Contraceptive Technology Update

Satellite Conference
Wednesday, February 9, 2005
2:00-4:00 p.m. (Central Time)

Produced by the Alabama Department of Public Health
Video Communications & Distance Learning

Faculty

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Objectives

1. Explain the need for advances in contraception.
2. Identify the recent advances in contraception.
3. Explain the risks and benefits of each new form of contraception and how to manage patients.

Contraceptive Update

- Unintended pregnancy rates
- OC update – extended use
- Levonorgestrel IUS, Mirena
- Combined E/P Vaginal Ring, Nuvaring
- Combined E/P Transdermal, Ortho Evra
- WHO medical eligibility criteria
- Widened or OTC use of emergency contraception

Current Trends in Contraception

- Developing new delivery systems
- Increasing access to full range of options
- Emphasizing greater *adherence to dosing*
- Widening use of emergency contraception
- Recognizing non-contraceptive benefits

Unintended Pregnancy:

A Major Public Health Challenge

Daily Maternal Morbidity and Mortality Due to Unintended Pregnancy in the United States*

- 1 death due to pregnancy-related conditions
- 660 women experience major pregnancy-related complications before labor begins
- 790 women have cesarean section delivery
- 820 women experience major labor-related complications

* extrapolated from CDC estimates, 1991

US Maternal Mortality

- 1982–1996: 7.5 maternal deaths/100,000 live births[1]
- 2–3 women die each day due to pregnancy related complications [1]
- 1987–1990: 1459 pregnancy related deaths[2]
- Highest ratio of pregnancy related deaths[2]:
  - African American women
  - Older women
  - Women without prenatal care (7.7x greater risk)

Contraception saves lives!

[1]*MMWR*. 1998;47(34):705-707. [2]Koonin LM, MacKay AP, Berg CJ, et al. *MMWR*. 1997;46(SS-4):17-36.

Why the Need for New Contraceptives

- High rate of unintended pregnancies
- About one-fourth of all pregnancies electively terminated, highest of Western developed countries
- 43% of U.S. women have had an elective abortion by age 45
- 20% of women selecting sterilization at ≤ 30 years of age later express regret

Henshaw SK. *Fam Plann Perspect* 1998;30:24-29.
Hillis SD et al. *Obstet Gynecol* 1999;93:889-895.

Inconsistent / improper OC usage or discontinuation of OC results in ~1 million unintended pregnancies

Why Reassess Her Birth Control Needs?

new methods

starting college

life changes

relationships

health issues

spacing children

postpartum

perimenopause

National Survey of Peri-partum contraception: monogamous women

- 252 pregnant women
- 250 postpartum women (within 12 months)
- Qualities of a contraceptive "extremely important" : reliability (88%), effectiveness (83%), safety during breastfeeding (79%), ease of use, no decrease in sexual pleasure, low cost, few side effects, recommended by health care provider, hassle free (73-77%)

Cwiak C, Gellash T, Zieman M. Contraception70: 5, 2004.383-6

National Survey, cont.

Postpartum women significantly more likely to find important:

- Ease of use
- Long-term protection
- No need for monthly pharmacy trips

Cwiak C, Gellash T, Zieman M. Contraception70: 5, 2004.383-6

IUC Knowledge

Participants were read a two sentence description of IUC. Described as being 99% effective, as effective as sterilization, effective for either 5 or 10 years, and readily reversible

- 65% women said the information was "an important increase in their knowledge of birth control options"
- 74% women felt that IUC was as good or better than their current method yet <1% chose it as a method

Cwiak C, Gellash T, Zieman M. Contraception70: 5, 2004.383-6

IUC Knowledge

- <30% pregnant women had discussed birth control options with their health care provider
- 37% of women who were sterilized did not discuss other long-term options with their provider

Cwiak C, Gellash T, Zieman M. Contraception70: 5, 2004.383-6

Oral Contraceptives: An Update

Are Pills the Gold Standard?

Will Pills remain the gold standard?

- Most thoroughly studied
- Numerous non-contraceptive health benefits
- Many formulations available
- US: still "pill culture"
- Very effective

Overview of Noncontraceptive Health Benefits - Ocs Product Labeling

- Menses-Related Benefits
  - ↑ menstrual cycle regularity
  - ↓ blood loss
  - ↓ iron-deficiency anemia
  - ↓ incidence dysmenorrhea
- Benefits from Inhibition of Ovulation
  - ↓ incidence functional ovarian cysts
  - ↓ incidence ectopic pregnancy

Overview of Noncontraceptive Health Benefits- Product Labeling (continued)

- Other Benefits
  - ↓ incidence fibroadenomas/fibrocystic breast changes
  - ↓ incidence acute PID
  - ↓ incidence endometrial cancer
  - ↓ incidence ovarian cancer

Emerging/Other NCHB

Growing Evidence
- Bone mass
- Acne
- Colorectal cancer

Limited Evidence
- Uterine leiomyomata
- Rheumatoid arthritis

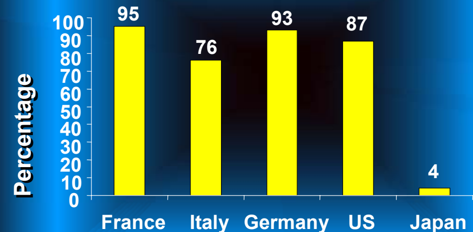
Emerging/Other NCHB

Treatment of medical conditions
- Bleeding disorders
- Hyperandrogenic anovulation
- Endometriosis

Extended Cycle Regimens

Perimenopausal changes

Ever Use of Oral Contraceptives



Roper Starch Worldwide, 1999

Properties of Contraceptives Desired by Women

- Easily accessible
- Highly effective
- Prolonged duration of action
- Privacy of use
- Rapidly reversible
- Amenorrhea or Absence of amenorrhea
- Protection against STI

Overview of OCs

- OCs are a highly effective method of contraception
- OCs cause very few and uncommon health risks in healthy nonsmoking women
- OCs provide many important noncontraceptive health benefits
- Women are unaware of – and need appropriate counseling regarding – safety and contraceptive and noncontraceptive benefits of currently used OCs

Recent OC Developments

- New Progestin: Drospirenone; Yasmin
- New Estrogen doses: 25mcg; Cyclessa, Ortho-Tricyclen Lo
- Extended Cycle Use: *tricycling/* longer cycling, Seasonale
- Widening EC use

OC Discontinuation: Impact of Side Effects

- 59%–81% discontinue due to side effects*
- Most common side effects leading to OC discontinuation:
  - Unscheduled bleeding 12%
  - Nausea 7%
  - Perceived weight gain 5%
  - Mood change 5%
  - Breast tenderness 4%
  - Headache 4%

*Excluding those who stopped to become pregnant or no longer needed contraception. Rosenberg J, Waugh MS. *Am J Obstet Gynecol.* 1998;179:577-582.

Oral Contraceptive Extended Cycling

Other methods are designed without a cycle: DMPA, POPs, Lng-IUS

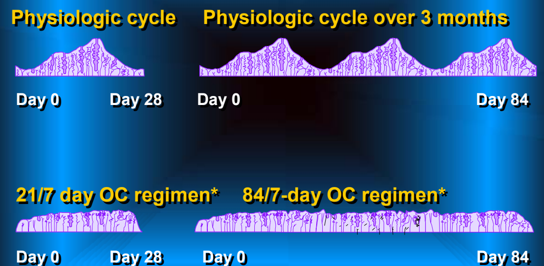
The Oral Contraceptive Cycle

- **Progestin prevents luteinizing hormone (LH) surge**
- **Estrogen suppresses follicle-stimulating hormone (FSH) and follicular development**
- **Together, the hormones in combination OCs inhibit proliferative changes in uterus, leading to endometrial atrophy**
- **When placebo pills are taken, a "pill period" results**

Ovulatory Endometrium

Endometrium with Oral Contraceptive Pills

Endometrial Thickness – Ovulatory Cycle With Oral Contraception



* After steady state is achieved

The ESHRE Capri Workshop Group. *Hum Reprod.* 2001;16:1527-1535.

Understanding the Pill Period

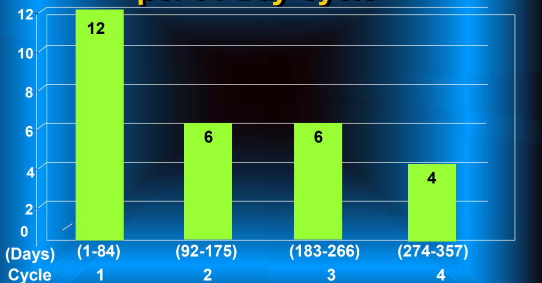
- Withdrawal bleeding during placebo pills:
  - Is “unnecessary”
  - May be associated with symptoms and discomfort
  - May interfere with personal or professional activity

Extended-Cycle OC Trial: Design and Methods

- Randomized, open-label, multi-center (47 sites), parallel-group clinical trial
  - 84/7-day regimen: n = 456
  - 21/7-day regimen: n = 226
- Included healthy women (18-40 yr) desiring pregnancy prevention
- Daily monitoring of adherence and bleeding patterns by electronic diaries
- Endometrial biopsies performed on subset of patients

Anderson FD, et al. *Contraception*. 2003;68:89-96.

Extended-Cycle OC Trial: Median Days of Spotting/BTB Days per 91-Day Cycle



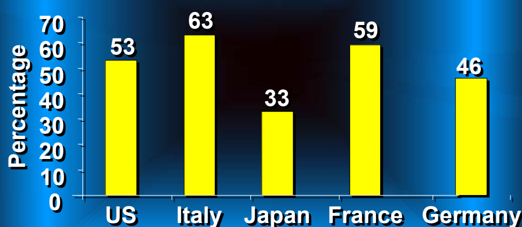
Used with permission. Anderson, FD, et al. *Contraception*. 2003;68:89-96.

Extended-Cycle OC Trial: Breakthrough Bleeding (BTB)

- BTB was observed almost exclusively during the first two 91-day cycles
- BTB diminished by 3rd or 4th 91-day cycle
- Counseling on the possibility of BTB is critical to patient acceptance

Used with permission. Anderson FD, et al. *Contraception*. 2003;68:89-96.

Women* Who Would Consider New Contraceptive Alternatives



*Women likely to use birth control in the future

Roper Starch Worldwide, 1999.

Overview

Recently Developed Steroidal Contraceptives

Levonorgestrel Intrauterine System

Single-rod Implant

Monthly Injectable

Vaginal Ring

Patch

Intrauterine System

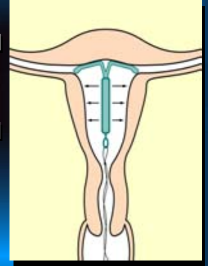
Levonorgestrel Intrauterine System (LNG IUS)

levonorgestrel 20 mcg/day

Intrauterine System

Levonorgestrel IUS: Mechanism of Action

- Fertilization inhibition:
  - Cervical mucus thickened
  - Sperm motility and function inhibited
  - Endometrium suppressed
  - Weak foreign body reaction induced
  - Ovulation inhibited (in some cycles)



Jonsson B, et al. *Contraception.* 1991;43:447-458.
Videla-Rivero L, et al. *Contraception.* 1987;36:217-226.

LNG IUS Typical Failure Rates (Pearl Index)

- First year 0.14%
- 5-year cumulative 0.71%

Anderson et al. *Contraception.* 1994;49:56. Luukkainen et al. *Contraception.* 1987;36:169. French RS et al. *Br J Obstet Gynecol.* 2000;107:1218-25

Candidates for LNG IUS Use

- Characteristics shared with Copper IUD
  - Parous
  - Stable, mutually monogamous relationship
  - No history of PID
  - Uterus 6-9 cm

Mirena Package Insert

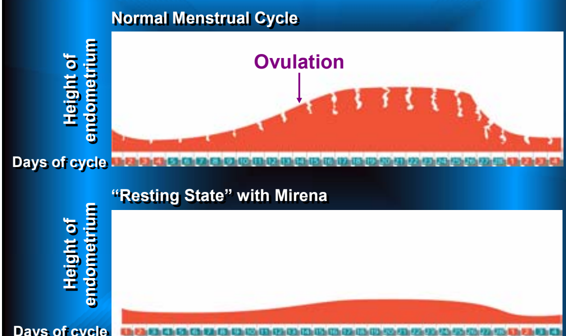
Candidates for LNG IUS Use

- Characteristics different from Copper IUD
  - LNG IUS not for women with history or risk factors for ectopic pregnancy
  - LNG IUS may be used for women with copper allergies, Wilson's disease and heavy menses

Mirena Package Insert

Changes in the Endometrium

Normal Menstrual Cycle



LNG IUS: Early Spotting

- Endometrial suppression effect is not immediate
- Takes three months for full effect on the endometrium
- Spotting is common during this time

Silverberg. Int J Gynecol Pathol 1986;5:235

LNG IUS: Bleeding Patterns

- 20 % of women will have no bleeding at all after twelve months

Pekonen et al. J Clin Endocrinol Metab 1992;75:660
Luukkainen et al. Contraception 1987;36:169

LNG IUS: Continuation Rates

	Clinical trials	Post marketing study
1 year	70%	93%
5 years	45%	65%

Backman T et al. *BJOG* 2000;107:335-9

LNG IUS: Return To Fertility

- Mean time to pregnancy: 4 months
- 12-month pregnancy rate: 90%
- Factors that do not influence fertility return
  - Duration of use
  - Age at insertion
  - Age at removal

Belhadj H et al. Contraception 1986;34:261-7

Intrauterine System

Levonorgestrel IUS: Counseling; Side Effects

- Possible hormonal side effects
  - Mood changes
  - Acne
  - Headache
  - Breast tenderness
  - Nausea
  - Persistent ovarian follicles
- No reported weight gain

LNG IUS: Therapeutic Possibilities

- Range of non-contraceptive benefits, including:
  - Treatment of heavy menstrual bleeding
  - Endometrial protection for women receiving estrogen replacement therapy

LNG IUS vs. Endometrial Resection

Crosignani et al. *Obstet Gynecol* 1997;90:257

LNG IUS: Hormone Replacement

- Prevention of endometrial hyperplasia from estrogen therapy
- "Local is logical"
- Oral progestins can cause side effects
- LNG IUS avoids most systemic side effects of oral progestins

Girdler et al. *J Womens Health Gend Based Med* 1999;8:637

Intrauterine System

Levonorgestrel IUS: Summary

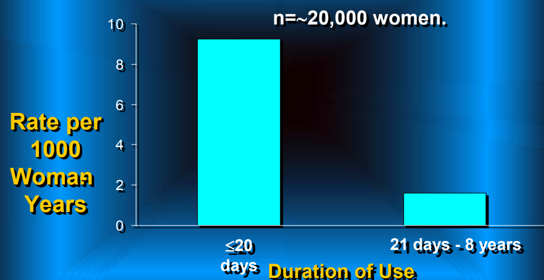
- High efficacy
- Requires clinician visit for initiation and discontinuation
- Early spotting
- Reduction in menstrual blood loss
- Low systemic levels of LNG

Safety: Intrauterine Contraception Does Not Cause PID

- PID incidence for IUC users similar to general population
- Increased risk only during first month after insertion
- Preexisting STI at time of insertion, not the IUD itself, increases risk

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

Rate of PID by Duration of IUC Use

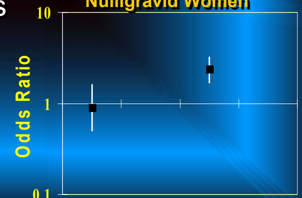


Adapted from Farley T, et al. *Lancet*. 1992;339:785-788.

Safety: Intrauterine Contraception Does Not Cause Infertility

- IUD not related to infertility
- Chlamydia was related to infertility

Tubal Infertility by Prior Copper T IUD Use & Presence of Chlamydia Antibodies, Nulligravid Women



Hubacher. *NEJM* 2001.

LNG-IUS vs. OCPs randomized trial in young nulliparous women/Finland

- N=94 in IUS/99in OC, median age 21, median uterine sound depth 7cm
- 2 IUS unsuccessful. 85% "easy"
- Paracervical block or dilation in 12 insertions
- One partial expulsion at 6 months
- No pregnancies or PID
- Of completers at 1 year: 88% IUS to continue/ 68% OC

Suhonen S et al. Contraception 2004;69(5):407-12

Termination Rates and Reasons

	LNG IUS	OC
Pain	6 (6.6)	0 (0)
Hormonal	4 (5)	9 (9.8)
Bleeding	2 (2.5)	0 (0)
Spotting	0 (0)	1 (1.3)
Expulsion	1 (1.2)	NA
Other medical	2 (2.1)	1 (1.1)
Wants preg	0 (0)	2 (2.6)
Other personal	4 (4.5)	14 (15.36)
Total	19	27

Suhonen S et al. Contraception 2004;69(5):407-12

Who Medical Eligibility Criteria

- "1": Can use the method.
- "2": Can use the method. Advantages Generally outweigh risks. More than usual follow-up may be needed.
- "3': Should not use the method unless clinician makes judgment that the patient can safely use. Method of "last choice."
- "4": Should not use. Unacceptable health risk.

WHO Medical Eligibilty Criteria

- Nulliparous or age <20 is a "2"
- Postpartum <48 hrs. IUD is a "2"/IUS is a "3"
- Past ectopic pregnancy. Both are "1"
- Current PID: "4" to insert/ "2" to continue
- Vaginitis (incl Trich, BV): "2"
- HIV infected: "2"
- Aids/Doing well on ARV: "2"

WHO Medical Eligibilty Criteria

- AIDS: "3" to insert/ "2" to continue
- Diabetes: may use both
- Smokers may use both
- HTN and Cardiac disease may use both (except continuation of IUS with ischemia= 3)
- Both may be inserted at time of first or second trimester abortions

Vaginal Ring Contraceptive Vaginal Rings

- Long development process – first published data in 1970 (Mishell/Lumpkin)
- Several rings in development
- Limited data on efficacy and safety
- Recent data on one ring
  - Etonogestrel/Ethinyl Estradiol

Etonogestrel/Ethinyl Estradiol Vaginal Ring

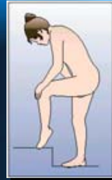
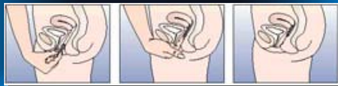
Etonogestrel/Ethinyl Estradiol Vaginal Ring

Progestin: Etonogestrel: 120 µg/day
Estrogen: Ethinyl estradiol: 15 µg/day

- Worn for three out of four weeks
- Self insertion & removal
- Pregnancy rate 0.65 per 100 woman–years

Roumen FJ, et al. *Hum Reprod.* 2001;16(3):469-475.

NuvaRing® Insertion

There is no wrong way to insert. If it is in the vagina, it is in correctly.

NuvaRing®: Summary of Pharmacokinetics and Drug Interactions

- Steady state serum hormone concentrations
- EE exposure is half that with a 30 µg OC
- ENG exposure with NuvaRing® is comparable with 30 EE/150 DSG
- Spermicide or anti-mycotic co-administration has not been shown to impair hormone release and/or absorption

NuvaRing® *Study Design*

- 52 centers in Europe, 48 centers in North America
- 2392 women
- 1 year of treatment (13 cycles)
- One NuvaRing® cycle comprises:
  - 3 weeks of ring use
  - 1 ring-free week

Roumen et al., Hum Reprod, 2001;16:469-75;
Dieben et al, in preparation

NuvaRing®: Metabolic and Safety Conclusions

- Minimal effect on lipid parameters
- No clinically relevant effect on carbohydrate metabolism
- Minimal effect on hemostatic variables, comparable with 30 EE/150 LNG COC
- Low androgenic effects confirmed with SHBG concentration
- No adverse effect on blood pressure
- No unfavorable effects - cervix and vagina

Vaginal Ring - Patient Management

- Patient inserts ring and it is supposed to remain in the vagina for 3 weeks
- Ring is removed during the fourth week, menstrual period should begin
- If ring is removed or slips out of place for > 3 hrs, back-up contraception is necessary for 7 days

Most Frequent Reasons for Vaginal Ring Discontinuations

Device related	2.6 %
Headache	2.1 %
Nausea	1.0 %
Vaginal discomfort	1.0 %
Bleeding	0.8 %

Roumen FJME et al., Hum Repro vol 16,No 3,p. 469-475, 2001

Expulsion of NuvaRing

- Spontaneous expulsion occurred infrequently
- Only 2.6% women experienced expulsion
- Occurred only once in almost all cases

Vaginal Ring Summary

- Provides uniform release of hormones
- Low estrogen exposure
- Effectively and reversibly inhibits ovulation
- Low incidence of adverse effects; bleeding
- Convenient with successful use
- Very well tolerated and accepted by women

Transdermal Contraceptive System

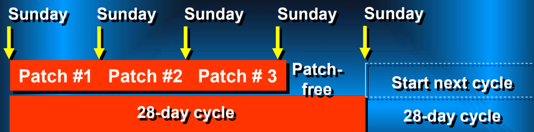
Contraceptive Patch – Where to Apply the Patch

- **Clean, dry, intact healthy skin**
  - **Buttock**
  - **Abdomen**
  - **Upper outer arm**
  - **Upper torso**
  - **In a place where it won't be rubbed by tight clothing**
  - **Should not be placed on skin that is red, irritated, or cut**
  - **Should not be placed on the breasts**

Patch Administration

- Simple administration schedule
  - Apply weekly for 3 weeks
  - Apply same day-of-the-week
  - 1 week patch-free

Example: Sunday Start



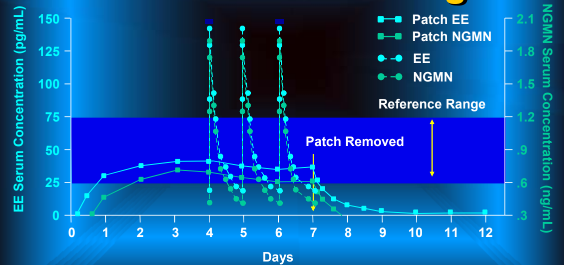
Pharmacokinetics Overview

- Delivers constant levels of NGMN and EE compared to the peaks and troughs of OCs
- Delivers NGMN 150 µg/day and EE 20 µg/day to the systemic circulation
- The patch can maintain serum concentrations of NGMN and EE in target range through 9 full days

Pharmacokinetics Overview

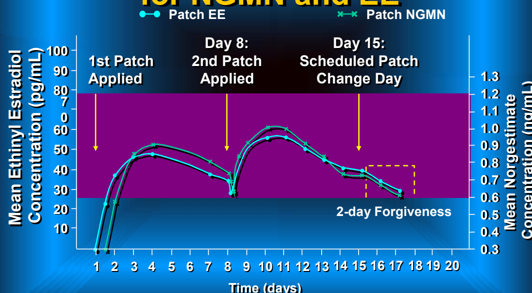
- Four anatomic sites are therapeutically equivalent
- C^{ss} is similar in weeks 1, 2, and 3 with no accumulation
- Activities with various conditions of heat and humidity do not have substantial effects on pharmacokinetics

Patch Continuously Delivers NGMN and EE Within Reference Ranges*



*Noncomparative data

Contraceptive Patch - Dosing Reserve Beyond 7 Days: Results for NGMN and EE



Abrams L, et al. Int J Gyn & Obstet. 2000;70(suppl 1):78.

Distribution of Pregnancies By Baseline Body Weight Deciles (n=3,319 subjects)

Decile Pregnancies (N)	Weight Range (kg)	Total
1 (334)	<52	1
2 (285)	52 - <55	2
3 (354)	55 - <58	0
4 (256)	58 - <60	0
5 (433)	60 - <63	2
6 (346)	63 - <66	0
7 (276)	66 - <69	1
8 (379)	69 - <74	0
9 (304)	74 - <80	2
10 (352)	≥80	7
	(80- <85)	1
	(85- <90)	1
	≥90 (N=83)	5

Zieman, et al. *Fertil Steril* 2001; vol. 76:S19 (abst O-48) .

Recent Patient Requesting Patch, Weight 250 lbs., para 5

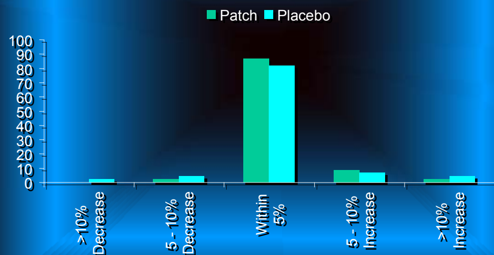
- Couldn't remember pills, got pregnant on pills
- Had recent STI
- DMPA bleeding problems
- WANTED PATCH
- Got patch with condoms!

Treatment-Limiting Events*

	Patch (%)
Application site reaction	2.6
Breast symptoms	1.0
Nausea	1.8
Headache	1.5

*Discontinuation rates associated with adverse events (AEs). Audet, et al., *JAMA*. 2001:.285:2347-54.

9 Cycle, Randomized, Placebo-Controlled Trial: Effect on Weight



Sibai et al., *Fertil Steril* 2001; vol. 76:S188 (abst P-225)

Patch Replacement for Complete and Partial Detachment

	Contraceptive Studies	US Centers With Warm Humid Climate*	4-Cycle Study	Exercise Study
Total no. of patches worn	70552	4877	1663	87
Replacement for complete detachment	1297 (1.8%)	85 (1.7%)	6 (0.4%)	1 (1.1%)
Replacement for partial detachment	2050 (2.9%)	128 (2.6%)	12 (0.7%)	0

*11 sites in Florida, Georgia, and Louisiana. Zacur et al. *Fertil Steril* 2001;76 vol. S19 (abst O-49).

Contraceptive Patch - Contraindications

- Similar to OCs
- Valvular heart disease with complications
- Severe hypertension
- Diabetes with vascular involvement

Contraceptive Patch - Contraindications

- Headaches with focal neurological symptoms
- Acute or chronic hepatocellular disease with abnormal liver function
- Hypersensitivity to any component of this product

Contraceptive Patch - Precautions

- Body weight ≥198 lbs. (90 kg)
  - Results of clinical trials suggest that the contraceptive patch may be less effective in women with body weight ≥198 lbs (90 kg) than in women with lower body weights
- No other changes

Transdermal Summary

- Transdermal System, a seven-day contraceptive patch, was well accepted by women
- In clinical studies, the patch was shown for most women to combine the proven efficacy and safety of OCs with the convenience of once-a-week dosing, resulting in improved compliance

Initiating Hormonal Methods -Menses-

- Ocs / Patch: First-day start /no back-up necessary
- Ring: Insert days 1-5, back-up first 7 days
- Mirena: First 7 days
- DMPA: First 5 days

Initiation per WHO (not necessarily according to labeling)

- <6 weeks PP/BF: hormonal methods are 3s,4s
- >6 weeks/BF: combined are 3s/pro-only are 1s
- Not BF: combined after 21 days
- After 1st and second trimester abortion: hormonal methods can be started that day, as can IUDs

www.who.int/reproductive-health/publications/mec_3/

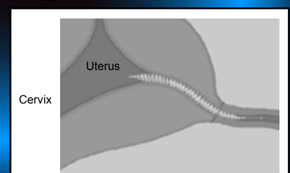
Essure®

- Soft, flexible micro-insert
- The Essure procedure is performed by a trained gynecologist and is an alternative to surgical sterilization
- Essure is 99.8% effective in preventing pregnancy

ESSURE® Package Insert.

Essure®

- Another method of birth control must be used for at least three months after the procedure, then
- HSG confirms blockage
- Not reversible



ESSURE® Package Insert.

Emergency Contraception

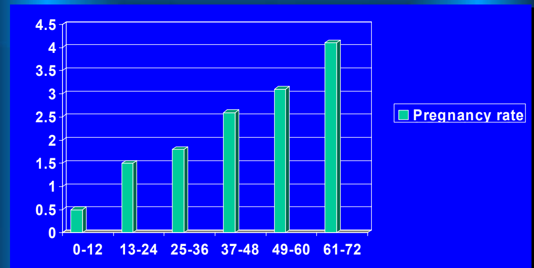
Regimen

- Plan B: 1.5 mg levonorgestrel in 1 dose up to 5 days after intercourse
  (2 tablets of 0.75mg)
- More effective the sooner taken after event
- COCs: “Yuzpe”/ preven 100 mcg ee/100 mcg lng 12 hours apart x 2 doses
- Copper IUD: insert up to 5 or more days post intercourse. Can be used up to 8 days if ovulation occurred 3 days after event

Efficacy

- Plan B reduces risk of pregnancy by 88% for that act(s) of intercourse
- COC’s reduce risk by 75%
- Copper IUD reduces risk by 99%
- EC accounts for 40% of the reduction in teen pregnancy that has occurred in recent years

Time After Intercourse



Mechanism of Action: Prevents Pregnancy / Cannot Interrupt an Established Pregnancy

- Inhibits ovulation
- Thickens cervical mucus
- Possibly inhibits corpus luteum function, ovarian hormone production, follicle development, tubal transport, fertilization, implantation.

Management Issues

- Next menses may be early (if taken before ovulation), on time or late
- If no menses within 3 weeks after using – pregnancy should be ruled out
- Precautions are few: pops:pregnancy, allergy to levonorgestrel. Coc: current migraine, history of DVT/PE

Management

- Advance prescription or provision recommended. If fills prescription, shelf life is 18 months
- Pharmacist provision: California, Hawaii, Washington, New Mexico, Alaska, Maine
- May start or resume contraceptive next day and add 7 days of backup

EC Resources

- www.not-2-late.com
- 1-888-not-2-late
- www.go2planB.com
- www.managingcontraception.com
- www.arhp.org

DMPA: New Labeling

WOMEN WHO USE DMPA may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.

It is UNKNOWN if use of DMPA during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture later in life.

DMPA should be used as a long term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate.

Unpublished Studies: Adult

- Use of DMPA for up to 5 years
- Loss of bone mineral density (BMD) in spine and hip: mean 5-6%
- SPINE: losses per year (means)
  - Year 1: -2.86%
  - Year 2: -4.11%
  - Year 3: -4.89%
  - Year 4: -4.93%
  - Year 5: -5.38%

Mean Percent Change From Baseline in BMD in Adults

Time in study	Spine DMPA	Spine control	Hip DMPA	Hip control	Femur DMPA	Femur control
5 years	minus 5.38% N=33	0.43% N=105	minus 5.16% N=21	0.19% N=65	minus 6.12% N=34	minus 0.27% N=106
7 years	minus 3.13% N=12	0.53% N=60	minus 1.34% N=7	0.94% N=39	Minus 5.38% N=13	minus 0.11% N=63

Unpublished Adolescent Data

- N=103
- Similar data as adults; partial recovery at 2 years post-treatment

Management per Pfizer

- In both adults and adolescents the decrease in BMD appears to be at least partially reversible upon discontinuation
- BMD should be evaluated when a woman needs to continue to use DMPA long-term. In adolescents, interpretation of BMD results should take into account patient age

Management per Pfizer

- Although no studies address Calcium and Vitamin D; all patients should have adequate CA/Vit D
- RHTP: black box may alarm women more than inform

Grady Management

- Women are offered and use DMPA
- Grady consent discusses loss in BMD
- Advise measures for bone health: Ca, Vit D and exercise
- Adolescents may be more of a concern although WHO gives adolescents using DMPA a “2”i.e., benefits generally outweigh risks
- Longer term use associated with more loss BMD; so discuss at periodic intervals

Recent Depo-Provera Issues

- Does DMPA increase risk of acquiring STI?*
- Supplemental estrogen when on DMPA?**

*Morrison CS et al. Sex Trans Dis. 31(9) 2004. 561-7
**Cundy T et al. J Clin Endocrinol Metab 88: &*-81, 2003

Overcoming Barriers to Contraceptive Counseling

Barriers to Successful Contraceptive Use

- Clinician-patient communication
- Clinician barriers
- Patient barriers
- Provision of contraceptive services

Stewart FH, et al. J Am Med Assoc. 2001;285:2232-2239.
Potter L, et al. Fam Plann Perspect. 1996;28: 154-158.

Barriers to Clinician-Patient Communication

- Clinicians often interrupt their patients[1,2]
- Patients retain ~50% of what clinician tells them 1 minute after leaving office
- Average patient can absorb ~3 take-home messages

[1]Marvel MK, et al. *JAMA*. 1999;281(3):283-287.
[2]Beckman HB, et al. *Ann Intern Med*. 1984;101:692.

Clinician Barriers

- Avoid personal biases:
  - personal experience, patient anecdotes, statistics,"my practice", fear, religion
- Counsel whether or not you provide the service (eg, IUD insertion, diaphragm fitting)
- Refer, if necessary, to a service provider

Association of Reproductive Health Professionals. Contraceptive Counseling for the Periodic Well Woman Visit. *Clinical Proceedings*. February 2004. Available at http://www.arhp.org.

Comparative Data: Most Common Adverse Events

	Pill (%)	Placebo (%)(p)
Breast symptoms	9.2	4.7 (0.07)
Headache	18.4	20.5 (0.64)
Weight Gain	2.2	2.1 (1.00)
Nausea	12.7	9.0 (0.23)
Abdominal pain	5.7	3.9 (0.39)
Dysmenorrhea	10.1	9.0 (0.75)

Redmond, et al., Contraception1999;60:81

Patient Barriers: Fears, Myths, and Misperceptions

- Women's fears relate to myths and misperceptions
- Address body image issues (eg, weight)
- Address cancer (older reproductive age women)

Patient Barriers: Fears, Myths, and Misperceptions

- Women generally unaware of numerous noncontraceptive benefits of OCs[1,2]
- 9 in 10 women unaware of protective benefits of OCs against osteoporosis and ovarian cancer[1]

[1]Kaiser Family Foundation Poll. Washington, DC; 1996.
[2]Louis Harris & Associates; 1996.

Patient Barriers: Pill-Taking

- On average, a woman misses at least 1 pill per cycle[1]
- >50% all OC users miss ≥3 active pills in their third cycle of use[2]
- First-year OC discontinuation rates: up to 50%-60%[1-3]

[1]Rosenberg MJ, et al. *Fam Plann Perspect.* 1998;30(2):89-92 & 104.
[2]Potter L, et al. *Fam Plann Perspect.* 1996;28:154-158.
[3]Ortho Birth Control Study, 1999.

Summary - Choosing a Contraceptive Method

- Patient goals for fertility control
- Anticipated levels of correct and consistent use

Summary - Elicit and Respect Patient Choice

- Patient and partner priorities may direct choice
- Recognize your possible biases
- Any one unique advantage of one method relative to others may be critical
- Women's needs often differ over time

Summary - Conclusions

- Impossible to predetermine women's contraceptive needs and/or desires
- A menu of options should be presented to all reproductive-aged women
- With good counseling, women will select a method that best suits their respective contraceptive needs
- Emergency Contraception and Dual Method Use! Should be considered

Future Trends

- The patients will select method used
- Efficacy and safety will be taken for granted
- Health benefits will be of greater consideration
- The most user-friendly methods will prosper