Evaluating the Safety, Efficacy, and Clinical Role of Intrauterine Devices for Contraception

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Educational Objectives
By the end of this activity, the participant should be better able to:
1. Describe the significant clinical and socioeconomic consequences of unintended pregnancy.
2. Differentiate between currently available methods of contraception, including failure rates and typical patient compliance.
3. Outline the latest data on safety, efficacy, and clinical role of intrauterine devices (IUDs).
4. Apply clinical outcomes and evidence-based guidance on contraceptive use to informed patient counseling and selection of the most effective and reliable methods of contraception.

Speaker Disclosure
Dr. Levine has disclosed that he is on the advisory board for Bayer Healthcare Pharmaceuticals and Pfizer, has received an educational training grant from Pfizer, and is on the speaker’s bureau for Merck & Company.

Supporter Disclosure
This activity is supported by an educational grant from Bayer Healthcare Pharmaceuticals. It has been planned and produced by NACCME and Texas Academy of Family Physicians strictly as an accredited continuing medical education activity.
INTENDED LEARNERS
This activity is designed for primary care physicians, nurses, nurse practitioners, and physician assistants who treat female patients.

Independent Clinical Reviewers: Cari Benbasset-Miller, MD, Physician, Family Medicine, Cambridge, MA; Brian McDonough, MD, Clinical Professor of Family Medicine, Temple University School of Medicine, Philadelphia, Pennsylvania; William C. Torrey, MD, Medical Director, DHPA, Associate Professor of Psychiatry, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire; Lorena A. Wright, MD, Clinical Assistant Professor Metabolism, Endocrinology and Nutrition, University of Washington Medical Center/Roosevelt, Harborview Medical Center, Seattle, Washington.

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PLANNING COMMITTEE
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Developed in partnership with the Texas Academy of Family Physicians

Evaluating the Safety, Efficacy, and Clinical Role of Intrauterine Devices for Contraception

Supported by an educational grant from Bayer Healthcare Pharmaceuticals.

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Faculty Disclosure

Jeffrey P. Levine, MD, MPH: Advisory Committee—Bayer, Pfizer; Nexplanon Trainer—Merck

Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.

Learning Objectives

• Describe the significant clinical and socioeconomic consequences of unintended pregnancy
• Differentiate between currently available methods of contraception, including failure rates and typical patient compliance
• Outline the latest data on the safety, efficacy, and clinical role of intrauterine devices (IUDs)
• Apply clinical outcomes and evidence-based guidance on contraceptive use to informed patient counseling and selection of the most effective and reliable methods of contraception

Affordable Care Act

• Effective August 2012, health plans have had to offer expanded wellness coverage without requiring a co-pay:
  - All FDA-approved contraceptive methods, and patient education and counseling
  - STI counseling, HIV screening and counseling
  - Well-woman visits
  - Gestational diabetes screening
  - Breastfeeding support, supplies, and counseling
  - Domestic violence screening
  - Mammograms and cervical cancer screening already are covered, without co-pay

FDA = US Food and Drug Administration; STI = sexually transmitted infection.
Available Contraceptive Methods

**Barrier**
- Male condom
- Female condom
- Diaphragm
- Cervical shield/Cap

**Spermicidal**
- Cream/Jelly/Suppository
- Sponge/Film
- Copper IUD

**Hormonal**
- Intrauterine progestin
- Injectable progestin
- Implantable progestin
- Oral pills – POPs/COCs
- Transdermal patches
- Intravaginal rings

**Sterilization**
- Tubal ligation
- Transcervical
- Vasectomy

**Other**
- Fertility awareness
- Lactational amenorrhea
- Withdrawal

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Pregnancies in the United States by Intention Status

(51% of the 6.6 million pregnancies in the United States are unintended)

Outcomes of Unintended Pregnancies in the U.S.
(excluding miscarriages)

Acknowleged: Sex, data, and statistics from National Center for Health Statistics, 2013, CDC Reproductive Health Surveillance System.


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Despite many more contraceptive choices....

2 in 5
unintended pregnancies in the U.S. end in abortion


---

And by the age of 45...

1 in 3
U.S. women will have had an elective abortion


---

Of the 3.4 million unintended pregnancies in the United States...

By consistency of method use during month of conception

A Woman’s Reproductive Timeline is LONG: 360 Ovulatory Cycles

If a woman wants 2 children, she must prevent pregnancy for:
• 336 cycles
• 28 years
• 93% of her reproductive lifespan


Long-Acting Reversible Contraception

• LARC methods should be first-line recommendations for all women and adolescents
• Increased use may decrease unintended pregnancy rates

LARC = long-acting reversible contraception.

Why are LARCs Relevant?
There is a need for effective contraceptive methods that are Forgettable


Contraceptive Method Choice by US Women, 2012


Why IUDs Are Underused in the U.S.
• Dearth of trained and willing professionals to insert devices
• Negative publicity
• Misconceptions
• Fear of litigation
• Up-front cost
• Lack of awareness of method among women


Dispelling Common Myths About IUDs

IUDs:
• Are not abortifacients
• Do not cause ectopic pregnancies
• Do not cause pelvic infection
• Do not decrease the likelihood of future pregnancies
• Are not large in size
• Can be used by nulliparous women

Hatcher et al, Contraceptive Technology 2011
I WANT YOU TO...

- Dispel myths and misperceptions about IUDs and other FDA-approved contraceptive methods
- Communicate contraceptive risk in relevant terms
- Promote increased use of LARCs
- Access the 2010 U.S. MEC as a point-of-care resource and educate other clinicians about it
- Provide evidence-based contraceptive counseling and management to your patients, especially those with medical co-morbidities

LARC = long acting reversible contraception; MEC = medical eligibility criteria.

FDA-Approved IUDs

- Levonorgestrel-releasing intrauterine system:
  - Liletta
  - Mirena
  - Skyla
- Intrauterine copper contraceptive
  - ParaGard

IUD Mechanism of Action

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
<th>Copper T IUD</th>
<th>LNG 52 IUS</th>
<th>LNG 13.5 IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prevents fertilization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Reduces sperm motility and viability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inhibits development of ovum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prevents fertilization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inhibits movement and viability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inhibits development of ovum</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IUDs do NOT prevent ovulation

LNG-IUS = levonorgestrel-releasing intrauterine device.


IUD Comparison

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Copper T 380A</th>
<th>LNG 52 IUS</th>
<th>LNG 52 IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>N/A</td>
<td>16mcg</td>
<td>10mcg</td>
</tr>
<tr>
<td>Size</td>
<td>32x36mm</td>
<td>26x30mm</td>
<td>20x32mm</td>
</tr>
<tr>
<td>Diameter</td>
<td>4.01mm</td>
<td>3.8mm</td>
<td>4.75mm</td>
</tr>
<tr>
<td>Efficacy</td>
<td>99.4%</td>
<td>99.5%</td>
<td>99.0%</td>
</tr>
<tr>
<td>Evidence based duration</td>
<td>12 years</td>
<td>3 years</td>
<td>7 years</td>
</tr>
</tbody>
</table>

Effect on menstruation:
- No effect on timing of cycle
- Regular cycles


Choosing an IUD

<table>
<thead>
<tr>
<th>Copper T IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Want to keep their regular periods</td>
</tr>
<tr>
<td>• Don’t want any hormones</td>
</tr>
<tr>
<td>• Would be ok with heavier/crampier periods</td>
</tr>
<tr>
<td>• Emergency Contraception</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LNG 52 IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Want lighter or no periods</td>
</tr>
<tr>
<td>• Have menorrhagia or dysmenorrhea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LNG 13.5 IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Don’t want heavier periods but prefer regular periods</td>
</tr>
</tbody>
</table>


Providing IUDs

- Counseling about side effects
  - Copper: increased cramping and bleeding which improves over time
    - “One more pad per day, one more day per month”
  - Hormonal: cramping and irregular bleeding with increased chance of amenorrhea over time
    - “Probably overall lighter periods but bleeding can come at any time during the month and last any number of days”
    - “Some women stop getting a period at all but we can’t predict who that might be”

Providing IUDs

When to insert?
- Patient has been adequately counseled and no contraindications to method
- Distorted uterine cavity
- Cervical cancer, endometrial cancer, unexplained suspicious vaginal bleeding
- Breast cancer, severe cirrhosis, liver tumors (LNG-IUS contraindicated)
- Pregnant, molar pregnancy, septic abortion/postpartum sepsis
- Current cervicitis, AIDS, Pelvic tuberculosis
- Lab screening
  - Screen GC/CT same day, but don’t insert if active purulent cervicitis
  - Pap not required prior to insertion
- Anytime that you are reasonably sure that your patient is not pregnant - “Quick Start”


Weight and Effect on ECP Efficacy

ECP failure among obese vs. non-obese women
Levonorgestrel (LNG): OR = 4.41
Ulipristal (UPA): OR = 2.62

Limit of efficacy reached at threshold of:
70 kg (154 lbs) for LNG
88 kg (194 lbs) for UPA
* On average: American women weigh 166 lbs


Copper IUD as Emergency Contraception

Most effective

Levonorgestrel

Ulipristal Acetate

Copper IUD


Copper-T IUD as Emergency Contraception (EC)

- Can insert up to 5 days after intercourse
- No hormones
- Provides 12 years of reliable birth control
- ↓ pregnancy risk by 99%


Providing IUDs

How to be reasonably sure patient is not pregnant
- LMP within 5 days
- No sex since LMP, delivery, or abortion
- Reliable method since LMP, delivery, or abortion
- Postpartum<4 weeks
- Postpartum<6 months, fully breastfeeding (no pumping), amenorrheic
- Abortion/miscarriage within last 5 days

If ANY of these are true, you can be reasonably sure
What if patient had unprotected sex within past 5 days?

Duration of use of IUDs

“Extended use” of IUDs = use beyond FDA approved duration
i.e. “How long can we go?”

Extended Use of IUDs: Findings

- Likely highly effective among parous women who are at least 25 years old at the time of insertion Level A
  - Copper (Cu T380A) IUD (ParaGard): up to 12 years
  - LNG-IUD 52 mg (Mirena, Liletta): up to 7 years
- Extended use should be effective in overweight and obese women Level B
- Extended use of LNG-IUS 13.5 mg (Skyla) not studied

Conditions Associated with Increased Risk for Adverse Health Events as a Result of Unintended Pregnancy

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>Malignant liver tumors (hepatoma) and hepatocellular carcinoma of the liver</td>
</tr>
<tr>
<td>Complicated valvular heart disease</td>
<td>Peripartum cardiomyopathy</td>
</tr>
<tr>
<td>Diabetes: insulin dependent; with nephropathy/retinopathy/neuropathy or other vascular disease; or of &gt;20 years duration</td>
<td>Schistosomiasis with fibrosis of the liver</td>
</tr>
<tr>
<td>Endometrial or ovarian cancer</td>
<td>Severe (decompensated) cirrhosis</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>Sickle cell disease</td>
</tr>
<tr>
<td>Hypertension (systolic &gt; 160 mm Hg or diastolic &gt; 100 mm Hg)</td>
<td>Solid organ transplantation within the past 2 years</td>
</tr>
<tr>
<td>History of bariatric surgery within past 2 years</td>
<td>Stroke</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Systemic lupus erythematosus</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>Thrombogenic mutations</td>
</tr>
<tr>
<td>Malignant gestational trophoblastic disease</td>
<td>Tuberculosis</td>
</tr>
</tbody>
</table>

Should consider long-acting, highly-effective contraception for these patients

Online Access

Centers for Disease Control and Prevention
United States Medical Eligibility Criteria for Contraceptive Use
www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm
There’s an App (and it’s free)

U.S. Medical Eligibility Criteria For Contraceptive Use

US Medical Eligibility Criteria: Categories

1. No restriction for the use of the contraceptive method for a woman with that condition
2. Advantages of using the method generally outweigh the theoretical or proven risks
3. Theoretical or proven risks of the method usually outweigh the advantages – not usually recommended unless no other methods are available or acceptable
4. Unacceptable health risk if the contraceptive method is used by a woman with that condition

Absolute and Relative Contraindications

All IUDs: Pregnancy, unexplained vaginal bleeding, distorted uterine cavity, purulent cervicitis or chlamydial infection or gonorrhea, PID, puerperal sepsis, post-septic abortion; endometrial cancer; cervical cancer, gestational trophoblastic disease; pelvic tuberculosis; AIDS; complicated solid organ transplantation, Copper only: Wilson’s disease; SLE+severe thrombocytopenia

Venous Thromboembolic Event (VTE-DVT/PE)

Diabetes

DM = diabetes mellitus.
Hypertension

<table>
<thead>
<tr>
<th>Condition</th>
<th>Classified as</th>
<th>Normal BP, mm Hg</th>
<th>Stage 1, mm Hg</th>
<th>Stage 2, mm Hg</th>
<th>Stage 3, mm Hg</th>
<th>Stage 4, mm Hg</th>
<th>SBP</th>
<th>DBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>1st degree, controlled hypertension</td>
<td>100-120/60-70</td>
<td>130-159/80-89</td>
<td>160-179/100-109</td>
<td>180-199/110-119</td>
<td>200+/120+</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2nd degree, uncontrolled hypertension</td>
<td>100-120/60-70</td>
<td>130-159/80-89</td>
<td>160-179/100-109</td>
<td>180-199/110-119</td>
<td>200+/120+</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heavy Menstrual Bleeding (HMB)

- HMB (aka: menorrhagia): menstruation at regular cycle intervals, but with excessive flow and duration
  - Defined as a total blood loss of >80 mL per cycle OR
  - A period of menses lasting for more than 7 days
- Common cause of iron deficiency anemia and impaired QOL
- Approximately 30% of women consider their menstruation to be excessive
- Symptom of several different underlying conditions
  - Structural disorders (e.g., fibroids, polyps, adenomyosis)
  - Bleeding disorders (e.g., von Willebrand disease, platelet disorder)
  - Hypothyroidism
  - Advanced liver disease

QOL = quality of life.

HMB and LNG IUS

- ECLIPSE trial compared effectiveness of the LNG-IUS to tranexamic acid, mefenamic acid, combined estrogen-progestogen, or progesterone alone in the primary care setting
- LNG-IUS was significantly more effective and cost-effective than other medical treatments
  - These improvements were reported to be maintained throughout the 2 year study
- The LNG-IUS should be considered as the first-line therapy for HMB, regardless of the need of contraception
  - A recent systematic review concluded that the use of the LNG-IUS is recommended over OCPs, luteal-phase progestins, and NSAIDs
  - For the reduction in mean blood loss in women with HMB presumed secondary to abnormal uterine bleeding presumed secondary to endometrial dysfunction

LNG-IUS = levonorgestrel-releasing intrauterine device; OCP = oral contraceptive pill.

Effective Contraceptive Counseling

- Contraceptive History
- Teaching about Risks

Taking a Contraceptive History

- Gender preference
- Frequency of intercourse
- Number of past and current partners
- Problems with past and current methods
- Method of STI prevention
- Partner’s participation
- Financial ability to pay for contraception
- Ability to cope with contraceptive failure
- Ability to use method correctly and consistently
- Personal beliefs about methods
- Medical conditions that may be affected
- Desire for future fertility (long- vs. short-term)

Counseling about Contraceptive Risk

- Will It Work?
- The Risk of Pregnancy
- Is It Safe?
- The Risk of Complications
### Will It Work?
**Communicating the Risk of Pregnancy**

Some methods work with little motivation

Ideal = Typical

Some methods require ongoing behavior

Ideal < Typical

### Pregnancy Rate in First Year of Use

<table>
<thead>
<tr>
<th>Method</th>
<th>Ideal</th>
<th>Typical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel IUD</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.5%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>0.6%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Medroxyprogesterone injection</td>
<td>0.3%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Pill, patch, ring</td>
<td>0.3%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Condom</td>
<td>2%</td>
<td>15%</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4%</td>
<td>27%</td>
</tr>
<tr>
<td>Periodic abstinence</td>
<td>5%</td>
<td>25%</td>
</tr>
<tr>
<td>Spermicides</td>
<td>18%</td>
<td>29%</td>
</tr>
<tr>
<td>No method</td>
<td>85%</td>
<td>85%</td>
</tr>
</tbody>
</table>


### Cumulative Risk of Pregnancy

- "Over time, your risk of pregnancy adds up"
- So if she doesn’t want to have a baby for 3 years:

<table>
<thead>
<tr>
<th>Method</th>
<th>Ideal</th>
<th>Typical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condom</td>
<td>5.9%</td>
<td>38.6%</td>
</tr>
<tr>
<td>Pill</td>
<td>0.9%</td>
<td>22.1%</td>
</tr>
<tr>
<td>Levonorgestrel IUD</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>


### Helping your patients understand method effectiveness

Is It Safe?
What are we afraid of vs. What are we at risk for

- How people make decisions, personal or medical, is based on facts and emotions
- As clinicians, our job is to teach the facts, understand the emotions, and correct misunderstandings

There is relative risk, and then there is absolute risk...

Relative risk (2):
“Using the pill will double your risk of having a heart attack!”

Absolute risk (4/1,000,000):
“Of 1 million pill users, 4 will have a heart attack each year - compared to 2 non-pill users”

Wow, that really puts things into perspective!

Comparative Risks

<table>
<thead>
<tr>
<th>Contraceptive Method/Activity</th>
<th>Annual Risk of Death (per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrauterine Device</td>
<td>0.1</td>
</tr>
<tr>
<td>Legal induced abortion &lt; 9 weeks</td>
<td>0.4</td>
</tr>
<tr>
<td>COCs nonsmoker &lt;35yrs old</td>
<td>0.5</td>
</tr>
<tr>
<td>Spontaneous abortion</td>
<td>0.7</td>
</tr>
<tr>
<td>Bilateral Tubal Ligation</td>
<td>1.5</td>
</tr>
<tr>
<td>Legal induced abortion at 13–15 weeks</td>
<td>1.7</td>
</tr>
<tr>
<td>Pregnancy (beyond 20 weeks)</td>
<td>14.5</td>
</tr>
<tr>
<td>COCs smoker (&gt;1/2ppd) &gt;35yrs old</td>
<td>142.9</td>
</tr>
</tbody>
</table>

Myths about Contraceptives

- “They cause abortions”
- “They cause PID”
- “They cause ectopic pregnancy”
- “You’re too old to go on them”
- “Not having a period each month is unnatural”
- “They cause breast cancer”
- “You’ll gain a lot of weight on them”
- “You’re infertile if you’re on them too long”
- “They cause breast cancer”

PID = pelvic inflammatory disease.

Shared Decision Making

Health Care Provider:
- Treatment options
- risks and benefits
- experience and skill

Patient:
- Personal preferences
- values and concerns
- lifestyle choices

Mutually Acceptable Decision

Benefits of Shared Decision Making

- Increased patient satisfaction
- Better adherence to treatment plans
- Greater treatment engagement
- Better quality decision making
Take Home Points

• Unintended pregnancy remains a major public health problem
• Preventing unintended pregnancy over a reproductive life time is challenging, especially for patients with certain medical conditions
• Keep up-to-date regarding the latest evidence about contraceptive options, safety, efficacy, and side-effect management.
• Utilize the US MEC for patients with chronic medical conditions who need / want effective contraception.
• Use “Shared Decision Making” approach for contraceptive counseling
• Provide adequate Advanced Counseling regarding proper use and potential side effects
• Consider IUDs first-line for most of your reproductive aged patients
• Offer “Quick Start”

“Must-Have” Contraceptive Resources

• “US Medical Eligibility Criteria for Contraceptive Use”
  - www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm
• “Managing Contraception”
• “Contraceptive Technology”

The following medications were discussed in this presentation. The table below lists the generic and trade name(s) of these medications.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper IUD</td>
<td>ParaGard</td>
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<td>Levonorgestrel-releasing IUD</td>
<td>Liletta, Mirena, Skyla</td>
</tr>
<tr>
<td>Ulipristal</td>
<td>Ella</td>
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</tbody>
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