days on, then 4 days Fe only
- Vs. Loestrin 1/20: EE 20 mcg + nor acetate 1 mg*
 - 21 days on, 7 days off

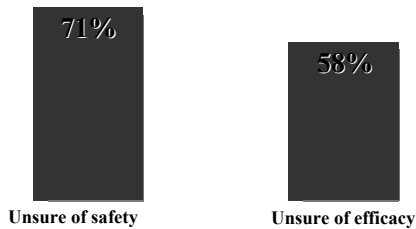
#7 Why IUCs Are Underused in the US?

- Lack of awareness of method among women
- Dearth of trained, willing clinicians to insert
 - Misconceptions regarding difficulty of insertion
 - Negative publicity, fear of litigation
 - Upfront cost
- 2007 Contraceptive Technology Update Survey
 - 40% of respondents inserted ≥ 6 IUDs in the last year...compared to 45% in 2006
 - 40% reported no insertions

Weir E. *CMAJ*. 2003.
 Stanwood NL, et al. *Obstet Gynecol*. 2002.
 Steinauer JE, et al. *Fam Plann Perspect*. 1997.

Most Young Pregnant Women Unsure About IUD Characteristics

Of women who had heard of IUDs (50%)



Stanwood NL, et al. *Obstet Gynecol*. 2006.

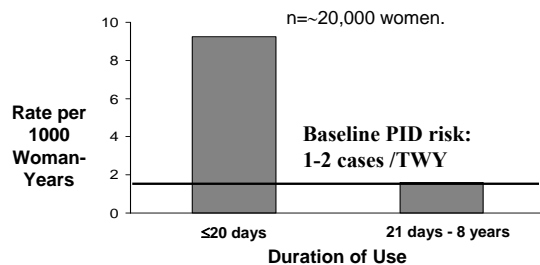
What Do Women Find Unacceptable About IUDs?

- Lack of objective information
- Reported side effects
- Anxiety about IUD insertion
- Infection risk
- Lack of personal control of IUD after insertion



Asker C, et al. *J Fam Plann Reprod Health Care*. 2006.

Rate of PID by Duration of IUC Use



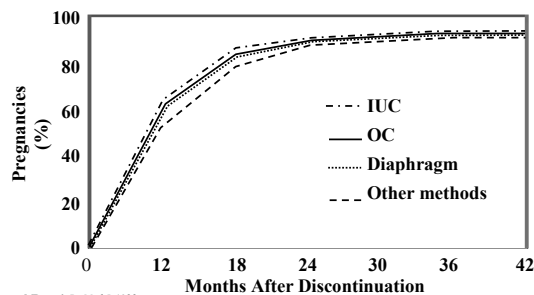
Adapted from Farley T, et al. *Lancet*. 1992;339:785-788.

IUCs Do Not Cause PID

- PID incidence for IUC users is similar to that of the general population
- Risk is increased only during the first month after insertion
- Preexisting STI at time of insertion, not the IUC itself, increases risk
- No reason to restrict use based on sexual behaviors

Svensson L, et al. *JAMA*. 1984.
 Shinn L, et al. *Contraception*. 1991.
 Farley T, et al. *Lancet*. 1992.

Fertility Rates in Parous Women After Discontinuation of Contraceptive



Vessey MP, et al. *Br Med J*. 1983.
 Andersson K, et al. *Contraception*. 1992.
 Belhadj H, et al. *Contraception*. 1986.

IUC: Use in Nulliparous Women

- Use of IUCs by nulliparous women with low risk of PID is safe and effective¹⁻⁴
- LNG-IUS is appropriate for nulliparous women with menorrhagia and/or dysmenorrhea
- IUC expulsion, bleeding, and pain are slightly more likely among nulliparous women²⁻⁵

1. Suhonen S. *Contraception* 2004;69:507-512.
 2. Nelson AL. *Obstet Gynecol Clin North Am*. 2000;27:723-740.
 3. Dardano KL, Burkman RT. *Am J Obstet Gynecol*. 1999;181:1-5.
 4. Li C. *Contraception* 2004;69:247-250.
 5. Treiman K, et al. *Population Reports*. 1995.

Indications for IUC Use

- Both IUC products
 - Long term contraception in fertile women
- WHO-MEC for IUD Use

▪ Menarche to age 20	WHO-2
▪ Age 20 and older	WHO-1
▪ Nulliparity	WHO-2
▪ Parous	WHO-1

WHO Medical Eligibility Criteria for Contraceptive Use, 2004

Pre-IUC Insertion Screening

- Evidence supports *no* routine screening tests
 - Ct, GC: if high risk sexual behaviors or <26 yo and annual screening Ct has not been done
 - Pregnancy test: only if pregnancy suspected
 - Pap smear: only if due for a routine Pap
 - Hematocrit: only if anemia suspected
- Any indicated screening test can be done on the day of IUC insertion

Pre-Insertion Guidelines

- Prophylactic antibiotics
 - No value based on randomized clinical trials
- Premedication
 - NSAID 1 hour before; cervical block if stenotic
- Timing of insertion
 - Copper: anytime, “as long as not pregnant”
 - LNG: insertion recommended by day 7
 - Back-up method if “off-cycle” insertion
- May insert after delivery or abortion, but slightly higher expulsion rate

Cervical priming with sublingual misoprostol prior to insertion of an intrauterine device in nulliparous women: a randomized controlled trial

Saav I et. al., *Human Reproduction* 2007; 22, (10): 2647

- 80 nulliparas treated 1 hour prior to IUD insertion
 - Misoprostol 400 mcg SL and diclofenac 100 mg
 - Diclofenac 100 mg PO alone (control group)
- Findings
 - Insertion easier with misoprostol than control group
 - Pain scores no different in the two groups
 - Most side effects equal
 - » Shivering, diarrhea more common in misoprostol group

Misoprostol for IUC Insertion

Table 2: Difficulty of IUD insertion, as estimated by the inserter

Estimation of difficulty of insertion	Misoprostol group, n = 39 (%)	Control group, n = 40 (%)
Easy	29 (74.4)	22 (55.0)
Intermediate or difficult	10 (25.6)	18 (45.0)

$P = 0.039$; Fisher's Exact test, mid- P -value. Degrees of freedom = 1.

- **Conclusion**
 - Misoprostol can facilitate IUD insertion and reduce the number of difficult and failed attempts of insertions in women with a narrow cervical canal

Elective Sterilization Rates Are Falling

- Documented in US and UK over the past 10 years
- Explanations
 - Later childbearing; fewer years of protection needed
 - Wider use of long acting contraceptives, especially IUCs and DMPA
 - » Advice from providers to use long acting contraceptives instead of sterilization
 - Low payment rates by Medicaid and state Family Planning Programs for ambulatory surgery

Will Abdominal Sterilization Become Obsolete?

Traditional belief	Now we know...
Hormones dangerous >35 yo	Can be used till menopause
IUCs dangerous at any age	IUCs are safe till menopause
ITS is the most effective contraceptive method	IUCs and Implanon have efficacy equal to ITS
Laparoscopy is safer than laparotomy	IUC, hysteroscopy are safer than laparoscopy and laparotomy
Regret is a rare event	40% with ITS at 18-24 yo later request information about reversal
ITS is the most cost-effective method over time	IUC is most cost effective method over 5 years

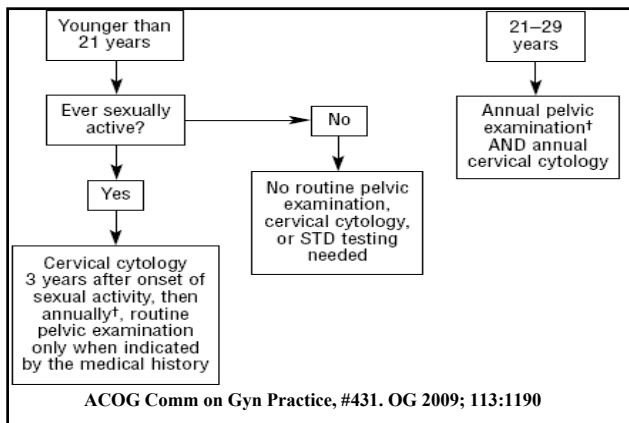
ITS: interval tubal sterilization

Grimes DA, Contraception 2008
Williams JK, The Female Patient, 2007

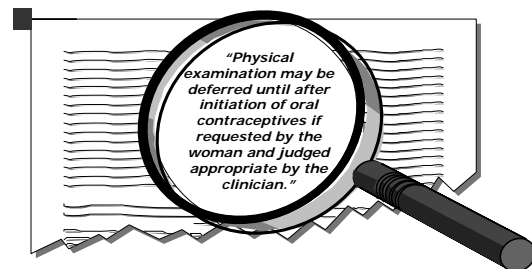
#8 Routine Pelvic Examination and Cervical Cytology Screening

ACOG Comm on Gyn Practice, #431.
Obstet Gynecol 2009; 113:1190

- The *annual* pelvic exam
 - Is not a routine part of annual assessment for women 13-20 yo, unless medically indicated
 - Is a routine part of preventive care for all women 21 years of age and older, even if Pap screening is not needed



FDA Advisory Committee's Recommendation on Delay of Pelvic Exam



FDA Advisory Committee Recommendation.

www.contraceptiononline.org

Is there a Need for “Routine” Screening of Hormonal Contraceptive Users?

- 2004 WHO Selected Practice Recommendations for Contraceptive Use
- BP before initiation of all hormonal contraceptives
- *Not recommended* as “contributing substantially to safe and effective use of contraceptive method”
 - Breast or genital tract examination
 - Cervical cancer screening
 - STI assessment or lab test screening
 - Hemoglobin determination
 - Other routine lab tests

Implications

In sexually active asymptomatic adolescents (< 21 y.o.), evidence-based screening visits, with or without a contraceptive prescription, consist of

- Blood pressure check, BMI, and PNP
- PNP= Pee, not Pap
- Pee: Chlamydia NAAT
- Pap: not until 3 years after sexual debut
- Pelvic exam: not until 21 years old