

Wash U's Contraceptive Choice Project is the best in the world

It is exciting whenever one has the opportunity to see the best. Like Rabun Wright, Eva Lathrop and Dr. Skoot Dimon, whom I described in last week's column.

Like Caroline White, whom I get to work with each week. Like my wife, Maggie, the incredible gardener, whom I get to live with every day. Like Dr. Ward Cates, whose enthusiastic encouragement brings out the best in all around him. And like Steve Hall, my favorite minister of the past six decades.

So, to all of you, thank you. Your excellence has made my days better. Each of us is in contact with the best from time to time and all too often we see it, focus on it for several moments, say "great" and move right on without really celebrating what we have seen.

On May 19, I saw the best up close and personal when I visited the CHOICE project in the Department of Obstetrics and Gynecology at Washington University in St. Louis.

And these words, "the best family planning program in the world," are not just hyperbole. These words are not said just because the person who developed this program, Dr. Jeffrey Peipert, was an Emory Medical School graduate I was privileged to work with for protracted periods of time early in his career. They are objectively the truth and the research papers coming out of this program will prove this.

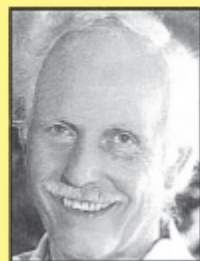
On my return May 20 from St. Louis to Tiger, I read a remarkable article in The New York Times on family planning by Nicholas D. Kristof. He writes about poverty and the pill.

Kristof begins with these words: "Earthquakes are more dramatic. Tsunamis make better television. AIDS is more visceral. But here's a far more widespread challenge, one that's also more fixable: the unavailability of birth control in many poor countries."

Kristof says later in his opinion piece: "If contraception were broadly available in poor countries, more than 50 million unwanted pregnancies could be averted annually. One result would be 25 million fewer abortions per year. Another would be saving the lives of as many as 150,000 women who now die annually in childbirth."

So why is the St. Louis CHOICE project the best? Why could programs like the

Bob Hatcher columnist



CHOICE project change the family planning landscape worldwide?

CHOICE has provided completely voluntary contraceptive services to just over 6,000 women. Mirena IUDs have been chosen by 46.9 percent of the women. This is the IUD that decreases menstrual blood loss by 90 percent (decreasing anemia in

women using this IUD) and markedly decreases menstrual cramps and pain. Mirena provides the most effective contraception of any reversible contraceptive for five to seven years.

Another 10.5 percent of CHOICE women have chosen the copper IUD, called ParaGard. This IUD provides excellent contraception for 12 years. And 12.4 percent of women have left the CHOICE clinics using an Implanon implant that lasts for three years.

These three methods, used by 69.8 percent of CHOICE patients, are called the LARC methods, the methods that are Long Acting Reversible Contraceptives. Others have called these three contraceptives the "you can't forget me methods" because once in place there is nothing a woman needs to do to remain protected against an unwanted pregnancy.

The CHOICE project will soon be telling the world of lower contraceptive discontinuation rates, higher levels of satisfaction, lower rates of pregnancy and lower rates of repeat abortion with the "you can't forget me methods."

I also hope to tell you in another article about the woman Peipert calls "my boss," Gina Secura. She manages the team of 50 clinicians and research assistants collecting data from the women in this superb contraceptive program.

Aside from their love and concern and wisdom, Secura and Peipert may have their hands on the most detailed information of any contraceptive program in the past decade. The devil is in the details and Secura is on top of the details. She is one of the major reasons why this program is the best family planning program in the world.

A resident of Tiger, Robert A. Hatcher, M.D., is professor of obstetrics and gynecology at the Emory University School of Medicine and senior author of "Something Nice To Do 365 Days a Year."

Failure Rates in CHOICE Project Participants

Method	Year 1	2	3
All LARC methods	0.3	0.6	0.9
Pills, Patches and Rings	4.8	7.8	9.9

A woman is more than 20 times more likely to become pregnant using pills, patches or rings than using a LARC method.

Final Tally of Contraceptives Chosen by Women in the CHOICE Project

LNG IUD (Mirena)	46%
Copper IUD (ParaGard)	12%
Implant (Implanon)	17%
Total Choosing LARC Method	75%

First Year Continuation Rates

LNG IUD (Mirena)	88%
Copper IUD (ParaGard)	84%
Implant (Implanon)	83%

Our she-roe, Gina is growing grapes and making wine in Italy. Our hero, Jeff is chair of the OB/GYN department at Indiana University.

Notes:



MESSAGE: Thanks to a very generous foundation, two wise and hard-working individuals, and close to sixty other counselors, nurse practitioners, physicians and research assistants, nearly 7,000 of 9,256 women received the most effective reversible contraceptives ever available to women wanting to avoid becoming pregnant. This presentation will tell you how.



Gina Secura and Jeffrey Peipert

1. The **effectiveness** of IUDs and implants is the first thing a woman is told about when she calls or arrives at one of the clinical sites. Before long researchers from this project were telling the world **"A woman is more than 20 times more likely to become pregnant if she uses pills, patches, or rings than if she uses an IUD or an implant."** (Winner, Peipert, NEJM 2012) (Renee Mestad, et al. Contraception, 2011) (Peipert Obstet Gynecol, 2012)
2. **Access.** At all the sites it was possible for women to receive an IUD or an implant quickly. Trained personnel were there. The IUDs and implants were there. Delay was minimized.
3. The price was right! Contraceptives, screening for STIs and treatment for STIs if necessary, condoms for all contraceptors and pelvic exams were provided at **no cost.**
4. The counseling presentation available for you to hear on the St. Louis Contraceptive CHOICE website ends with the words of one woman who was asked to tell 20 others of her experience of getting a Mirena IUD. She did it. And each of them were asked to tell 20 more people... and most of them did it. That is remarkable power to the people and led Peipert to say repeatedly that recruitment of women into this research project occurred more rapidly than occurred in any previous research effort.
5. Teen births fell to 6.3 per 1,000 in the Choice/St. Louis cohort vs. 34.3 per 1,000 in the U.S. (Peipert, Madden Obstet Gynecol, 2012) The percent of abortions that were repeat abortions fell to less than half the average when compared to the national rate. (Peipert, Madden Obstet Gynecol, 2012)
6. The entire country is inspired and is now replicating as extensively as possible the St. Louis CHOICE efforts.
7. Peipert, Secura, Maddon, Zhao, Allsworth, Winner, Mestad and Buckel and their large team worked well together. One reads often of the importance of groups communicating well to achieve a desired end. That is what happened with this team.

So what can each of us do differently to decrease the number of unintended pregnancies by increasing provision of LARC methods?

1. **Speak about and offer all three LARC methods. Focus first on the effectiveness of LARC methods.**
2. **Recommend ParaGard as the emergency contraceptive of choice.**
3. **Place IUDs or an implant right after deliveries, after miscarriages and after abortions.**
4. **Accurately describe the duration of effectiveness of our contraceptive options:**
 - ParaGard, the Copper T 380-A, is effective for at least 12 years
 - Mirena, the levonorgestrel IUD, is effective for at least 7 years
 - Implanon, the etonogestrel implant, is effective for 4 years (more likely 5 or 6 years)
 - Depo-Provera injections are effective for 15 weeks
 - NuvaRings prevent ovulation for 35 days
5. **"Quick Start" is the right way to start all contraceptives whenever possible.**
6. **Tonight, use a condom, withdrawal, abstinence or outercourse.** Advice for anyone considering having unprotected sex when not wanting to become pregnant. **No mistakes. Not once. Not ever.**
7. **The money vein runs right through the heart.** Since free contraceptives, sterilization or abortion are not available for everyone, everywhere, here is a message for all sexually active women and men: If you are committed to never, ever having an unintended pregnancy, start a savings account dedicated to that goal. **Each girl, boy, woman and man should have such a savings account!** This recommendation became part of my thought processes long before the November 2016 election. It is even more important today, when the Affordable Care Act and our current contraceptives are under attack.

Please read this handout for 7-10 minutes before the presentation begins.

Before answering this question, a riddle: Three frogs were sitting on a log. Two of them decided to jump off into the water. How many frogs were now on the log? Read on!!



MESSAGE: Thanks to a very generous foundation, two wise and hard-working individuals, and close to sixty other counselors, nurse practitioners, physicians and research assistants, nearly 7,000 of 9,256 women received the most effective reversible contraceptives ever available to women wanting to avoid becoming pregnant. This presentation will tell you how.

World Population Growth and the History of Long Acting Reversible Contraceptives

A Riddle: Three frogs were sitting on a log. Two frogs decided to jump off the log into the water. How many frogs were now on the log?

If two of the three frogs decide to jump into the water... well, those are just words. No action yet. We don't know if any frogs actually jumped.

SO, there are still three frogs on the log. If you want to emulate the CHOICE Project, here are 4 actions you can take:

1. Emphasis effectiveness
2. Access is essential, minimize delays
3. Keep costs as close to zero as possible
4. Word of mouth can really help

THE LEVONOGESTREL IUD CALLED MIRENA, LILETTA, KYLEENA AND SKYLA

Effectiveness: Typical use failure rate for first year: 0.2% or 2 in 1,000 women become pregnant. [Trussell, CT 20th ed., p.50] Failure rate at 7 years: 1.1%. (Sivin, Contraception, 1991) "The levonorgestrel IUD can be used for at least 7 years and probably for 10 years." [Speroff and Darney A Clinical Guide for Contraception Fifth Ed. 2011 Lippincott, page 249]

- Cervical mucus is thickened creating a barrier to sperm penetration. Women using an LNG-IUD are 50% less likely to develop a pelvic infection and are 10 times less likely to have an ectopic pregnancy than women not using any contraceptive. [Toivonen 1996; Sivin 1991]
- Atrophy of the endometrium leads to 90 – 95% less blood loss at the time of menses and decreased risk for endometrial hyperplasia, endometrial cancer or endometriosis. **Beware-use of this IUD to prevent menstrual cycle problems is associated with an 10-13% expulsion rate.**
- Mirena inhibits sperm capacitation, penetration and survival.
- Ovarian follicular development and ovulation are partially inhibited. After the first year of using a Mirena IUD, 50-75% of a woman's cycles are ovulatory regardless her bleeding pattern. (Barbosa Contraception 1995)
- Implantation is inhibited if the levonorgestrel IUD called Mirena has not prevented ascent of sperm, capacitation of sperm, penetration of the ovum by sperm or fertilization.

THE COPPER T 380 A IUD CALLED PARAGARD

Effectiveness: In the 20th Ed. of Contraceptive Technology, the typical use failure rate of the Paragard (Copper T) IUD is 0.8% or 8 in 1,000 women. While copper T 380 A IUD is approved for 10 years, it remains effective for 12 years and studies have found no pregnancies from the 12th to the 20th year.

If a woman has sex without a contraceptive, the copper T 380A (ParaGard) is by far the most effective emergency contraceptive. Each night 800,000 to 1,000,000 women in the U.S. have intercourse using no contraceptive at all or experience breakage of a condom. Trussell describes a study that found not one of 1,963 women who received a ParaGard IUD for emergency contraception became pregnant. In the 12 months after these women requested emergency contraception there were only 0.23 pregnancies per 100 women. [Trussell, Contraception Technology 20th Ed., p.152] [Wu, BJOG 2010]

- This IUD is the reversible method of birth control chosen most often by women throughout the world.
- Probable protection against endometrial cancer [Hubacher, Grimes 2002; Guleria 2004] and possible protection against cervical cancer. [Grimes 2004]
- The IUD is the method of birth control chosen most often throughout the world. In the St. Louis CHOICE project, just over 10% of women chose to use a Paragard IUD.
- Women continue to have regular periods using a copper IUD. However, there may be some increase in blood loss and cramping.

NEXPLANON IMPLANTS

Effectiveness: The most effective of all currently available contraceptive methods. In the 20th Ed. of Contraceptive Technology, Trussell states that in typical users the failure rate Implanon (and presumably Nexplanon) is 0.05% or 5 in 10,000 women. [Trussell, Guthrie 2011] [Trussell, CT 20th ed., p.50] Because ovulation is so consistently suppressed, pregnancies are extremely rare among women using this implant. However, a woman must have Implanon in her arm for it to work. If the clinician placing the implant permits it to fall out of the inserter without being noticed a woman may become pregnant. This was the most common cause of Implanon failures.

Three studies in which women used Implanon for longer than 3 years no pregnancies during the fourth year of use. [Kiriwat 1998; Zheng 1999; Zheng 1999] [Peipert 2016]

- The Nexplanon implant is 4 cm long and 2 mm in diameter with a core of 68 mg of the progestin, etonogestrel.
- Single implant 4 cm long and 2 mm in diameter with a core of 68mg of the progestin, etonogestrel
- Implanon and Nexplanon also alter cervical mucus and endometrial structure.
- Implantation may rarely be inhibited.

JADELLE IMPLANTS

Jadelle, developed by the Population Council and first approved in Finland in 1983, consists of two rods 4.3 cm long and 2.5 mm in diameter, each containing 75mg levonorgestrel. Jadelle is effective for at least five years. (Sivin, Alvarez, Mishell, Contraception, 1998)

Notes:

Immediately after delivery, within 10 minutes of delivery of the placenta, whether delivery is by C-section or vaginally, a LNG IUD (Lilette or Mirena), a Copper IUD or an Implant may be placed and, similarly, immediately following an induced abortion or miscarriage a LNG IUD (Lilette or Mirena), a Copper IUD or an Implant may be placed.

Note the absence of decimal points. This chart points out how much more effective Nexplanon is than pills.

Nexplanon has a typical use failure rate of 0.05%. Just what does 0.05% mean? This chart shows you!

* Estrogen increases risk for stroke, heart attack, and blood clots.

This ingenious method of explaining the differences in typical use failure rates by placing the number of pregnancies in the first year in 10,000 typical users. It comes to you because of the creative genius of Dr. Claude Burnett in Athens, GA. It was derived from James Trussell's table 3-2 on page 50 of Contraceptive Technology, 20th ed. 2011.

Offer to provide combined pills continuously (no hormone-free days) to lower the extremely high failure rate of combined pills in typical users.

WORLD'S BEST BIRTH CONTROL

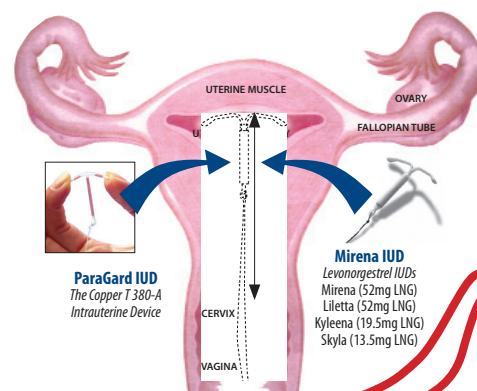
BIRTH CONTROL EFFECTIVENESS IN 10,000 TYPICAL WOMEN

CONTRACEPTIVE METHOD	PREGNANCIES IN FIRST YEAR
NEXPLANON	5
MALE STERILIZATION	15
MIRENA IUD	20
FEMALE STERILIZATION	50
PARAGARD IUD	80
DEPO SHOT	600
MINIPILL	900
COMBINATION PILLS*	900
CONDOM	1,800
WITHDRAWAL	2,200
NO METHOD	8,500

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Notes:



Nexplanon and Implanon Implants
The etonogestrel implant
The most effective of all reversible methods.
And for 4-5 years, more effective than most male or female sterilization procedures.



1930: World population now 2 billion (this billion took 100 years)

- 1930:** Knaus (Austria) and Ogino (Japan) develop rhythm method
- 1930:** Pope Pius XI in Of Chaste Marriage virulently attacks both contraception and abortion
- 1927:** Novak (Hopkins) describes suction as means of performing an abortion
- 1920:** Women can vote in the United States
- 1914:** Margaret Sanger coins phrase "birth control" and fights for women's suffrage
- 1909:** German surgeon Richard Richter reports success with silk-worm-gut shaped into a ring
- 1898:** New Zealand becomes the first country in the world where women can vote
- 1893:** First vasectomy by Harrison in London
- 1882:** First contraceptive clinic established in Amsterdam
- 1880:** First tubal ligation and Dr. Wilhelm Mensinga invents a larger cervical cap eventually known as the diaphragm

1800: It took many thousands of years for world population to reach 1 billion people

- 1798:** Thomas Robert Malthus proposes dismal economic theory that population growth eventually will exceed the ability of the earth to provide food, resulting in starvation
- Late 1770's:** Casanova popularizes condoms for infection control and contraception. He recounts his attempts to use the shelled out rind of a lemon as a cervical cap. Lemon juice is a strong spermicide.



Molokhia

2050: World population will reach 9.7 billion. By 2050, Africa's population is expected to be 2.4 billion, up from 1.1 billion in 2014. [Population Reference Bureau, www.prb.org]

If you believe the information in this publication would be of interest to friends, relatives, colleagues or women who might benefit from one of the Long Acting Reversible Contraceptives, go to www.managingcontraception.com for a free download of What's Next.

2025: World population to reach 8 billion (this billion will take 14 years)

2016: FDA approves 19.5mg LNG IUD, Kyleena, for 5 years contraceptive use. Same size as Skyla but approved for more years

2016: World population 7.4 billion. (83% in less developed countries) [Population Reference Bureau, www.prb.org]

2015: Liletta, the latest LNG IUD available, less expensive than Mirena

2013: The mini-Mirena IUD called Skyla (13.5mg LNG) arrives in the USA. Inserter barrel 15% smaller. Approved for 3 years of contraceptive use

2012: Brooke Winner, Peipert, Zhao, Buckel, Maddon, Allsworth, Secura published the classical paper on the effectiveness of long acting reversible contraceptive in the St. Louis Contraceptive CHOICE Project. [NEJM May 24, 2012]

2011: World population reaches 7 billion (this billion took 12 years)

2011: 20th Edition of Contraceptive Technology

2006: First HPV vaccine, Gardasil, released

2002 and 1996: Forest, Hubacher and Grimes point out A GLOBAL PARADOX. "Although the most common reversible contraceptive in the world, it (the IUD) has the worst reputation of all contraceptives... except among those using IUDs." [Hubacher D., Grimes DA. 2002; Forest JD. 1996]

2001: Ortho Evra Patch and NuvaRing approved

2000: Women can vote in all but 3 countries (see 1898!!)

1999: World population hits 6 billion (this billion took 12 years)

1996: World Health Organization publishes evidence-based guidelines on the safety of contraceptives for women with over 150 characteristics and medical conditions

1992: First female condom, Femidom, marketed in Denmark (Reality in USA)

1991: Sivin describes 7 year cumulative failure rate of LNG IUD of 1.1%

1987: World population reaches 5 billion (this billion took 12 years)

1983: Implanon implant developed by Population Council and first approved in Finland

1983: Jadelle implant developed by Population Council and first approved in Finland

1982: Baulieu describes medical abortion using mifepristone followed by misoprosol

1981: First case of HIV/AIDS described in MMRW (CDC)

1980s: Per capita caloric consumption starts to fall (held off for decades by the green revolution)

1975: World population reaches 4 billion (this billion took 15 years)

1974: Al Yuzpe in Canada describes emergency contraception using Ovral pills

1969: First edition of Contraceptive Technology

1969: Jaime Zipper in Chile describes suppression of fertility by intrauterine copper IUD [Am J Obstet Gynecol, 1969]

1968: Vatican pronouncement reaffirms opposition of Catholic Church to artificial contraception

1964: Dr. Alexander Langmuir makes family planning a public health priority at the Centers for Disease Control

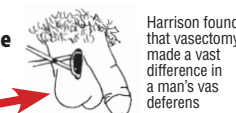
1960: It took but 30 years to add the 3rd billionth person to our little spaceship Earth

1960: Combined birth control pills formally approved by FDA

1950s: Birth control pills taken continuously to treat endometriosis

1936: German gynecologist Friedrich Wilde describes first cervical cap (fitted from a wax impression)

1936: John Rook opens rhythm birth control clinic in Boston



Harrison found that vasectomy made a vast difference in a man's vas deferens

2040: 9 Billion

2025: 8 Billion

2011: 7 Billion

1999: 6 Billion

1987: 5 Billion

1975: 4 Billion

1960: 3 Billion

1930: 2 Billion

1800: 1 Billion