The Potential of Long Acting Reversible Contraception (LARC) in Adolescents…

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ACOG District II ACM Bermuda
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Disclosures

No financial relationships

- ACOG National LARC Work Group
- ACOG District II LARC Work Group
Learning Objectives
At the end of this session, the participant will be able to:

• Describe the potential role of LARC methods in reducing unintended pregnancy and abortion rates at the population level.

• Compare the different IUDs currently available

• Analyze recent data on safety, effectiveness and acceptability of LARC methods in adolescents

• Dispel myths about IUDs and teens:
  • They don’t want them or will like them
  • Insertion is too painful
  • STI risk is too high

“Everything we can do to give women control over their bodies and their fertility enhances their health and also changes the world for the better”

Dr. Malcolm Potts, Cosgrove Memorial Lecture, Annual Clinical Meeting; ACOG, May 2005
Unintended Pregnancies (U.S.)

6.4 Million Pregnancies

- Intended: 51%
- Unintended: 49%
  - Unintended births: 22%
  - Elective abortions: 20%

*Rate highest among women aged 20-24 yrs
*Decline in rate among adolescents aged 15-17 yrs

Cost of Unintended pregnancy

- Estimate of total costs of unintended pregnancy in the U.S.— conservatively estimated U.S. $4.6 billion annually
- Portion of those costs that is due to imperfect adherence to contraceptive methods: 53%, or U.S.$2.5 billion each year.

Trussel et al, Contraception, Feb 2012

REPRODUCTIVE LIFE PLANNING TO REDUCE UNINTENDED PREGNANCY
ACOG Committee Opinion, Obstet Gynecol, 2016

- Approximately one half (51%) of the 6 million pregnancies each year in the United States are unintended
- The 3.4 million unintended pregnancies each year in the United States can result in negative health consequences for women and children and an enormous financial burden to the health care system
- Unintended pregnancies account for most of the 1.1 million abortions that occur annually
- support initiatives that reduce poverty and racial and ethnic health inequities, both of which are major drivers of unintended pregnancy.
“Contraception is not a luxury, it’s preventive care…”

Access to contraception is essential to women's health and livelihood. Though contraception's most vital role is empowering women to take control over their reproductive health, it touches every corner of their lives, from helping with management of other health issues to ensuring women can pursue their educational goals and achieve professionally without interruption from unintended pregnancy.

Acogpresident
Dr. Haywood Brown, June 27, 2017

Use of Specific Methods by females, 15-19 years old

Changes in Use of Long-Acting Reversible Contraceptive Methods Among U.S. Women

- Prevalence of LARC use among U.S. contraceptive females
  - 2.4% in 2002 to 11.6% in 2012

- Most significant increase occurred:
  - Among Hispanic females (8 to 15%)
  - Those who were nulliparous

- Multivariate analysis
  - Poverty status was not associate with LARC use
  - No differences among minority groups in discontinuation of LARC methods

Kavanaugh and Finer, Obstet & Gynecology 2015

LARC Use Among U.S. Women Aged 15-44

- Most recent data:
  - 5-fold increase in LARC use in last decade
  - 1.5% (2002) to 7.2% (2011-13)
  - Percentage of women using LARC highest among 25-35 year-old women
Typical Effectiveness of Contraception

More effective
Less than 1 pregnancy per 100 women in 1 year

Tier 1
- Implants
- IUD
- Female sterilization
- Vasectomy

Tier 2
- Injectables
- LAM
- Pills
- Patch
- Vaginal ring

Tier 3
- Male condoms
- Diaphragm
- Female condoms
- Fertility awareness methods

Tier 4
- Withdrawal
- Spermicides

Adapted from: WHO. Family Planning: A Global Handbook

What is special about LARC and Teens?
Teen Sexual Activity is Similar Across Developed Countries…

Percentage of High School Students Who Ever Had Sexual Intercourse, by Sex,* Grade,* and Race/Ethnicity,* 2015

* M > F; 10th > 9th, 11th > 9th, 12th > 9th, 12th > 10th, 12th > 11th; B > W (Based on t-test analysis, p < 0.05.)
All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.
Note: This graph contains weighted results.

National Youth Risk Behavior Survey, 2015
Percentage of High School Students Who Used Birth Control Pills; an IUD or Implant; or a Shot, Patch, or Birth Control Ring,* by Sex,† Grade,† and Race/Ethnicity,† 2015

*Before last sexual intercourse to prevent pregnancy among students who were currently sexually active
†F > M; 10th > 9th; 11th > 9th; 11th > 10th; 12th > 9th; W > B, W > H (Based on t-test analysis, p < 0.05.)
All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.
Note: This graph contains weighted results.

National Youth Risk Behavior Survey, 2015

Percentage of High School Students Who Used an IUD (e.g., Mirena or Paragard) or Implant (e.g., Implanon or Nexplanon)*

*Before last sexual intercourse to prevent pregnancy among students who were currently sexually active

State Youth Risk Behavior Surveys, 2015
LARC Update

- ACOG Supportive Documents
- EURAS studies
- CHOICE studies
- New IUDs available

ACOG Support

- Reproductive Life Planning to Reduce Unintended Pregnancy: Committee Opinion, in progress, 2017
- Counseling Adolescents about Contraception: Committee Opinion, #710, 2017
CONTENTS
• ACOG Supports Evidence-Based Teen Pregnancy Prevention Programs
• Device Update: FDA Approves Liletta® for Up to Four Years of Continuous Use
• Three New ACOG Committee Opinions on Contraception
• ACOG LARC Program Fall 2017 Exhibiting
• CDC Continuing Education Opportunities: U.S., MEC, U.S. SPR, and Teen Pregnancy Prevention

ACOG Support

• LARC methods should be offered as first-line contraceptive methods and encouraged as options for most women

• LARC methods have few contraindications and initiation protocols should be simplified

• Almost all women are eligible for the implant and IUDs, including young and nulliparous women
Contraceptive CHOICE Project

- Longitudinal, observational study enrolled 9256 women (aged 14-45 years) in St. Louis area

- Objectives
  - Remove barriers of access (provider and cost) to contraception
  - Promote most effective methods of contraception
  - Evaluate use, satisfaction, and continuation of use
  - Reduce unintended pregnancies

- When offered free contraception for 3 years and counseled about all contraceptives, 75% chose LARC
  - >40% of adolescents aged 14-17 years chose the implant
  - >40% of young women aged 18-20 years chose an IUD
Baseline Characteristics

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-17</td>
<td>485</td>
<td>5.2</td>
</tr>
<tr>
<td>18-20</td>
<td>1548</td>
<td>16.7</td>
</tr>
<tr>
<td>21-25</td>
<td>3559</td>
<td>38.5</td>
</tr>
<tr>
<td>26-35</td>
<td>3029</td>
<td>32.7</td>
</tr>
<tr>
<td>36-45</td>
<td>635</td>
<td>6.9</td>
</tr>
</tbody>
</table>

Race

<table>
<thead>
<tr>
<th>Race</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>4660</td>
<td>50.6</td>
</tr>
<tr>
<td>White</td>
<td>3861</td>
<td>41.9</td>
</tr>
<tr>
<td>Other</td>
<td>693</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Choice of LARC Methods in Adolescents

![Graph showing choice of LARC methods in adolescents](chart.png)

- IUD
- Implant
CHOICE PROJECT: Continuation of Teenagers and Young Women

- Prospective Cohort, analyzed 7,472 participants
- **12 month continuation** by age: (14-19; 20-25, over 26)
  - LARC: 81%, 84%, 86%
  - Non-LARC: 44%, 52%, 52%
- **12 month continuation** rate, just teens (14-19), for free!
  - OCs: 46.7%
  - Patch: 40.9%
  - Ring: 31.0%
  - DMPA: 47.3%

12-Month Satisfaction*:
Overall Cohort & By Age

<table>
<thead>
<tr>
<th>Method</th>
<th>Overall (%)</th>
<th>14-19 (%)</th>
<th>20-45 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG-IUS</td>
<td>83.1</td>
<td>77%</td>
<td>84%</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>80.2</td>
<td>72%</td>
<td>81%</td>
</tr>
<tr>
<td>Implant</td>
<td>77.0</td>
<td>74%</td>
<td>78%</td>
</tr>
<tr>
<td>Any LARC</td>
<td>81.2</td>
<td>75%</td>
<td>82%</td>
</tr>
<tr>
<td>DMPA</td>
<td>50.1</td>
<td>43%</td>
<td>52%</td>
</tr>
<tr>
<td>Pills</td>
<td>49.3</td>
<td>46%</td>
<td>50%</td>
</tr>
<tr>
<td>Ring</td>
<td>49.7</td>
<td>31%</td>
<td>52%</td>
</tr>
<tr>
<td>Patch</td>
<td>37.2</td>
<td>35%</td>
<td>38%</td>
</tr>
<tr>
<td>Non-LARC</td>
<td>48.8</td>
<td>42%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Can increase in LARC use change abortion rates at the population level?

- Clinically and statistically significant reduction in abortion rates, repeat abortions, and teenage birth rates
- 4.4-7.5 abortions per 1,000 women in study compared with 13.4 to 17 abortions per 1,000 women overall in St. Louis region compared with 19.6 per 1,000 in U.S.
- Teenage birth rate 6.3 per 1,000 compared with U.S. rate of 34.1 per 1,000.

Peipert et al, CHOICE project, Obstet & Gynecol, Dec 2012
Can CHOICE Help Shape Policy?

Teen Outcomes: CHOICE Compared to U.S.

<table>
<thead>
<tr>
<th></th>
<th>CHOICE Annual Rate*</th>
<th>2008 U.S. Rate*</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy</td>
<td>34.0</td>
<td>158.5</td>
<td>64%</td>
</tr>
<tr>
<td>among sexually active teens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth</td>
<td>19.4</td>
<td>94.0</td>
<td>63%</td>
</tr>
<tr>
<td>Abortion</td>
<td>9.7</td>
<td>41.5</td>
<td>65%</td>
</tr>
</tbody>
</table>

*All rates per 1,000 teens 15-19 years

Secura et al. NEJM 2014
Provision of No-Cost, Long-Acting Contraception and Teenage Pregnancy

Gina M. Secura, Ph.D., M.P.H., Tessa Madden, M.D., M.P.H., Colleen McNicholas, D.O., Jennifer Mullersman, B.S.N., Christina M. Buckel, M.S.W., Qiuhong Zhao, M.S., and Jeffrey F. Peipert, M.D., Ph.D.

Pregnancy Rates: Sexually Experienced U.S. Teens Compared to CHOICE Stratified by Race

<table>
<thead>
<tr>
<th>Race</th>
<th>U.S.</th>
<th>CHOICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>137.0</td>
<td>26.9</td>
</tr>
<tr>
<td>Black</td>
<td>253.0</td>
<td>31.8</td>
</tr>
</tbody>
</table>
European Active Surveillance (EURAS IUD) Studies

61,448 women with a newly inserted IUD were enrolled in six European countries between 2006 and 2012, with baseline and 12 month questionnaires…

• Effectiveness at preventing pregnancy
  • The life-table estimates of the rate of contraceptive failure for the first year of use were 0.07% and 0.63% for LNG IUS and copper IUD, respectively.

• Effectiveness at preventing ectopic pregnancy

• Risk of perforation

Heinemann et al, Contraception, 2015
Long-Acting Reversible Contraception

**LNG-IUS**
- 99% effective
- 20 mcg levonorgestrel/day
- Up to 5 years

**Copper T IUD**
- 99% effective
- Copper ions
- Up to 10 years

**Subdermal Implant**
- 99% effective
- 60 mcg etonogestrel/day
- Up to 3 years
Etonogestrel (ENG) Implant

Core: 40% ethylene vinyl acetate (EVA)
60% etonogestrel (68 mg)

Rate-controlling membrane: (0.06 mm)
100% EVA

Release Rate: 60 µg/day to 70 µg/d initially then decreases to
25 µg/d to 30 µg/d by end of third year

Main Mechanisms of Action

• Primarily inhibits ovulation
  • No ovulation was observed for 30 months
  • Only 2 out of 31 (6.5%) subjects ovulated in year 3, with no resulting pregnancies

• Secondarily increases viscosity of cervical mucus
CHOICE Data: 
Nexplanon, BMI, and Failures

- 1,188 ENG implant users
  - 28% overweight
  - 35% obese

- 3-year cumulative failure rate:
  - Did not vary by BMI status
  - ONE failure in an obese patient in 1st month
  - Transition from OCPs to implant

Discontinuation Rates

<table>
<thead>
<tr>
<th>Reason</th>
<th>Rate</th>
<th>Count (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding irregularities *</td>
<td>11.0%</td>
<td>(104/942)</td>
</tr>
<tr>
<td>Weight gain</td>
<td>2.3%</td>
<td>(22/942)</td>
</tr>
<tr>
<td>Emotional lability</td>
<td>2.3%</td>
<td>(22/942)</td>
</tr>
<tr>
<td>Headache</td>
<td>1.6%</td>
<td>(15/942)</td>
</tr>
<tr>
<td>Acne</td>
<td>1.3%</td>
<td>(12/942)</td>
</tr>
<tr>
<td>Depression</td>
<td>1.0%</td>
<td>(9/942)</td>
</tr>
</tbody>
</table>

* includes frequent, heavy, prolonged, spotting and other patterns of bleeding irregularity
Copper IUD: Pargard

Polyethylene wrapped with copper wire
Approved for use up to 10 years

Mechanisms of action:
- Inhibition of sperm migration and viability
- Change in ovum transport speed
- Damage to or destruction of ovum
- Damage to or destruction of fertilized ovum
- All effects occur before implantation

Highly effective: Ten-year failure rate comparable to female sterilization (1.9 per 100 women)

Comparison of Current Devices

<table>
<thead>
<tr>
<th>IUD</th>
<th>FDA Approved for:</th>
<th>FDA approved Duration</th>
<th>Evidence effectiveness to</th>
<th>Dose of Hormone</th>
<th>Frame size (cm)</th>
<th>Effective ness for duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liletta J7297</td>
<td>All women</td>
<td>4 years</td>
<td>7 years</td>
<td>52mg LNG</td>
<td>3.2 x 3.2</td>
<td>0.6%</td>
</tr>
<tr>
<td>Mirena J7298</td>
<td>Parous women; HMB</td>
<td>5 years</td>
<td>7 years</td>
<td>52mg LNG</td>
<td>3.2 x 3.2</td>
<td>0.5-1.1%</td>
</tr>
<tr>
<td>Kyleena J3490</td>
<td>All women</td>
<td>5 years</td>
<td>5 years</td>
<td>19.5mg LNG</td>
<td>2.8 x 3</td>
<td>0.2%</td>
</tr>
<tr>
<td>Skyla J7301</td>
<td>All women</td>
<td>3 years</td>
<td>3 years</td>
<td>13.5mg LNG</td>
<td>2.8 x 3</td>
<td>0.9%</td>
</tr>
<tr>
<td>Paragard J7300</td>
<td>All women</td>
<td>10 years</td>
<td>15-20 years</td>
<td>Copper ions</td>
<td>3.2 x 3.6</td>
<td>2.2%</td>
</tr>
</tbody>
</table>
Does Size/Dose Matter?
Mirena/Kyleena/Skyla

- Duration of effectiveness: 7 – 5 – 3 years
- Suppression of menses: Indication for HMB
- Amenorrhea rate at end of year 1 – year 3 – year 5
  - Mirena: 20%
  - Kyleena: 12% - 20% - 23%
  - Skyla: 6% - 12 %
    - release rate of 14mcg/day after 24 days;
    - down to 5 mcg/day after 3 years
- Hormonal side effects – not able to detect a difference

Dispelling Myths of LARC and Teens

- Demand & Acceptability
  - They don’t want them or won’t like them if started
  - Side effects
    - Weight interaction: effectiveness or side effect
    - Bleeding pattern intolerable
- Too painful to insert
- Increase risk of STI/PID/future infertility
Pain and IUD insertion

- Meta-analysis 2014
- Cochrane Review 2015

- Reducing Pain During IUD Insertion: A Randomized Controlled Trial in Adolescents and Young Women,
  Akers et al, Obstet Gynecol, Oct 2017

Pain and IUD insertion

- 95 teens and young nulliparous women
  - 20% were age 14 - 17
- Ibuprofen 800 mg PO at least 20 minutes before insertion
- Used the smallest frame IUD (Skyla)
- Randomized to sham or 10cc 1% lidocaine paracervical block
  Akers et al, Obstet Gynecol, Oct 2017
Lidocaine paracervical block during IUD insertion in adolescents

IUD Initiation and STIs
College Recommendations

Committee Opinion # 642- October 2015
Increasing Access to Contraceptive Implants and Intrauterine Devices
to Reduce Unintended Pregnancy

Box 2. Best Practices for Long-Acting Reversible Contraception Insertion

• Provide long-acting reversible contraception (LARC) methods the same day as
  requested, whenever possible, if pregnancy can reasonably be excluded.

• Offer LARC methods at the time of delivery, abortion, or dilation and
  curettage for miscarriage.

• Screen for sexually transmitted infections at the time of intrauterine device
  (IUD) insertion; if the screening test result is positive, treat the infection
  without removal of the IUD.

• Offer the copper IUD as the most effective method of emergency
  contraception.

Committee on Gynecologic Practice
Long-Acting Reversible Contraception Working Group

US SPR

BOX 1. How To Be Reasonably Certain that a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs
of pregnancy and meets any one of the following criteria:
• is ≤ 7 days after the start of normal menses
• has not had sexual intercourse since the start of last
  normal menses
• has been correctly and consistently using a reliable
  method of contraception
• is ≤ 7 days after spontaneous or induced abortion
• is within 4 weeks postpartum
• is fully or nearly fully breastfeeding (exclusively
  breastfeeding or the vast majority [≥85%] of feeds are
  breastfeeds),* amenorrheic, and <6 months
  postpartum

*Source: Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea
Method (LAM): a postpartum introductory family planning method with
Prevalence of Dual Protection among Female Teens in the U.S.

<table>
<thead>
<tr>
<th>Source</th>
<th>Population</th>
<th>Dual Method (at last sex) (hormonal and condom)</th>
<th>Consistent Condom Use (last 4 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSFG, 2006-2008</td>
<td>Ages 15-19, sexually active unmarried females</td>
<td>20.8%</td>
<td>51.6%</td>
</tr>
</tbody>
</table>


Percentage of High School Students Who Used a Condom,* by Sex,† Grade,† and Race/Ethnicity,‡ 2015

*During last sexual intercourse among students who were currently sexually active
†M > F; 9th > 12th, 10th > 12th; B > H (Based on t-test analysis, p < 0.05.)
‡All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.

Note: This graph contains weighted results.

National Youth Risk Behavior Survey, 2015
Percentage of High School Students Who Used Both a Condom During and Birth Control Pills; an IUD or Implant; or a Shot, Patch, or Birth Control Ring Before Last Sexual Intercourse,* by Sex,† Grade,† and Race/Ethnicity,† 2015

*To prevent STD and pregnancy among students who were currently sexually active
†F > M; 11th > 9th, 11th > 12th; W > B, W > H (Based on t-test analysis, p < 0.05.)
All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.
Note: This graph contains weighted results.

Fertility Rates in Parous Women After Discontinuation of Contraceptive

Non-surgical Management of Heavy Menstrual Bleeding

- Systematic Review
- 26 articles met inclusion criteria, only RCTs included
- Interventions: LNG IUS, OCPs, extended cycle oral PG, transeamic acid, and NSAIDs.
- Outcomes: mean blood loss, QOL, pain, sexual health, additional treatments, adverse events, patient satisfaction
- Results:
  - Reduction of mean blood loss: recommend IUS over all other treatments (Clinical Practice Guideline Statement)
  - Other outcomes: unable to make recommendations
  

LNG IUD to treat bleeding disorders in adolescents

- Series of 13 adolescents with HMB due to bleeding disorders (low VW activity, VW disease, factor 5 or 7 deficiencies)
- Prior hormonal and hemostatic therapy ineffective
- LNG IUD inserted with anesthesia
- Significant improvement in HMB
- 60% achieved amenorrhea

Adeyemi-Fowode et al, J Pediatr Adolesc Gynecol Aug 2017
Intrauterine delivery of Progestins in the prevention of gynecological disease

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<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Heavy menstrual bleeding</td>
<td>Ovulatory or anovulatory DUB, PCOS</td>
</tr>
<tr>
<td></td>
<td>Intramural or subserous fibroids</td>
</tr>
<tr>
<td></td>
<td>Adenomyosis and endometriosis</td>
</tr>
<tr>
<td></td>
<td>Disorders of hemostasis</td>
</tr>
<tr>
<td></td>
<td>Menopause transition</td>
</tr>
<tr>
<td>Pain</td>
<td>Primary dysmenorrhoea</td>
</tr>
<tr>
<td></td>
<td>Recurrent endometriosis</td>
</tr>
<tr>
<td></td>
<td>Adenomyosis</td>
</tr>
<tr>
<td>Infertility</td>
<td>Endometriosis</td>
</tr>
<tr>
<td></td>
<td>Uterine fibroids</td>
</tr>
<tr>
<td>Prevention of cancer</td>
<td>Endometrial hyperplasia and adenocarcinoma</td>
</tr>
<tr>
<td></td>
<td>Prevention of cervical cancer</td>
</tr>
</tbody>
</table>

Take-Home Messages

- Reproductive Autonomy:
  - Education/knowledge/access is KEY
  - Eliminating old habits

- LARC Methods are THE most effective and most acceptable methods for teenagers

- Increased use of LARC will…
  - Reduce incidence of many benign gyn conditions
  - Not increase STI acquisition/PID/Infertility
  - Decrease abortions and unintended pregnancies
  - Decrease racial/SES disparities
Resources for efficient and evidence based LARC practice

- CHOICE project tools are on their website
  - Patient education
  - Scripts for front desk

- ACOG National LARC Program
  - Bedsider
  - CDC and MEC links

- District II LARC Program
  - Coding/billing/reimbursement guide
  - Post-partum implementation

How you can use the US SPR

U.S. Selected Practice Recommendations for Contraceptive Use, 2013
Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd edition
2016 U.S. MEC and SPR App

Online access

http://wwwdev.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm