

Educational presentation on Bayer levonorgestrel-releasing intrauterine systems (LNG-IUS)

Unintended Pregnancy and Long Acting Reversible Contraception (LARC) Methods

Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

This presentation will refer to Bayer LNG-IUS when information applies to Mirena, Kyleena, and Skyla

**Please see Important Safety Information on slides 3-14 of this presentation.
For important information about Mirena[®], Kyleena[®], and Skyla[®] please see the Full
Prescribing Information for each product available at this presentation.**

Indications and Important Safety Information about Bayer LNG-IUS

Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5 mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

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Bayer LNG-IUS Indications

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg is indicated for:

- Prevention of pregnancy for up to 5 years.
- The treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.
- Mirena should be replaced after 5 years if continued use is desired.

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg is indicated for:

- Prevention of pregnancy for up to 5 years.
- Replace the system after 5 years if continued use is desired

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg is indicated for:

- Prevention of pregnancy for up to 3 years.
- Replace the system after 3 years if continued use is desired.

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Important Safety Information

Who is not appropriate for Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing system) 13.5mg

- **Use of Mirena, Kyleena, or Skyla is contraindicated in women with:**
 - Known or suspected pregnancy and cannot be used for post-coital contraception
 - Congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity
 - Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past
 - Known or suspected uterine or cervical neoplasia
 - Liver disease, including tumors
 - Untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled

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Important Safety Information (continued)

Who is not appropriate for Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing system) 13.5mg

- **Use of Mirena, Kyleena, or Skyla is contraindicated in women with (cont.):**
 - Untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled
 - Postpartum endometritis or infected abortion in the past 3 months
 - Unexplained uterine bleeding
 - Current IUD
 - Acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy)
 - Conditions increasing susceptibility to pelvic infection
 - Hypersensitivity to any component of Mirena, Kyleena, or Skyla

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Important Safety Information (continued)

Clinical considerations for use and removal of Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing system) 13.5mg

- Use Mirena, Kyleena, or Skyla with caution after careful assessment in patients with:
 - Coagulopathy or taking anticoagulants
 - Migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia
 - Exceptionally severe headache
 - Marked increase of blood pressure
 - Severe arterial disease such as stroke or myocardial infarction
- Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice
- If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus
- If Mirena, Kyleena, or Skyla is displaced (e.g., expelled or perforated the uterus), remove it
- Kyleena and Skyla can be safely scanned with MRI only under specific conditions.

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Important Safety Information (continued)

Pregnancy related risks with Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing system) 13.5mg

- If pregnancy should occur with Mirena, Kyleena, or Skyla in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor
- Removal or manipulation may result in pregnancy loss
- Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Mirena, Kyleena, or Skyla
- Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding
- Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility
- Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy

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Important Safety Information (continued)

Educate her about PID

- Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing system) 13.5mg are contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy
- IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion
- Promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores.
- Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death
- PID is often associated with sexually transmitted infections (STIs); Mirena, Kyleena, and Skyla do not protect against STIs, including HIV
- PID may be asymptomatic but still result in tubal damage and its sequelae.

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Important Safety Information (continued)

Educate her about PID (continued):

In clinical trials with:

- **Mirena**[®] (levonorgestrel-releasing intrauterine system) 52mg – upper genital infections, including PID, occurred more frequently within the first year. In a clinical trial with other IUDs and a clinical trial with an IUD similar to Mirena, the highest rate occurred within the first month after insertion
- **Kyleena**[®] (levonorgestrel-releasing intrauterine system) 19.5mg – PID occurred more frequently within the first year and most often within the first month after insertion
- **Skyla**[®] (levonorgestrel-releasing intrauterine system) 13.5mg – PID occurred more frequently within the first year and most often within the first month after insertion

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Important Safety Information (continued)

Expect changes in bleeding patterns with Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

- Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months
- Periods may become shorter and/or lighter thereafter
- Cycles may remain irregular, become infrequent, or even cease
- Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation
- Because irregular bleeding/spotting is common during the first months of Mirena, Kyleena, or Skyla use, exclude endometrial pathology (polyps or cancer) prior to the insertion of the IUD in women with persistent or uncharacteristic bleeding.
- If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

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Important Safety Information (continued)

Be aware of other serious complications and most common adverse reactions

- Some serious complications with IUDs like Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, and Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg are sepsis, perforation, and expulsion.
- Severe infection, or sepsis, including Group A streptococcal sepsis (GAS) have been reported following insertion of a LNG-releasing IUS. Aseptic technique during insertion of the IUD is essential in order to minimize serious infections, such as GAS.

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Important Safety Information (continued)

Be aware of other serious complications and most common adverse reactions (continued)

- Perforation (total or partial, including penetration/embedment of Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, or Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later.
- Perforation may reduce contraceptive efficacy. If perforation occurs, locate and remove the intrauterine system. Surgery may be required.
- Delayed detection or removal of the intrauterine system in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera.
- The risk of perforation may be increased if inserted when the uterus is not completely involuted or fixed retroverted.

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Important Safety Information (continued)

Be aware of other serious complications and most common adverse reactions (cont)

- A postmarketing safety study over a 1-year observational period reported that lactation at the time of insertion of an IUS/IUD was associated with an increased risk of perforation.
 - In this study, for Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg users, the incidence of uterine perforation was reported as 6.3 per 1,000 insertions for lactating women, compared to 1.0 per 1,000 insertions for non-lactating women.
- Partial or complete expulsion of Mirena, Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg, or Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg may occur resulting in the loss of contraceptive protection.
- Delay insertion a minimum of six weeks or until uterine involution is complete following a delivery or a second trimester abortion.
- Remove a partially expelled IUD. If expulsion has occurred, a new Mirena, Kyleena or Skyla can be inserted anytime the provider can be reasonably certain the woman is not pregnant.
- Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts.

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Important Safety Information (continued)

Be aware of other serious complications and most common adverse reactions (continued)

- In clinical trials with:
 - Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg – adverse reactions reported in ≥5% users are alterations of menstrual bleeding patterns [including unscheduled uterine bleeding (31.9%), decreased uterine bleeding (23.4%), increased scheduled uterine bleeding (11.9%), and female genital tract bleeding (3.5%)], abdominal/pelvic pain (22.6%), amenorrhea (18.4%), headache/migraine (16.3%), genital discharge (14.9%), vulvovaginitis (10.5%), breast pain (8.5%), back pain (7.9%), benign ovarian cyst and associated complications (7.5%), acne (6.8%), depression/depressive mood (6.4%) and dysmenorrhea (6.4%)
 - Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5 mg – the most common adverse reactions (≥5%) were vulvovaginitis (24%), ovarian cyst (22%), abdominal/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%)
 - Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg – the most common adverse reactions (≥5% users) were vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%), and nausea (5.5%).
- Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of Mirena, Kyleena, or Skyla and then yearly or more often if clinically indicated

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Outline

Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5 mg

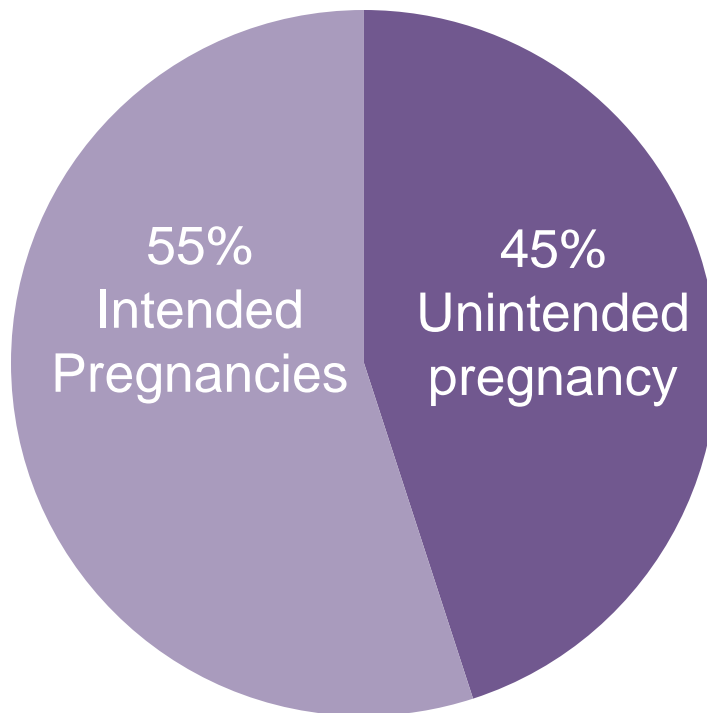
Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

- **Unintended Pregnancy**
- **LARC**
- **Agency Statements**

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Unintended pregnancy

The rate of unintended pregnancy in the United States in 2011, was estimated to be 45% (2.8 Million pregnancies were unintended)



As calculated from two nationally representative sources:

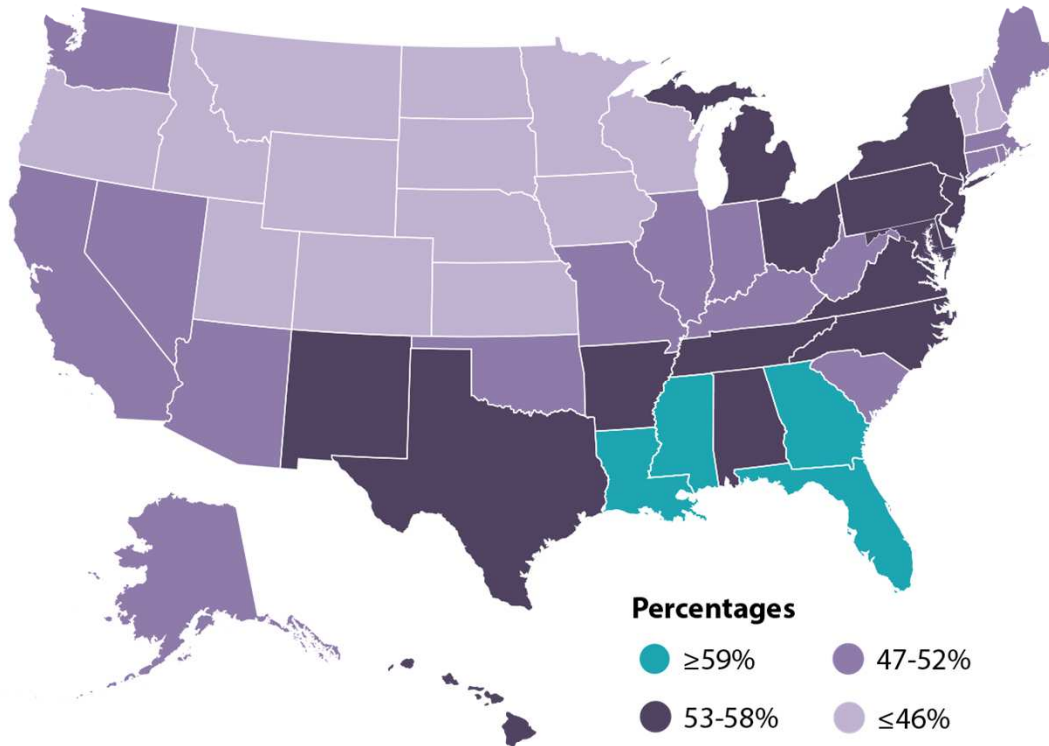
- The National Survey of Family Growth (NSFG) which evaluated 1975 pregnancies that ended between 2009 and 2013, with 2011 as central reference year,
- Abortion Patient Survey, a national survey of patients who had abortions conducted by the Guttmacher Institute from a representative sample of 9,493 women who had abortions in the USA

Both data sets were weighted to represent all pregnancies in the USA in 2011

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Unintended pregnancies vary geographically

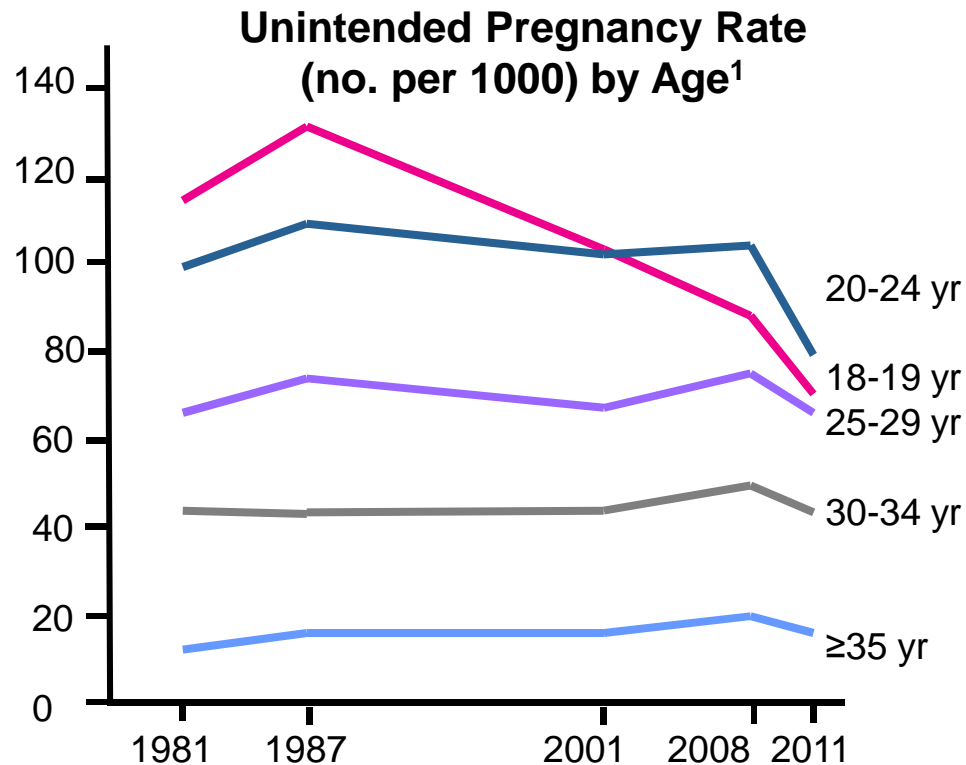
US Unintended Pregnancy Rates
by State (data from 2010)¹



State-level estimates for unintended pregnancies were based on data from the Pregnancy Risk Assessment Monitoring System (PRAMS) or similar survey programs for states not participating in PRAMS. Multivariate linear regression models were used to determine estimates for states without PRAMS or PRAMS-like survey data: Arizona, District of Columbia, Indiana, Kansas, Nevada, New Hampshire, South Dakota, Montana, and North Dakota.

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Decline in Unintended Pregnancies National Survey of Family Growth (NSFG)



Unintended pregnancy rates have declined from 2008-2011

- Decline seen across all age, income, and ethnicity
- First substantial decline since 1981

Based on data from NSFG surveys conducted in reproductive aged women:
N=7,969 (1982), N=8,450 (1988), N=7,643 (2002), N=12,279 (2006-2010),
N=5,601 (2011-2013)

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Pregnancy Related Risks

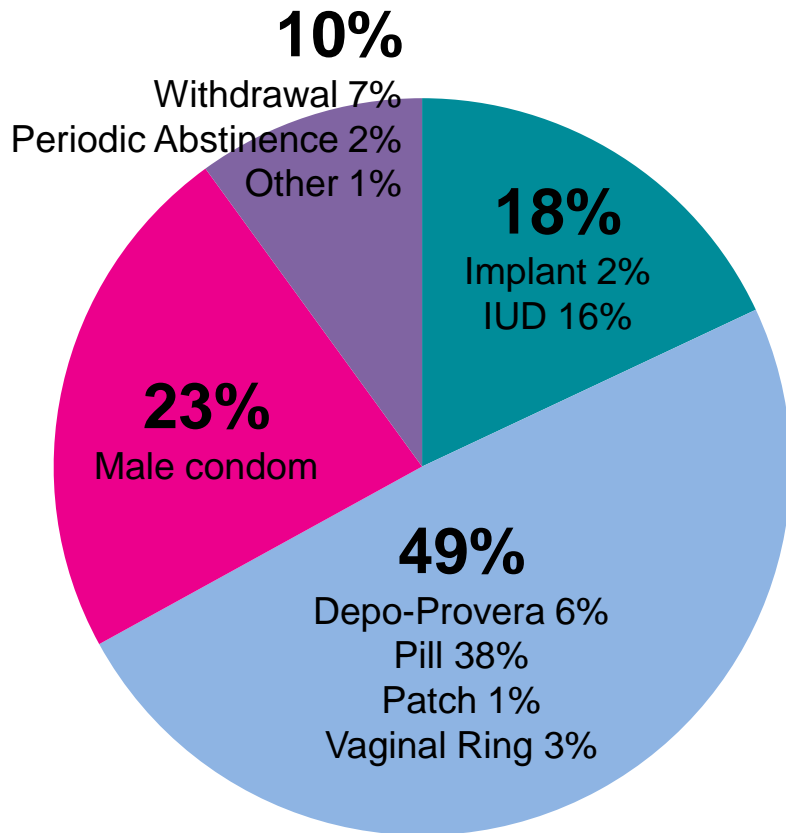
Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg, **Kyleena**[®] (levonorgestrel-releasing intrauterine system) 19.5 mg, **Skyla**[®] (levonorgestrel-releasing intrauterine system) 13.5 mg

- If pregnancy should occur with Mirena, Kyleena, or Skyla in place, remove it because leaving it place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss
 - 5-year cumulative rate of pregnancy : 0.7% (Mirena), 1.45% (Kyleena)
 - 3-year cumulative rate of pregnancy: 0.9% (Skyla)
- Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Mirena, Kyleena or Skyla.
- Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding
- Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy

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Reversible Contraceptive Method Use

2011-2013 National Survey of Family Growth, women currently using contraception, aged 18-45 (N=23.7 Million)



- Multiple reasons may explain the decline in unintended pregnancy, including the type of contraceptive method being used¹
- Based on analysis of the 2011-2013 NSFG², among women currently using contraceptives, aged 18-45 the most commonly used methods are:
 - Pill 38%
 - Male Condom 23%
 - Intrauterine Device (IUD) 16%

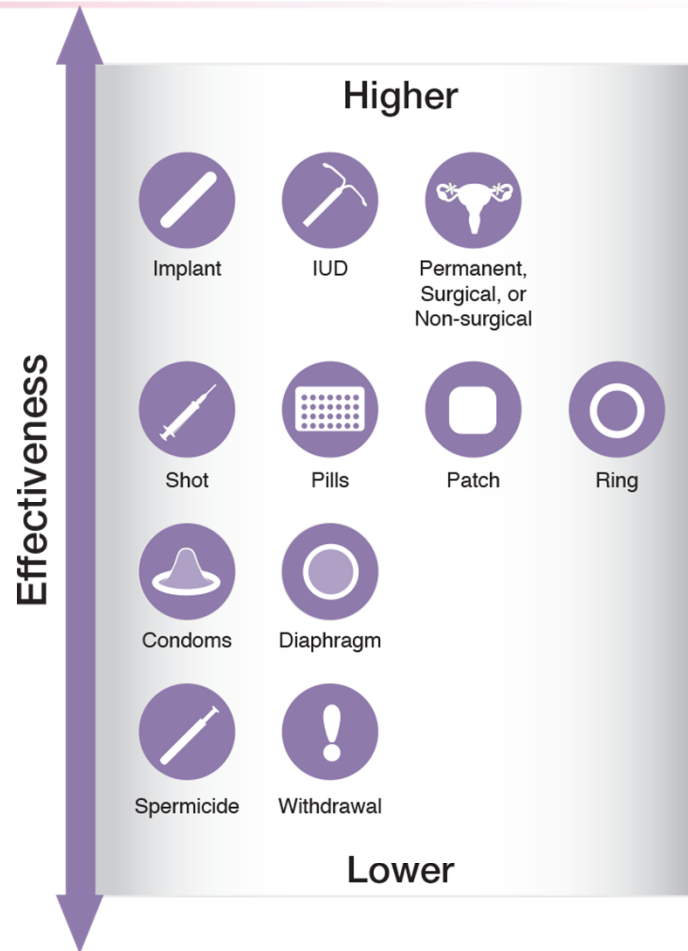
1. Finer and Zolna, M.P.H. N Engl J Med 2016; 374:843-852. 2. Bayer Data on File; Secondary analysis of the 2011-2013 NSFG. Based on surveys of n=5,010 women aged 18-45, extrapolated to 23.7Million . Women were excluded from the analysis if they were currently pregnant, trying to conceive, postpartum, abstaining from sex, or sterile. Morning after pill was excluded. Other includes sponge, diaphragm, or spermicide (suppository , insert, jelly, or cream.)

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Contraceptive Efficacy

Generally the less you have to do, the more effective the birth control method tends to be¹

The American College of Obstetricians and Gynecologists (ACOG) states that **implants and IUDs, called long acting reversible contraceptives (LARC), are the most effective reversible contraceptive methods²**



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[1] World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP) INFO project. *Family Planning: A Global Handbook for Providers (2011 Update)*. Baltimore and Geneva: CCP and WHO; 2011.[2] ACOG Practice Bulletin 186 Obstet Gynecol. 2017 Nov;130(5):e251-e269.

FDA Approved LARC Options



Copper IUD

ParaGard® (Intrauterine copper contraceptive)

- Effective for up to 10 years



Progestin-only IUD

Mirena® (levonorgestrel-releasing intrauterine system) 52mg, Liletta® (levonorgestrel-releasing intrauterine system) 52mg, Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg, Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

- Effective for up to 3-5 years;
- **Mirena** has secondary indication for treatment of heavy menstrual bleeding in women who choose an IUD for contraception



Implants

Nexplanon® (etonogestrel implant) 68mg

- Effective for up to 3 years

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Agency Statements

ACOG Practice Bulletin: Implants & IUDs¹

- “Intrauterine devices and implants, also called long-acting reversible contraceptives (LARCs), are the **most effective** reversible contraceptives”

CDC/OPA:² Providing Quality Family Planning Services

- “Providers are encouraged to present information on potential reversible methods of contraception by using a **tiered approach** (i.e., presenting information on the most effective methods first, before presenting information on less effective methods)”

ACOG Committee Opinion: Increasing access to LARC to reduce Unintended Pregnancy³

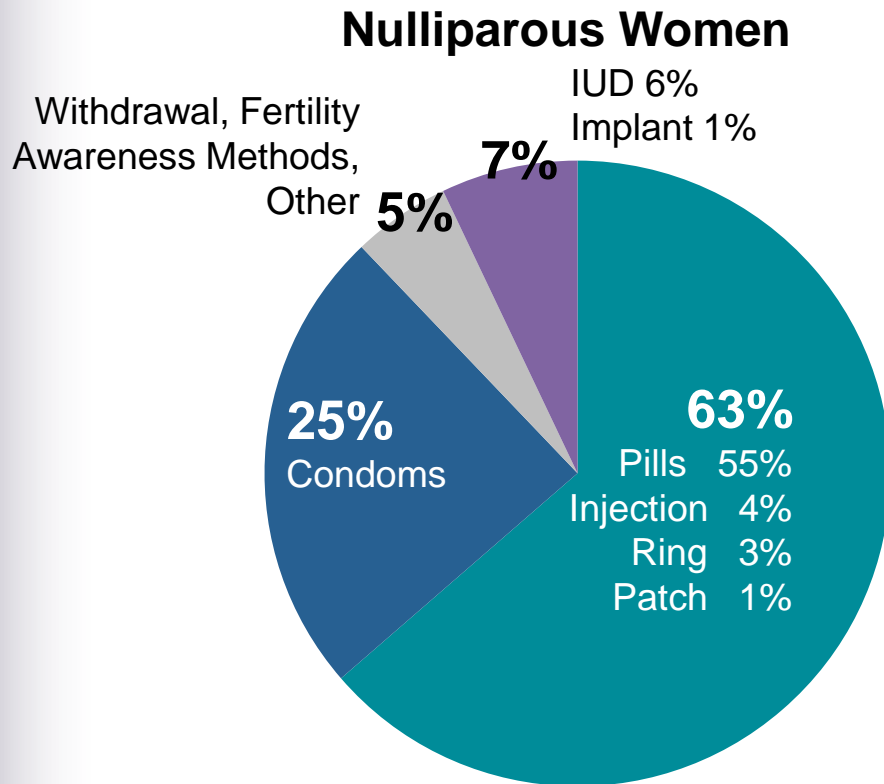
- “Encourage consideration of implants and IUDs for all appropriate candidates, including **nulliparous** women...”

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[1] ACOG Practice Bulletin No. 186: Obstet Gynecol. 2017 Nov;130(5):e251-e269. [2] Gavin L et al. MMWR Recomm Rep 2014. Apr 25 (63) RR-04: 1-54; updated in March 11, 2016 / 65(9);231–234 [3] ACOG Committee Opinion No 642, Obstet Gynecol. 2015 Oct;126(4):e44-8

Reversible Contraceptive Method Usage by Parity

Analysis of 2011-2013 NSFG, women currently using contraception, aged 18-45 (extrapolated to millions)



Extrapolated to n=10,825,139

Bayer Data on File; Secondary analysis of the 2011-2013 NSFG, based on surveys of 5,010 women aged 18-45. Women were excluded from the analysis if they were currently pregnant, trying to conceive, postpartum, abstaining from sex, or sterile. Morning after pill was excluded. Other includes sponge, diaphragm, or spermicide (suppository, insert, jelly, or cream.)

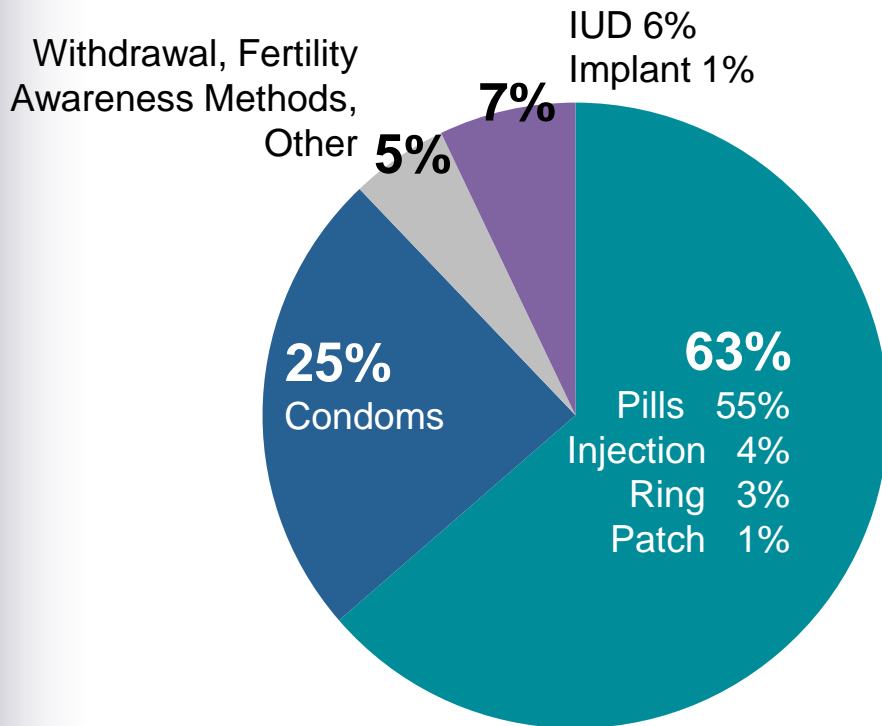
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1. Bayer HealthCare Pharmaceuticals, Data on File 2. 2011-2013 NSFG Pregnancy Data File (2011_2013_FemPreg.dat); Centers for Disease Control and Prevention, National Center for Health Statistics. Public use data file documentation 2011-2013 National Survey of Family Growth: users guide, Hyattsville, MD 2011

Reversible Contraceptive Method Usage by Parity

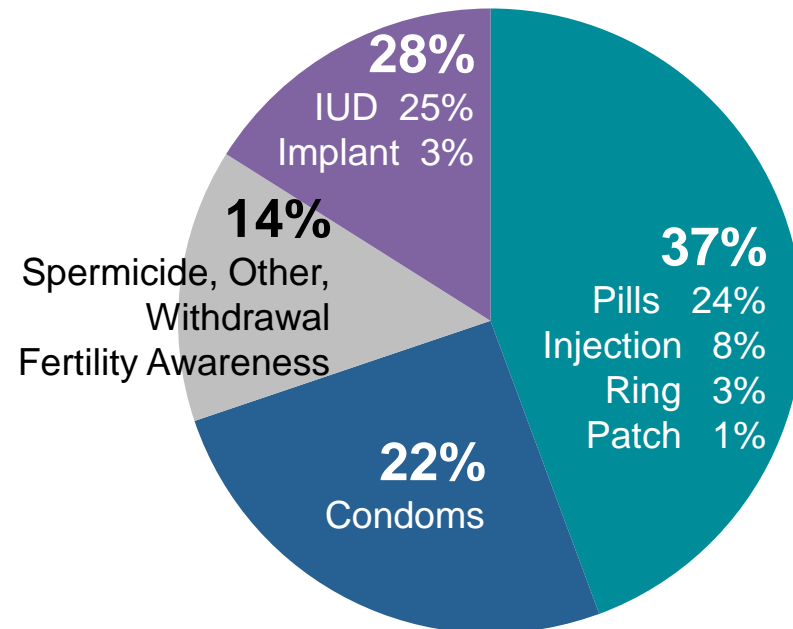
Analysis of 2011-2013 NSFG, women currently using contraception aged 18-45 (extrapolated to Millions)

Nulliparous Women



Extrapolated to N=10,825,139

Parous Women



Extrapolated to N=12,892,162

Bayer Data on File; Secondary analysis of the 2011-2013 NSFG, based on surveys of 5,010 women aged 18-45. Women were excluded from the analysis if they were currently pregnant, trying to conceive, postpartum, abstaining from sex, or sterile. Morning after pill was excluded. Other includes sponge, diaphragm, or spermicide (suppository, insert, jelly, or cream.)

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1. Bayer HealthCare Pharmaceuticals, Data on File 2. 2011-2013 NSFG Pregnancy Data File (2011_2013_FemPreg.dat); Centers for Disease Control and Prevention, National Center for Health Statistics. Public use data file documentation 2011-2013 National Survey of Family Growth: users guide, Hyattsville, MD 2011

Reducing Barriers and Increasing Access to LARC Methods

ACOG Recommendations to Reduce Barriers and Increase Access to LARC Methods¹

- For all women at risk of unintended pregnancy, OB-GYNs should provide counseling on all contraceptive options, including implants and IUDs
- Encourage consideration of implants and IUDs for all appropriate candidates, including nulliparous women and women of reproductive age
- Adopt best practices for LARC insertion
- Advocate for coverage and appropriate payment and reimbursement for every contraceptive method by all payers in all clinically appropriate circumstances
- Become familiar with and support local, state (including Medicaid), federal, and private programs that improve affordability of all contraceptive methods

National Quality Forum: 2904 Contraceptive Care - Access to LARC²

- The National Quality Form endorsed a measure of contraceptive care measuring LARC Access
- It is an access measure intended to identify situations in which women do not have access to LARC

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1. ACOG Committee Opinion No. 642. *Obstet Gynecol.* 2015;126(4):e44-e48.

2. National Quality Forum. Perinatal and Reproductive Health 2015-2016 Final Report: December 2016

Summary

- An analysis of the NSFG showed a decline in the percentage of unintended pregnancy, with 45% of pregnancies being unintended in 2011¹
- ACOG states that **LARC** methods (IUDs and Implants) are **the most effective** reversible contraception methods²
- ACOG has recommended ways to **reduce barriers and increase access** to LARC³
- The CDC and OPA (Office of Public Affairs) **encourages use of a tiered approach** during contraceptive counseling⁴
- **The NQF (National Quality Forum) endorsed a quality measure on contraceptive care, specifically looking at access to LARC methods**⁵

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[1] *Finer and Zolna, M.P.H. N Engl J Med 2016; 374:843-852* [2] *ACOG Practice Bulletin 186 Obstet Gynecol. 2017 Nov;130(5):e251-e269* [3] *ACOG Committee Opinion No. 642. Obstet Gynecol. 2015;126(4):e44-e48.* [4] *Gavin L et al. MMWR Recomm Rep 2014. Apr 25 (63) RR-04: 1-54; updated in March 11, 2016 / 65(9);231–234* [5] *National Quality Forum. Perinatal and Reproductive Health 2015-2016 Final Report: December 2016*

Prescribing Information

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg

https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg

http://labeling.bayerhealthcare.com/html/products/pi/Kyleena_PI.pdf

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

http://labeling.bayerhealthcare.com/html/products/pi/Skyla_PI.pdf

**Please see Important Safety Information on slides 3-14 of this presentation.
For important information about Mirena[®], Kyleena[®], and Skyla[®] please see the Full
Prescribing Information for each product available at this presentation.**