Long Acting Reversible Contraceptives (LARC) Get it and forget it!

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Conflict of Interest

- I have no financial interests to disclose.
- I will be discussing off label uses of medication.



Roadmap

- Teens and sex and pregnancy in Ohio/US
- Access barriers (provider focused)
- Introduction to LARC
- Dispelling Myths
- Local efforts at Nationwide Children's



Teens and Sex in Ohio?



- In 2013, 43% of high school teens reported having sexual intercourse
- Among currently sexually active girls (35%)
 - 54% did not use a condom at last sex
 - 56% did not use birth control pills, patch, shot, ring, implant or IUD at last sex

CDC. Youth Risk Behavior Surveillance Survey— United States, 2013



Teen Birth Characteristics (<18 years) US 2000-2005

- 79% pregnancy is unintended
- Of those not trying to become pregnant
 - 48% were not using contraceptives at time of conception
 - 52% were using contraceptives



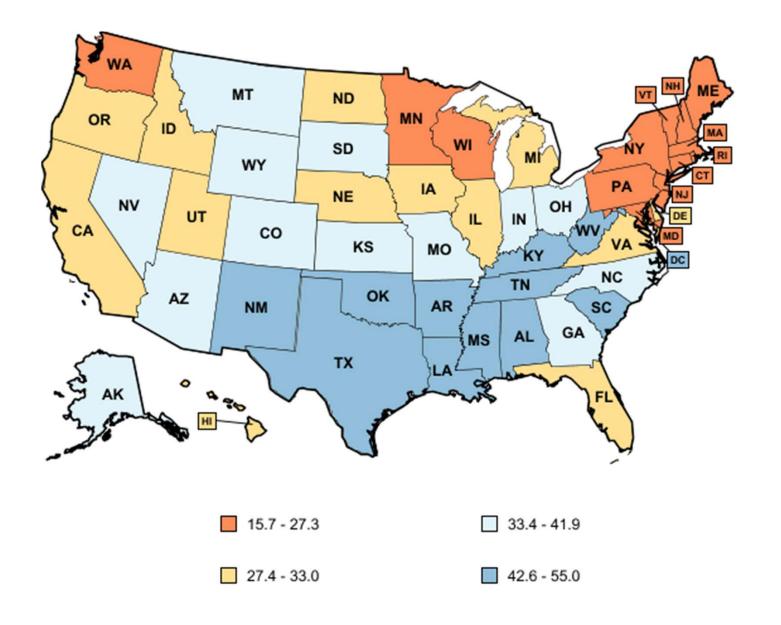
Teen pregnancy

- Is cited as primary reason by 30% female high school drop outs
- Is a risk factor for prematurity and infant mortality and other adverse health, educational, and social outcomes for child and mom
- Public cost to U.S. taxpayers/year: >\$11 billion
- 31% end in abortion

http://www.thenationalcampaign.org/resources/pdf/teen-preg-hs-dropout.pdf

K Kost and S Henshaw. U.S. Teenage Pregnancies, Births and Abortions, 2008: National Trends by Age, Race and Ethnicity. Guttmacher Institute. 2012

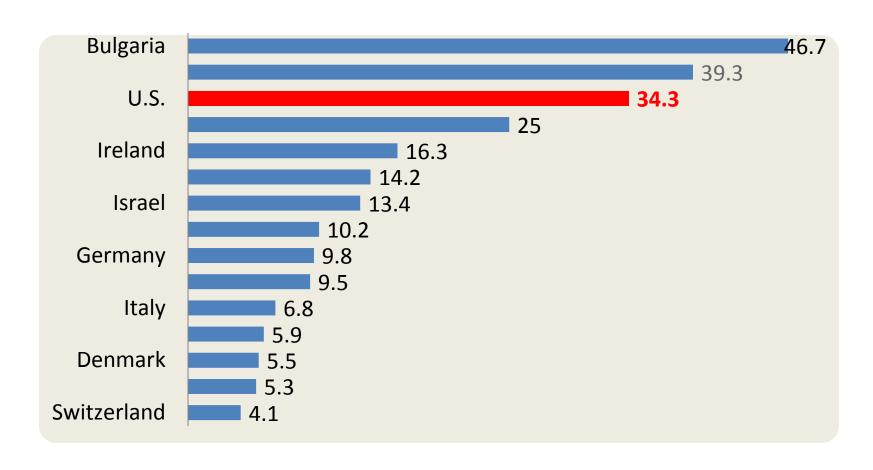




Teen Birth Rate per 1,000 Population Ages 15-19, 2010

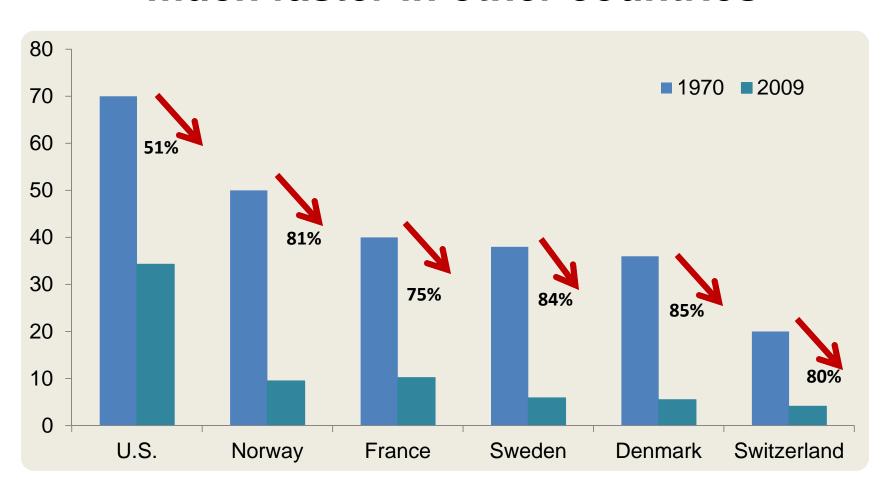


U.S. teen birth rate one of highest among industrialized countries



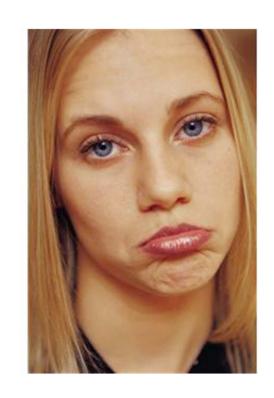
Teen birth rates internationally, per 1,000 girls aged 15-19 years, 2009 and 2010 SOURCE: UN Demographic Yearbook (all data for 2009, except US 2010 preliminary data). Slide attribution: http://www.cdc.gov/winnablebattles/teenpregnancy/index.html

Rates are far lower <u>and</u> are decreasing much faster in other countries



Access Barriers

- Only 55% sexually active high school girls received a method of birth control or a prescription from a health-care provider in the preceding year
- Difficulty obtaining contraception more than doubled an adolescent's risk of unintended birth
- Pediatricians are less likely than their OB/GYN and family practice colleagues to provide reproductive health services to teens



LARC Access Barriers

- Providers may have misconceptions about LARC methods
- Providers may be uncertain how to counsel
- LARC may not be available
- Route to obtaining a LARC unclear
- Concerns about confidentiality



Access Opportunities

- Pediatricians provide majority of primary care visits
- Most report it would be helpful to discuss their sex life with a doctor they trusted
- More positive perception of their provider when sensitive topics are discussed and most want to have more time alone with their primary care provider



Freed GL, et al. *J Pediatr*. 2010, Schuster MA, et al. *Arch Pediatr Adolesc Med*. 1996. Brown JD, Wissow LS. *J Adolesc Health*. 2009

ROELEPHANTOM



History of intrauterine contraception

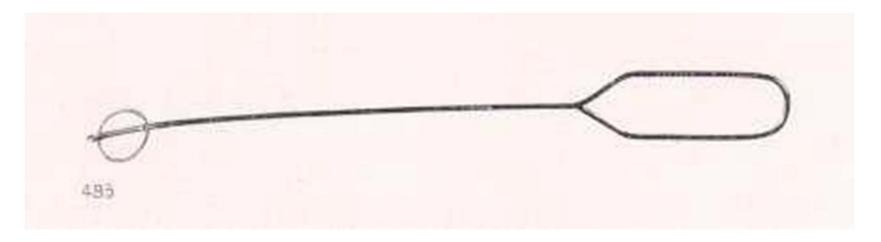
- Stories exist about placing a pebble in a camel's uterus before crossing the Sahara
- Interuterine devices are noted at the end of the 19th century (cervico-uterine or wishbone pessary)

Sonnendecker et al. SAMT 1987.



History of intrauterine contraception

- First recorded paper on an **intrauterine** device was published in Germany by Dr. Richter in 1909 (insertions of a ring made of silkworm gut), followed by innovations in 1920s
- Fall from favor until wave of interest 1960s



Dalkon Shield® experience

- Introduced in 1971 by DH Robbins
 - Prior to devices being regulated by FDA
 - Design flaws
 - Problems with PID, septic maternal death, infertility
- Bankruptcy of manufacturer and recall of all devices
- Public and health professionals lose faith in intrauterine devices



Norplant®

- 6 capsule levonorgestrel implant system
- FDA approved 1990
- Marketed by Wyeth Pharmaceuticals
- Voluntarily removed from US market in 2002 amidst controversy:
 - settlements regarding side-effects disclosure (bleeding, headache, nausea, and depression)
 - concerns about compromised effectiveness of certain lots (never substantiated)

US teen women who used a LARC method at last sex (2006-2008)

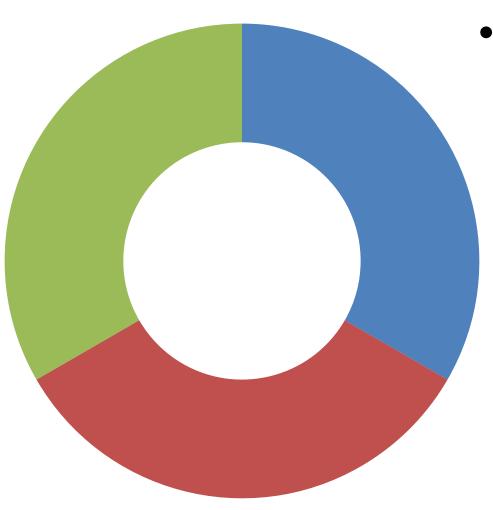


MMWR Morb Mortal Wkly Rep. 2011;60:414-420 Finer et al. Fertility and Sterility, 2012.



Barriers





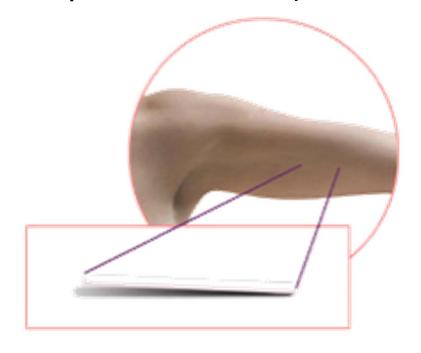
Study rationale:

- Eliminate access and cost barriers
- Provide brief counseling that focuses on efficacy
- Trust each woman to pick the best method for her unique needs

What we learned about LARC...

- CHOICE adolescents overwhelmingly picked LARC
 - 69% of 14-17 year olds (63% implant, 37% IUD)
 - 61% of 18-20 year olds (29% implant, 71% IUD)





What we learned about LARC...

- Highest rates of satisfaction and continuation of all reversible methods!!!
 - 81% continuation rate at 1 year vs. 53% discontinue non-LARC method
 - Same rate of continuation as older women



What we learned about LARC...

- 20 times more effective than combined hormonal methods
- Teen birth in CHOICE was 1/5 the national teen birth rate
 - 6.3/1,000 vs. 34.3/1,000
- Abortion rates in CHOICE were less than half the regional and national rates

Winner, B, et al. NEJM 2012 Peipert, J, et al. Obstetrics and Gynecology 2012

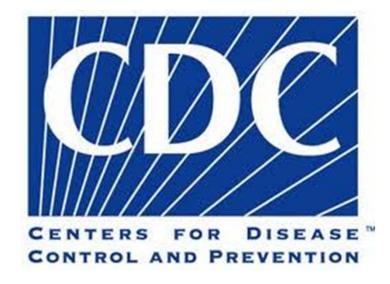
Endorsements/ Practice recommendations

2010 United States Medical Eligibility Criteria for Contraceptive Use for women < 20 years

Implant: No restrictions

IUD: Advantages generally outweigh proven or

theoretical risks



Endorsements/ Practice Recommendations ACOG Committee Opinion (October 2012)

LARC are safe and appropriate contraceptive methods for most women and adolescents

Providers concerns about LARC use by adolescents are a barrier to access



Endorsements/ Practice Recommendations

Society of Family Planning Clinical Guidelines (2010) "Use of the Mirena™ LNG-IUS and Paragard™ CuT380A intrauterine devices in nulliparous women"

Adolescent women should be considered candidates for IUDs



Endorsements/ Practice Recommendations

New AAP Contraception practice guideline to be released September 29, 2014



Case 1.

Aisha is a **15 year old** who presents to your office with her mother to discuss contraception options.

- She has heavy periods with lots of cramping.
- She tried pills for one month, experienced nausea and worsening headaches, and then forgot to tell her mother when she ran out of her pack.
- She is sexually active.

"Shouldn't you have had a baby before getting an IUD?"

- Skyla® and Paragard® are FDA indicated for nulliparous females
- Mirena® has been demonstrated in numerous studies to be safe in nulliparous females and in adolescents
- Contemporary IUDs are not associated with infertility
- Insertions have not been demonstrated to be more difficult in nulliparous females

"Doesn't having an IUD increase the risk of a pelvic infection?"

- The risk of pelvic inflammatory disease is elevated for 20 days after the insertion of an IUD
- This is related to inserting an IUD through an infected lower genital tract, and nothing to do with the IUD itself
- Screen for sexually transmitted infections prior to or during placement

"I've seen those scary lawyer commercials about Mirena®..."

- The risk of perforation is less than 1/1,000
- The risk of a serious adverse event is extremely small
- LARCs are far safer than combined hormonal contraceptives, and far more effective in typical use
 - "Get it and forget it!!!"

Common provider myths

- Teens won't like IUDs: FALSE
- Someone who is high risk for STI should not get an IUD: FALSE
- She can't afford it: FALSE
- She already knows what she wants: FALSE
- I don't have time to tell her about every single method: FALSE
 - Start with LARC, which are more than 20X more effective!!!

Comparing Effectiveness of Family Planning Methods

More effective

Less than 1 pregnancy per 100 women in 1 year









sterilization



How to make your method more effective

Implants, IUD, female sterilization: After procedure, little or nothing to do or remember

Vasectomy: Use another method for first 3 months



Injectables









Injectables: Get repeat injections on time

Lactational amenorrhea method, LAM (for 6 months): Breastfeed often, day and night

Pills: Take a pill each day

Patch, ring: Keep in place, change on time





Male condoms



Diaphragm





Fertility awareness methods

Condoms, diaphragm: Use correctly every time you have sex

Fertility awareness methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be easier to use.

Withdrawal, spermicides: Use correctly every time you have sex

Less effective

About 30 pregnancies per 100 women in 1 year





Female condoms









Steiner MJ, Trussell J, Mehta N, Condon S, Subramaniam S, Bourne D. Communicating contraceptive effectiveness: a randomized controlled trial to inform a World Health Organization family planning handbook. Am J Obstet

World Health Organization/Department of Reproductive Health and Research (WHO/RHR), Johns Hopkins Bloomberg School of Public Health (JHSPH)/Center for Communication Programs (CCP). Family Planning: A Global Handbook for Providers. Baltimore, MD and Geneva: CCP and WHO, 2007.

Trussell J. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Stewart F, Nelson AL, Cates W Jr., Guest F, Kowal D, eds. Contraceptive Technology, Nineteenth Revised Edition. New York: Ardent Media, Inc., in press.

CDC Medical Eligibility Criteria

Category	Restriction	
1	No restriction	
2	Advantages generally outweigh theoretical or proven risks	
3	Theoretical or proven risks usually outweigh advantages	
4	Unacceptable health risk	

LARC Use with Medical Conditions

Condition	Copper IUD	LNG IUS	Implant
Hypertension (controlled)	1	1	1
Multiple cardiovascular risk factors	1	2	2
History of DVT/PE/Thrombogenic mutations	2	2	2
DVT/PE (on anticoagulant therapy)	1	2	2
Stroke	1	2	2

LNG = levonorgestrel IUS = Intrauterine system

LARC Use with Medical Conditions

Condition	Copper IUD	LNG IUS	Implant
Migraines with aura	1	2	2
Diabetes	1	2	2
Obesity	1	1	1
HIV infection	2	2	1
AIDS (on ARV therapy)	2	2	2 or 1*

LNG = levonorgestrel

^{*}depending on the type of therapy

Selected Contraindications

Condition	Copper IUD	LNG IUS	Implant
Post-puerperal sepsis or septic abortion	4	4	1
Current PID, purulent cervicitis, CT/GC	4	4	1
Breast cancer	1	4	4
Malignant GTN	4	4	1
Cervical/Endometrial cancer	4	4	2/1
Distorted uterine cavity incompatible with IUD insertion	4	4	1

Case 1.

"Aisha, I'm so glad you are here to talk with me today about birth control. It sounds like you had a rough time with the pill. The good news is that there are some extremely effective options available to you. What I'd like to do would be to tell you a bit about your options, starting with the most effective. Okay?"

Contraceptive Implants (Implanon®/Nexplanon®)

- A small, thin, implantable hormonal contraceptive that is effective for at least 3 years
- Mechanism: suppression of ovulation, progestin-induced changes in cervical mucus.
- Inserted under the skin in the inner arm using local anesthesia
- Failure rate is 0.05%

Contraceptive Implants (Implanon®/Nexplanon®)

- Bleeding is unpredictable on this method
 - Most women have fewer days of bleeding, but about ¼ have more
 - 15% reported removal rate for bleeding
- Does not appear to affect bone density
- 2-3 pounds weight gain

Progestin-releasing IUD (Mirena®)

- A small flexible intrauterine device that releases levonorgestrel locally
- Mechanism: thickens cervical mucus, inhibition of sperm motility and function, atrophic endometrium

Progestin-releasing IUD (Mirena®)

- Is FDA-approved for heavy menstrual bleeding indication
- Reduces menstrual bleeding by 90%
- Effective for at least 5 years
- Failure rate is 0.2%

Progestin-releasing IUD (Mirena®)

- No effect on bone density or weight
- Patient may have irregular bleeding for 4-6 months, then many are amenorrheic
- Most women still ovulate

Progestin-releasing IUD (Skyla®)

- Available February 2013
- FDA approved for nulliparous women
- Failure rate is <1%
- Effective for 3 years
- Lower dose of levonorgestrel than Mirena®



Copper-T IUD (Paragard®)

- Effective for at least 10 years
- Failure rate is 0.8%
- Women may experience heavier menses and increased cramping
- Hormone free

Case 1.

Aisha is very interested in Nexplanon[®]. She reports her last intercourse was six months ago. Her insurance is Ohio Medicaid. Her urine pregnancy test is negative.

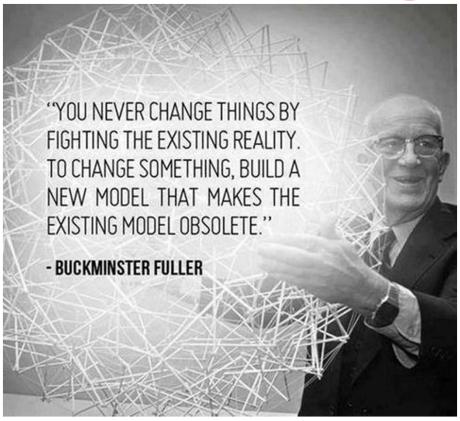
Since you know many young women do not return for their LARC placement, you decide to QuickStart Nexplanon[®].

Case 1.

Aisha tolerates the procedure well.

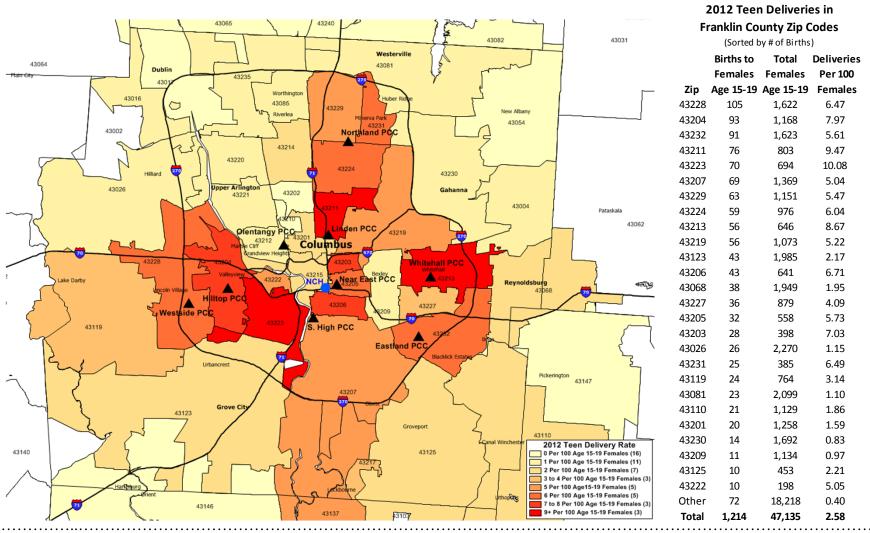
She and her mother leave assured that an unintended pregnancy is extremely unlikely.

Teen Pregnancy Prevention Program





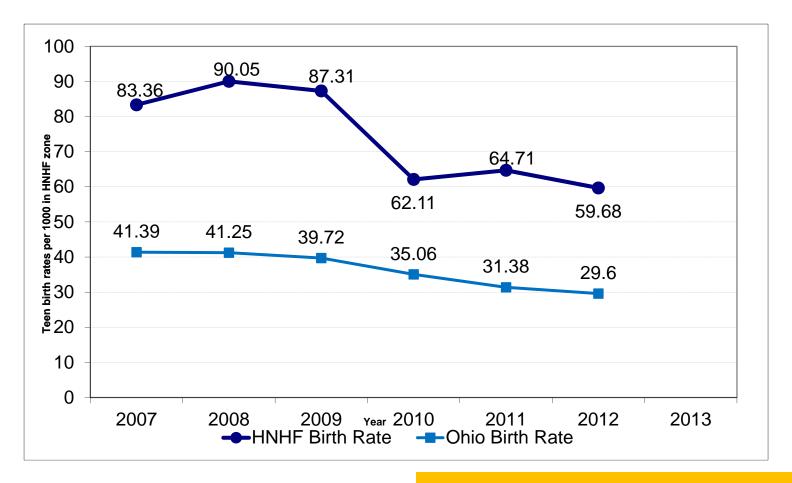
Franklin County Expansions: The Near Westside, Whitehall and Linden Represent the Highest Teen Pregnancy Rates in Franklin County



Sources: Columbus Public Health Dept. Data Represents Births to Mothers Age 15-19



Ohio Teen Birth Rates vs. HNHF Teen Birth Rates

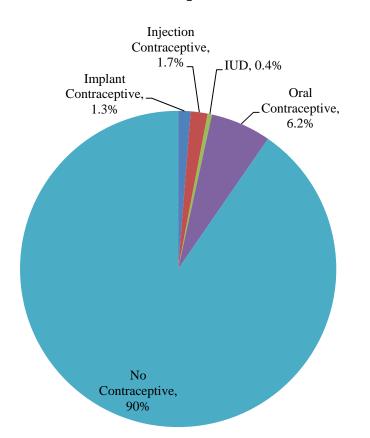


Source: Population Data from OHA Ohio Birth Data from ODH CAGR for Ohio Teen Birth Rate = -6.39 % CAGR for HNHF Teen Birth Rate = -5.49 %

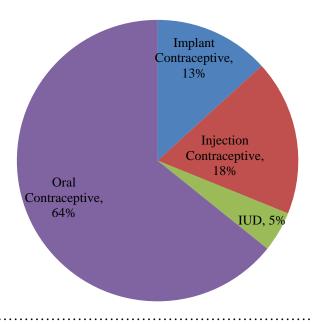


Only 10% of HNHF Females, 15-18 Years of Age, Use ANY Form of Contraception

HNHF Total Population



HNHF Population on Contraceptives



Sources: PFK Claims Data

Claims Incurred 1/1/2012 - 12/30/2012

Teen Pregnancy Prevention Program

Specific Aim: To reduce by 20 % the birth rate in adolescent females15-19 years of age in the HNHF Zone from 59.7 in 2012 to 47.7 in 2017.



Teen Pregnancy Prevention Program

- Efficacy-based contraception counseling clinical program
- Community outreach and education
- Partnerships with community pediatricians
- Strategic alliances



BC4TEENS

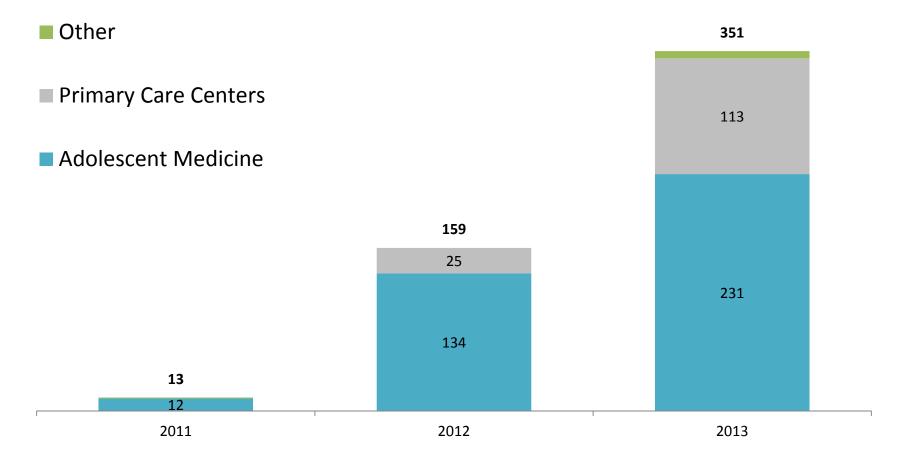
New Service at Nationwide Children's Hospital

- Comprehensive, outpatient contraceptive services for teens and young women.
- Teen friendly approach to family planning.
- Same day LARC insertions.
- Appointments scheduled within 14 days.
- Efficacy-based contraceptive counseling and contraceptive of choice if medically eligible.
- Evening and weekend appointments available.



Number of LARC Insertion Procedures

January 1, 2011 thru December 31, 2013



Source: EDW 'LARC' defined as CPT Codes: 58300, 58301, 11976, or 11980-11983



Contraceptive Implant Discontinuation at Nationwide Children's

- Of 488 patients, 11.5% discontinue within one year
- Lower than most published adult studies!

(unpublished data)



Scheduling an appointment

- Call Central Scheduling: 614-722-2450
- Via Internet @ Nationwidechildrens.org
 - <Request an Appointment
 - <Adolescent Medicine
 - <Contraception
- Email me directly if you are having any trouble
 Elise.berlan@nationwidechildrens.org



Nexplanon®

- Training for Nexplanon[®] insertion and removal is via Merck
 –(Clinical Training Program for Nexplanon[®])
- Sign up at: http://www.nexplanon-usa.com/en/hcp/servicesand-support/request-training/index.asp
- Only clinicians who have completed the training program are eligible to purchase the product
- The Clinical Training Program is available to:
 - U.S. clinicians authorized to perform medical procedures, as evidenced by a State License number or a Medical Education (ME) certificate
 - Advanced practice clinicians and physicians



What can I do?

- Learn more
- Share information with your stakeholders
- Network and collaborate
- Design and implement programs
- Clinical research/QI
- Use efficacy based counseling
- Refer clients and patients to LARC providers
- Become a LARC provider



Additional Resources

Association of Reproductive Health Professionals "You Decide Toolkit"

• http://www.arhp.org/Publications-and-Resources/Clinical-Practice-Tools/You-Decide
Reproductive Health Access Project

http://www.reproductiveaccess.org/

The Contraceptive Choice Project

http://choiceproject.wustl.edu/

The National Campaign to Prevent Teen and Unplanned Pregnancy

http://www.thenationalcampaign.org/

Advocates for Youth

http://www.advocatesforyouth.org

Guttmacher Institute

http://www.guttmacher.org/

American Academy of Pediatrics

Society for Adolescent Health and Medicine

American Congress of Obstetricians and Gynecologists

Adolescent Health Working Group (CA)

www.ahwg.net/resources/toolkit.htm

Thank you!

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