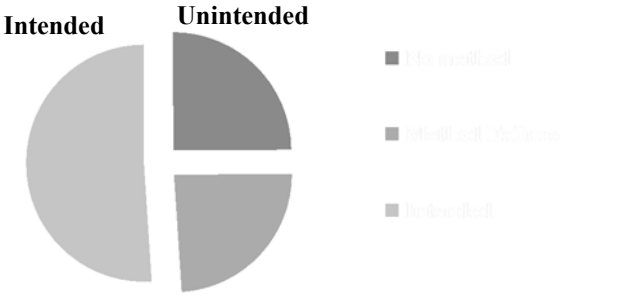
National Survey of Family Growth (CDC)
American Females 15 to 44 years

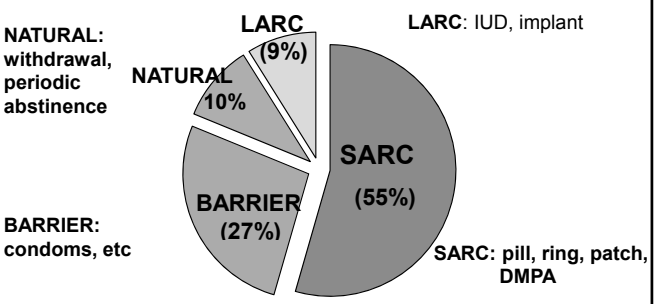
Method	1982	1995	2002	2011-13
Birth Control Pill	16%	18%	19%	16%
Contraceptive Ring	N/A	N/A	N/A	1.3%
Contraceptive Patch	N/A	N/A	N/A	0.3%
Condom	7%	13%	11%	9.4%
DMPA	N/A	1.9%	3%	2.8%
Implant	N/A	0.9%	?	0.7%
IUD	4%	0.5%	1.3%	6.4%
Diaphragm	5%	1.2%	0.2%	?
Sterilization	19%	25%	22%	20%

Importance of Contraception
4 million pregnancies/yr in U.S.



CDC 2013

Reversible Contraceptive Use in U.S.



Trussell, Contraception 2015;91:49-56

EFFICACY OF CONTRACEPTIVE AGENT
*** % unintended pregnancies/ first yr of use**

SARC	PERFECT USE *	TYPICAL USE *
OCP	0.3	9
Ring	0.3	9
Patch	0.3	9
DMPA	0.2	6
LARC ("Get It and	Forget It" methods)	
LNG-IUS	0.2	0.2
Copper IUD	0.8	0.8
Implant	0.05	0.05

Trussell J, Contraceptive Technology Update, 2011

Long Acting Reversible Contraceptives
Contraceptive CHOICE Trial

Winner et al, NEJM 2012;366:1998)

- prospective cohort trial 7,486 women, 334 unintended pregnancies (2007-2011)
- contraceptive failure rates:
  - **pill, patch, ring**: **4.55 per 100 women-yrs**
  - **LARC and DMPA: 0.27 per 100 women-yrs**

LARC: IUD, implants

Contraceptive User Satisfaction Rates
CHOICE Trial

METHOD	12-mo continuation (%)	Very satisfied (%)
LNG-IUS	87.5	70.4
Copper IUD	84	65.6
Implant	83	54.8
DMPA	56.5	42
OCP	55.1	41
Ring	54	46
Patch	49	35

Obstet Gynecol 2011;117:1105

Combined Oral Contraceptives Current Trends

- most popular reversible method

Current Trends:

- "Quick Start"
- Extended-cycle OCPs

Oral Contraceptives "Quick-Start"

- first BCP taken on the same day of the office visit
- 25 percent do not fill it with standard delayed OCP initiation
- compliance enhanced with "Quick Start" [1]

1. Contraception 2002;66:141

"Quick-Start" Issues

- impact of taking OCP during pregnancy
  - ✓ perform pregnancy test
  - ✓ EC if unprotected sex prior
  - ✓ repeat pregnancy test in 2 weeks
- impact on BTB (Fertil Steril 2003;79:322)
- effectiveness: B/U for 7 days

"Extended-Cycle OCPs
Reduction of the Pill-Free Interval

- **"Loestrin 24 Fe"** (FDA approval 3/06)
  - 24 d (20 mcg EE + 1 mg NA) + 4 d 75 mg Fe
- **"Yaz"** (FDA approval 3/06; 10/06- PMDD)
  - 24 d (20 mcg EE + 3 mg DRSP + 4 d inert
- **"Seasonique"** (FDA approval 5/06)
  - 84 d (30 mcg EE + 0.15 mg LNG) + 7 d 10 mcg EE
- **"LoSeasonique"** (FDA approval 5/08)
  - 84 d (20 mcg EE + 0.1 mg LNG) + 7 d 10 mcg EE
- **"Lo Loestrin" (FDA approval Oct 2010)**
  - 24 d (10 mcg EE + 1 mg NA) + 2 d 10 mcg EE + 2 d inert

Continous-Cycle OCPs "Elimination of the Pill-Free Interval"

- **"Lybrel"** (FDA approval 5/07)
  - continuous 0.02 mg EE/0.09 mg L-NG
  - 28 day per packet x 13 packets per year
    - **1-yr study of 2,134 women (18-49 yrs)**
    - **pack # 13, 79 % no bleeding (but had spotting) and 58.7 % amenorrhea (no bleeding or spotting)**
    - **57% subjects did not complete study**

Archer et al, Contraception 2006;74:439

Oral Contraceptives "Shortening the Pill-Free Interval"

<u>Potential advantages</u>:

- **reduced risk for follicular development** (Am J Ob Gyn 2004;190;943; Sem Reprod Med 2010;28:140; Cochrane Database Syst Rev 2005:CD004695)
- **reduced sxs during hormone-free period** (Ob Gyn 2000;95:261; Contraception 2005;71:304; J Fam Plann Reprod Hlth Care 2010;36(4):231)

IUD History

1970: severe cases of PID reported
1975: Dalkon Shield- production halted
1980: Dalkon Shield- recall of device
1985: A.H. Robins bankruptcy
10,000 lawsuits
$480 million

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IUD History

1984: Schmidt Laboratories removes Saf-T-Coil from U.S. market
1985: Ortho removes Lippe's Loop
1986: Searle Laboratories withdraws Copper-7 and Tatum-T from U.S. marketplace

IUD History

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1988: GynoPharma introduces Paraguard in May 1988

IUD: Making a Comeback

- highly effective
- convenient
- high user satisfaction rate
- no increased risk of PID[1-3]

1, Contraception 2007;75:S41-7)
2. Lancet 2000;356:1013;
3. Lancet 1992;339:785

Intrautuerine Contraceptive Devices
Contraindications

- active pelvic infection
- known or suspected pregnancy
- unexplained or unevaluated uterine bleeding
- severe uterine distortion
- Wilson's disease or copper allergy*

* Copper IUD only

Intrautuerine Contraceptive Devices
Busting myths and misconceptions

- **can be used in nulliparous women[1-3]**
- **does not increase risk of ectopic pregnancy[2.4]**
- **does not increase risk for tubal infertility**

1. Contraception 2010;81:367-71
2. CDC MEC MMWR 59(RR-4) 2010
3. WHO MEC, 5th edition, 2015
4. ACOG. Ob Gyn 2011;118:184

IUD Use and Risk of Tubal Infertility

- case-control study of 1,895 nulligravid women in Mexico by Hubacher et al
- prior copper IUD use not associated with higher risk of tubal infertility
- risk associated with antibodies to chlamydia

N Engl J Med 2001;345:561;
Contraception 2009;81:367

Intrautuerine Contraceptive Devices
Busting myths and misconceptions

- **can be used in nulliparous women[1-3]**
- **does not increase risk of ectopic pregnancy[2.4]**
- **does not increase risk for tubal infertility**
- **can be safely used in adolescents**

1. Contraception 2010;81:367-71
2. CDC MEC MMWR 59(RR-4) 2010
3. WHO MEC, 5th edition, 2015
4. ACOG. Ob Gyn 2011;118:184

LARC Underutilization

- ACOG Committee Opinion (2012):
  - encourages IUD use in adolescents
- AAP 2014 Technical Report: "Contraception for Adolescents"
  - recommends for the first time pediatricians discuss LARCs before other birth control methods for teens
  - "… LARC methods should be considered first-line contraceptive choices for adolescents….

Obstet Gynecol 2012;120:983-8
Pediatrics 2014;134;e1244-56;

Long-Acting Progestin-Only Agents

- **Subdermal progestin implants**
  - **LARC**
  - **used by 0.7 %**
- **Intramuscular progestin injections**
  - **used by 2.8 %**

Levonorgestrel Implant
General Comments

- **innovative progestin-only device**
- **received FDA approval 1990**
- **composed of 6 silastic capsules**

Levonorgestrel Implant Removal

Frank et al, Contraception 1995;
Crosby et al, Contraception 1993:

- **50% required longer than 30 minutes**
- **20% required longer than 1 hour**
- **5% classified as "complicated"**

Levonorgestrel Implant

- **1992: 800 insertions/day in U.S.**
- **1994: sudden decline spurred by difficult implant removals & lawsuits**
- **1996: 80 insertions/day**
- **1997: 50,000 lawsuits filed against Wyeth-Ayerst**
- **2000: all shipments suspended**

Etonogestrel Implant: Nexplanon®

- **Single implant rod**
- **FDA approved 2006**
- **68 mg of etonogestrel (initially 50-60 mcg/d down to 25-30 mcg/d**
- **Effective for 3 years**
- **Inhibits ovulation**

FDA approval 7/2006
www.contraceptiononline.org

Etonogestrel Implant Contraindications

- **Unexplained uterine bleeding**
- **SLE with (+) APA**
- **Severe cirrhosis**
- **Benign or malignant liver tumor**
- **Current or past breast cancer**
- **Use of ritonavir-boosted protease inhibitor, certain anticonvulsants*, rifampin, rifabutin**

• * phenytoin, carbamazepine, primidone, topiramate, oxycarbazepine

Etonogestrel Implant Advantages

- highly effective and rapidly reversible
- coitally independent
- effective for 3 years
- does not contain estrogen
- can be used during lactation
- may improve dysmenorrhea

Etonogestrel Implant Adverse Reactions

- irregular vaginal bleeding: 50-60 %
  - 23 % discontinue early due to bleeding concerns [1]
- amenorrhea: 30-40 %
- acne: 15 %
- mastalgia: 9.1 %
- headache: 8.5 %
- weight gain: 6.4 %

J Fam Plann Reprod Health Care 2014;40:158-160
Ob Gyn Clin North Am 2015;42:593-602

Management of BTB with Implant

- NSAIDs: Ibuprofen* 600 mg TID x 5 days or Naproxen* 500 mg BID x 5-7 days
- COC*: 0.30 mg EE + 0.15 L-NG x 10-20 d
- Estrogen* :
  - CEE 1.25 mg/d x 7-14 days
  - Ethinyl estradiol 20 mcg/d x 10-20 days
  - Micronized estradiol 2 mg/d x 7-14 days
  - Transdermal patch 0.1 mg x 7-14 days

* off-label use

J Fam Plann Reprod Health Care 2014;40:158-160
Ob Gyn Clin North Am 2015;42:593-602
Ob Gyn 2015;126:508-13

Management of BTB with Implant

- Mefenamic acid (Ponstel ®)*: 500 mg BID-TID x 5-7 days
- Doxycycline* 100 mg BID x 5-7 days
- Tranexamic acid (Lysteda®)*- antifibrinolytic agent 500 mg BID x 5-7days

* off-label use

J Fam Plann Reprod Health Care 2014;40:158-160
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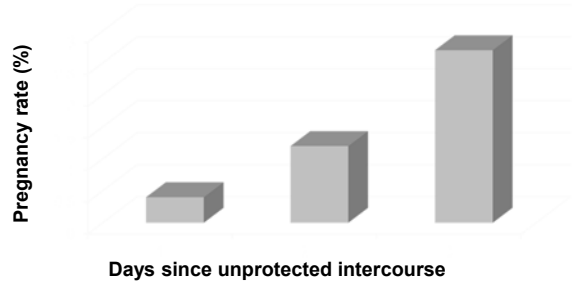
Emergency Contraception

- **underutilized means for reducing the number of unintended pregnancies**
- **prior to September 1998, no FDA-approved product for use as an emergency contraceptive**
- **2 dedicated EC methods, off-label Yuzpe methods equivalents**

LNG-based EC

- **progestin-only method, FDA approval 1999**
- **one tablet (0.75 mg l-norgestrel) now, repeat dose 12 hrs from now, within 72 hrs**
- **Plan B® One Step approved 7/09**
- **Generic: Next Choice®, My Way®, L-NG tabs**
- **OTC for women 18+ in 8/06, 17+ yrs in 3/09**
- **available (1-step) OTC 4/30/13 for women >15**
- **FDA approved One-Step® for all on 6/2013**
- **FDA added one-dose generics 2/2014**

Pregnancy Rate vs Day of Administration of LNG- EC



Lancet 2008;352:428-433

Ulipristal acetate (ella®)

- **progesterone receptor modulator**
- **FDA approval in August 2010**
- **one tablet (30 mg) as a single dose**
- **blocks ovulation by suppressing LH surge even after it starts**
- **effective up to 120 hours after unprotected intercourse and superior to Plan B (Fine, Contraception 2010;115:257; Glasier, Lancet 2010;375:555)**

LNG- EC Efficacy and Weight
Contraception 2011; 84(4):363-367

- WHO study of 3,893 women

Weight	R.R. of pregnancy
BMI < 25	1.0
BMI 25-30	2.09 (CI, 0.86–4.87)
BMI > 30	4.41 (CI 2.05–9.44)

LNG- EC Efficacy and Weight
November 25, 2013

Change in European labeling: NorLevo:

"In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg [165 pounds] or more and levonorgestrel was not effective in women who weighed more than 80 kg [176 pounds]."

LNG- EC Efficacy and Weight
July 24, 2014 EMA Press Release

EMA CHMP* :

- "considered that the data available are too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased bodyweight."
- recommended "the current statements on the impact of body weight in the product information for Norlevo should be deleted"

*CHMP: Committee for Medicinal Products for Human Use

Pregnancy Rate After LNG-EC, By Weight

Weight, in kilograms

	<55 kg	55-65 kg	65-75 kg	75-85 kg	> 85 kg
N total	349	608	426	155	193
N pregnancies	3	8	6	10	11
% pregnancies	0.9	1.3	1.4	6.4	5.7
95% CI	0.2-2.5	0.6-2.6	0.5-3.0	3.1-4.5	2.5-6.0

Kapp et al, Contraception 2015;91:97-104

Condom Use in United States

- **enjoyed great surge of popularity in the 90's- relied upon by 11 million American females**
- **benefit: contraceptive effect, protection against STD transmission**
- **fact: 84 % do not rely upon the condom**

CONDOMS
Overcoming Barriers To Its Use

- counseling
- explicit instruction
  - purchase
  - proper use

CONDOMS
Overcoming Barriers To Its Use (con't)

- **anticipatory guidance**
  - **advice of dealing with a reluctant partner**
  - **provide hard-to-argue-with responses**

Condoms
Anticipatory Guidance

If the partner says:	*You can say:*
"I'm on the Pill, you don't need a condom."	"I'd like to use it anyway. We'll both be protected from infections we may not realize we have."
"I *know* I'm clean (disease-free); I haven't had sex with anyone in X months."	"Thanks for telling me. As far as I know, I'm disease-free, too. But I'd still like to use a condom since either of us could have an infection and not know it."
"I'm a virgin."	"I'm not. This way we'll both be protected."
"I can't feel a thing when I wear a condom; it's like wearing a raincoat in the shower."	"Even if you lose some sensation, you'll still have plenty left."
"I'll lose my erection by the time I stop and put it on."	"I'll help you put it on—that'll help you keep it."

Condoms
Anticipatory Guidance

If the partner says:	*You can say:*
"What kinds of alternatives?"	"Maybe we'll just pet, or postpone sex for a while."
"This is an insult! Do you think I'm some sort of disease-ridden slut (gigolo)?"	"I didn't say or imply that. I care for you, but in my opinion, it's best to use a condom."
"None of my other boyfriends uses a condom. A *real* man isn't afraid."	"Please don't compare me to them. A real man cares about the woman he dates, himself, and about their relationship."
"I love you! Would I give you an infection?"	"Not intentionally. But many people don't know they're infected. That's why this is best for both of us right now."
"Just this once."	"Once is all it takes."
"I don't have a condom with me."	"I do." or "Then let's satisfy each other without intercourse."

CONDOMS
Overcoming Barriers To Its Use (con't)

- **variety of condoms available**
- **countering the objection that "condoms are just not me"**

CONDOMS
Overcoming Barriers To Its Use (con't)

- **"designer" jeans**
- **"designer" cars**
- **"designer" homes**