Updates in Permanent Contraception

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Objectives

- (knowledge) Attendees will learn how permanent contraceptive techniques have changed over time
- (competence) Attendees will be able to assist their patients with permanent contraceptive decision making
- (performance) Attendees will improve their patient centered counseling
- (patient outcomes) Patients will be able to determine what permanent method is best for them (or if permanent is not a good option for them)

Disclosures

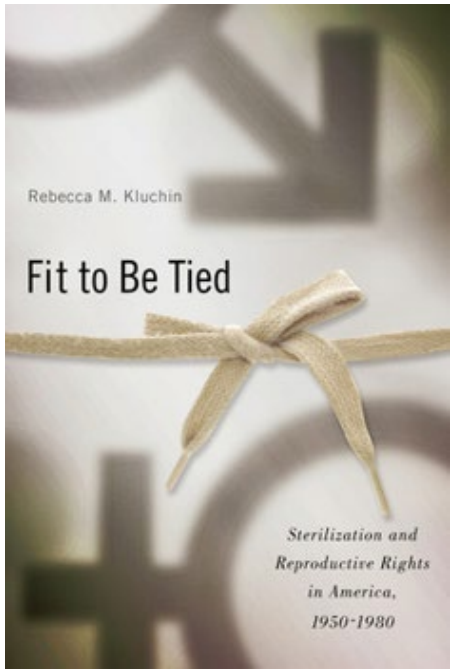
- No financial disclosures related to this presentation

Words matter…

- Sterilization → Permanent Contraception
- Connotation of a coercive process → respects autonomy

- LONG hx of coercive practices and efforts to minimize
- Federal regulations in 1976 for Medicaid patients
- Reproductive Justice movement in 1990's

Why I am giving this talk…



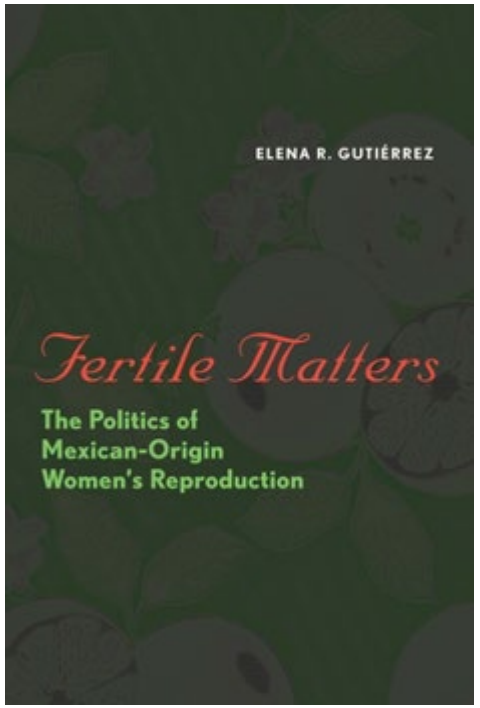
ORIGINAL RESEARCH

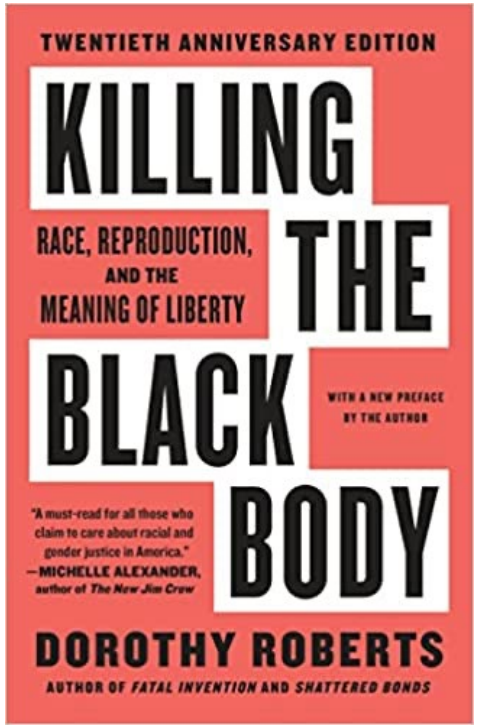
Failure to Obtain Desired Postpartum Sterilization: Risk and Predictors

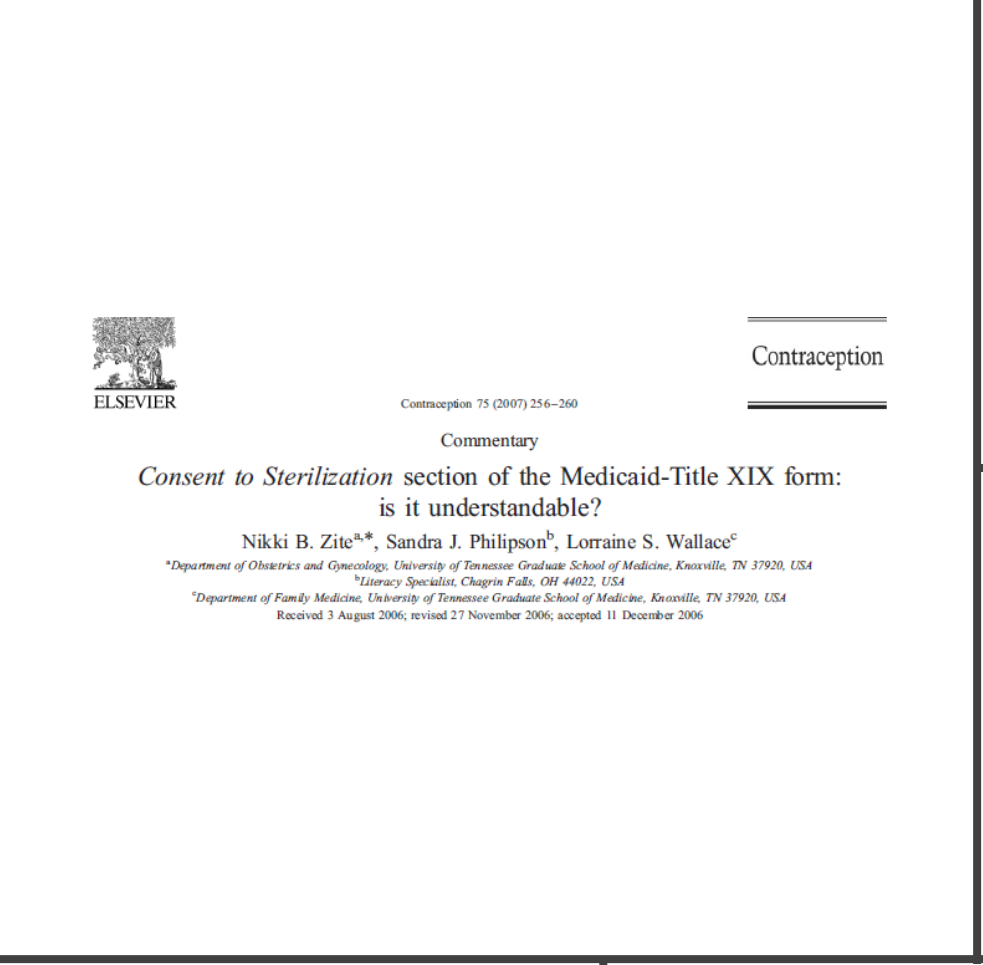
Zite, Nikki MD, MPH; Wuellner, Sara MPH; Gilliam, Melissa MD, MPH

Author Information

Obstetrics & Gynecology 105(4):p 794-799, April 2005. | **DOI:** 10.1097/01.AOG.0000157208.37923.17







ELSEVIER

Contraception 75 (2007) 256–260

Contraception

Commentary

Consent to Sterilization section of the Medicaid-Title XIX form: is it understandable?

Nikki B. Zite[a,*], Sandra J. Philipson[b], Lorraine S. Wallace[c]

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Received 3 August 2006; revised 27 November 2006; accepted 11 December 2006

ELSEVIER

Contraception 73 (2006) 404–407

Contraception

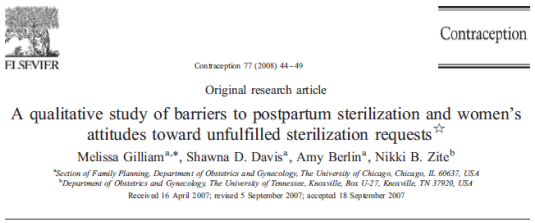
Original research article

Barriers to obtaining a desired postpartum tubal sterilization

Nikki Zite, Sara Wuellner, Melissa Gilliam*

Department of Obstetrics and Gynecology, University of Illinois at Chicago, Chicago, IL 60612, USA

Received 28 June 2005; revised 17 October 2005; accepted 21 October 2005



ELSEVIER

Contraception 77 (2008) 44–49

Contraception

Original research article

A qualitative study of barriers to postpartum sterilization and women's attitudes toward unfulfilled sterilization requests ☆

Melissa Gilliam[a,*], Shawna D. Davis[a], Amy Berlin[a], Nikki B. Zite[b]

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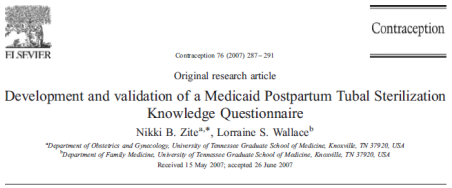
Received 16 April 2007; revised 5 September 2007; accepted 18 September 2007



ELSEVIER

Contraception 76 (2007) 287–291

Contraception

Original research article

Development and validation of a Medicaid Postpartum Tubal Sterilization Knowledge Questionnaire

Nikki B. Zite[a,*], Lorraine S. Wallace[b]

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Received 15 May 2007; accepted 26 June 2007

COMMENTARY

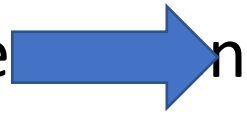
Federally Funded Sterilization: Time to Rethink Policy?

In the 1970s, concern

Sonya Borrero, MD, MS, Nikki Zite, MD, and Mitchell D. Creinin, MD

- Access
- Consent
  - Understanding of permanence
- Ovarian cancer prevention

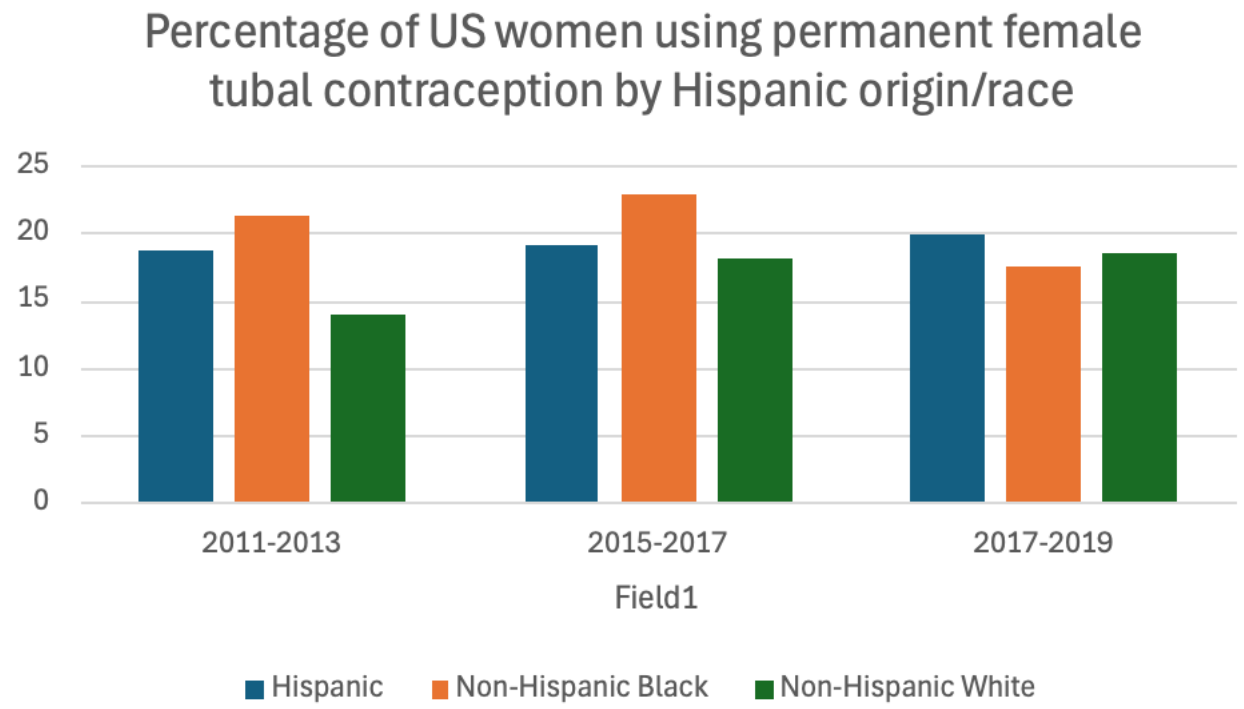
History of permanent Contraception (PC)

- First tubal pe  nt contraception reported during cesarean in 1881
- Laparoscopy advent/advances in 1970's allowed interval options
- Hyste  copic methods were used in early 2000's
- LARC increased contraceptive options and decreased percent PC
- Improvements in L/S allowed to move from occlusion to removal

Facts about Female Permanent Contraception

- Highly utilized method
  - ≈11 million women in USA
  - 30% of contraceptors
- *Mortality* rate is 1-4 per 100,000 procedures
  - Less than that related to pregnancy/ childbirth
  - Most related to anesthesia
- *Complication* rate is .4 to 1%
  - Wound infection, bleeding, or perforation of internal organs
  - Obesity, diabetes, or having previous abdominal or pelvic surgery are risk factors for complications

Racial/Ethnic Differences in Utilization



US Collaborative Review of Sterilization (CREST) Study

- A prospective cohort study in U.S. academic medical centers (teaching hospitals)
- 12,138 women who underwent tubal sterilization (cases)
  - 9 centers
  - Enrolment ***1978-86***
- 573 women whose partners (all husbands) had a vasectomy (controls)
  - 5 centers
  - Enrolment ***1985-87***

Academic Medical Centers

Failure Rates - Higher Than Expected

Method	% failing within 1 year
Bipolar coagulation	0.23
Unipolar coagulation	0.07
Silicone rubber band	0.59
Spring clip (Hulka)	1.82
Interval partial salpingectomy	0.73
Postpartum partial salpingectomy	0.06
All methods	0.55

Am J Obstet Gynecol. 1996;**174**:1161-8

Failures persist longer than expected

Table 1. Pregnancy Rates by Sterilization Method

Method	5-year (per 1,000 procedures)	10-year (per 1,000 procedures)	Ectopic (per 1,000 procedures)
Postpartum partial salpingectomy	6.3	7.5	1.5
Bipolar coagulation*	16.5	24.8	17.1
Silicone band methods	10.0	17.7	7.3
Spring clip	31.7	36.5	8.5
Hysteroscopy (Essure)†	1.64	—	—
Vasectomy	11.3		No association

*Secondary analysis of 5-year failure rates with bipolar coagulation performed in different decades found that failure was significantly lower in later periods, reflecting improved technique with the method: 19.5 per 1,000 procedures for 1978–1982 versus 6.3 per 1,000 procedures for 1985–1987 (Peterson 1999).

Age was correlated with risk of long-term failure

Table 2. Life-Table Cumulative Probability of Pregnancy Among Women Who Had Undergone Sterilization by Age and Method, U.S. Collaborative Review of Sterilization

Age at Sterilization	10-Year Cumulative Probability of Pregnancy
18–27 y	
Bipolar coagulation	54.3 (28.3–80.4)
Unipolar coagulation	3.7 (0.0–11.1)
Silicone rubber band application	33.2 (10.6–55.9)
Spring clip application	52.1 (31.0–73.3)
Interval partial salpingectomy	9.7 (0.0–28.6)
Postpartum partial salpingectomy	11.4 (1.6–21.1)
28–33 y	
Bipolar coagulation	21.3 (9.6–33.0)
Unipolar coagulation	15.6 (0.0–31.4)
Silicone rubber band application	21.1 (6.4–35.9)
Spring clip application	31.3 (15.1–47.5)
Interval partial salpingectomy	33.5 (0.0–74.3)
Postpartum partial salpingectomy	5.6 (0.0–11.9)
34–44 y	
Bipolar coagulation	6.3 (0.1–12.5)
Unipolar coagulation	1.8 (0.0–5.3)
Silicone rubber band application	4.5 (0.6–8.4)
Spring clip application	18.2 (0.0–36.4)
Interval partial salpingectomy	18.7 (0.0–39.6)
Postpartum partial salpingectomy	3.8 (0.0–11.4)

Data are n/1,000 procedures (95% confidence interval).

Reprinted from Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol 1996;174:1161–8. Copyright 1996, with permission from Elsevier.

Ectopic Pregnancy

- 47 ectopic pregnancies in 10,685 women
- 10-year cumulative probability 7.3 per 1000
- Substantial variation by age and method
- Women <30 with bipolar tubal coagulation had a 10-year probability of 3.2%
- Annual rate in the 4th through 10th years after sterilization no lower than that in the first 3 years

N Engl J Med. 1997;**336**:762-7

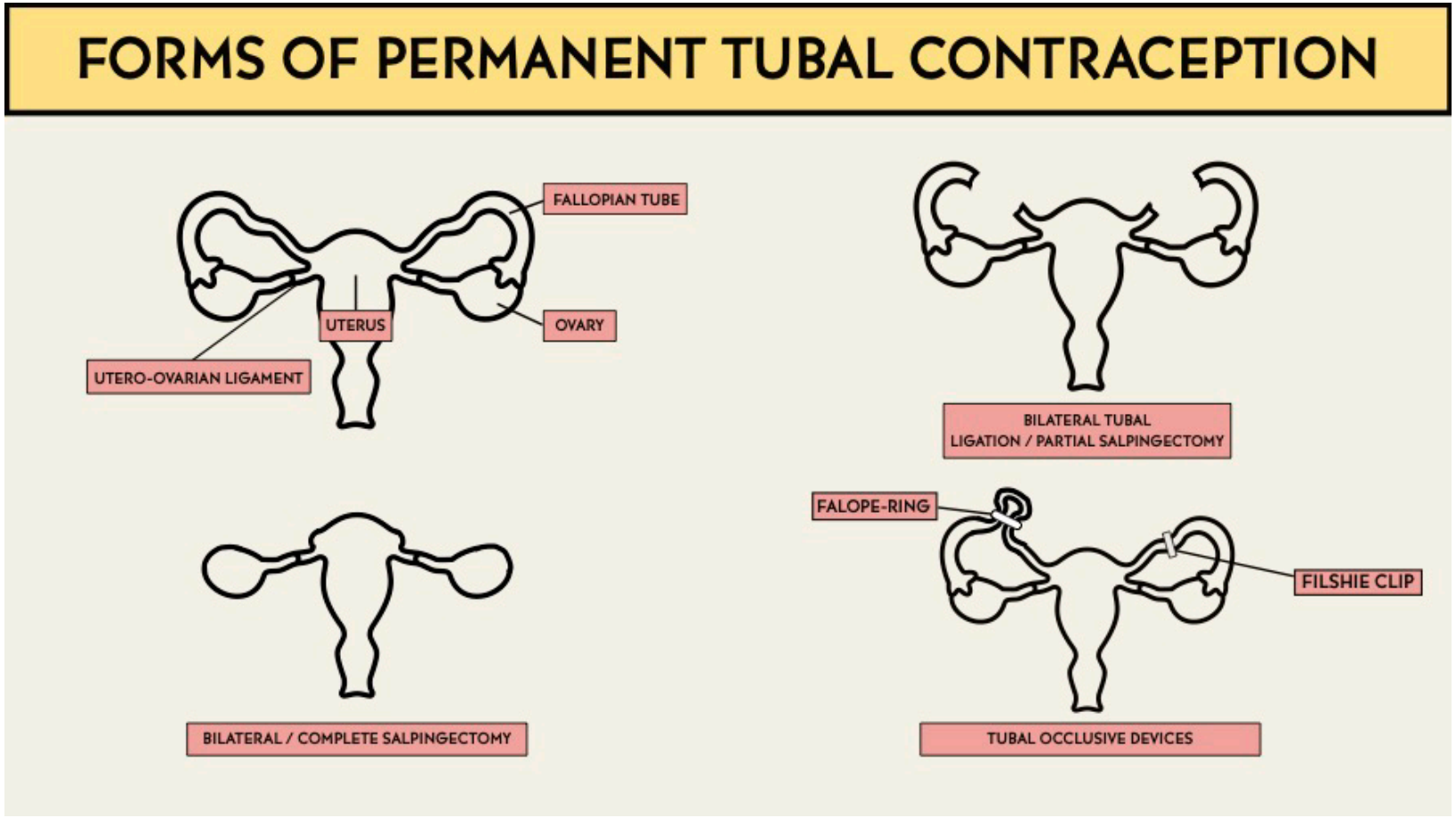
Table 4. Life-Table Cumulative Probability of Ectopic Pregnancy 10 Years After Tubal Sterilization According to Age at the Time of Sterilization, U.S. Collaborative Review of Sterilization

Method	Less Than 30 y	30 y or More
Bipolar coagulation	31.9 (15.2–48.7)	7.6 (1.9–13.2)
Unipolar coagulation	5.9 (0.0–17.5)	0.0
Silicone rubber band application	7.8 (0.0–17.8)	6.9 (0.2–13.7)
Spring clip application	11.1 (0.0–23.4)	5.8 (0.0–14.9)
Interval partial salpingectomy	14.6 (0.0–34.7)	3.7 (0.0–11.1)
Postpartum partial salpingectomy	1.2 (0.0–3.5)	1.8 (0.0–5.2)

Data are n/1,000 procedures (95% confidence interval).

Adapted from Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. U.S. Collaborative Review of Sterilization Working Group. N Engl J Med 1997;336:762-7.

Filshie Clip & Salpingectomy Not in CREST Data



Timing – Show of Hands….

- Who offers post-partum tubal ligations?
  - Salpingectomy?
- Who performs salpingectomy during cesareans?
- Who performs falope rings currently?
- Who performs Filshie clips currently?

Timing

- Lots of barriers to post-partum after vaginal delivery
- High rate of repeat pregnancy in patients that plan a PPTL and do not obtain….. Strategies to decrease
  - Medicaid extended to 12 months PP (?)
  - IPP LARC or other bridge methods
  - Have a back-up plan, especially if high risk of not obtaining

Evidence for “Opportunistic” Salpingectomy

- Distal fallopian tube contributes to ovarian cancer pathogenesis
- Nurses’ health study showed 24% reduces risk with ligation (2014)
- Opportunistic Salpingectomy led to 50-80% reduced risk (2015-2023)
- Also reduces risk of failure and ectopic
  - To date only reported ectopic after salpingectomy is with ART
- Small increase in OR time, no increase risk of complications
- ACOG recommends OS for permanent contraception AND at time of Hyst
  - Should not alter route of HYST
  - Can be safely completed at time of Cesarean or Postpartum

Tubal Sterilization Regret

- From CREST long term follow-up
- Cumulative probability of expressing regret during a follow-up interview within 14 years after tubal sterilization
  - 20.3% for women ≤30 at the time of sterilization
  - 5.9% for women >30 at the time of sterilization

Obstet Gynecol. 1999;**93**:889-95

Reversal – surrogate for regret?

- 14-year cumulative probability of requesting reversal information among 11,332 women after sterilization 14.3%
- 40.4% among women aged 18 to 24 at sterilization
- 1.1% overall cumulative probability of obtaining reversal (multifactoral)
- Women aged18 to 30 at sterilization 8 times as likely to obtain reversal

Fertil Steril. 2000;**74**:892-8

Subsequent Menstrual Abnormalities – 5-year follow-up

- 9,514 women who had undergone sterilization were no more likely than 573 women whose partners underwent vasectomy to report persistent changes in intermenstrual bleeding or the length of the menstrual cycle
- More likely to have decrease in the number of days of bleeding, amount of bleeding, menstrual pain, and to have an increase in cycle irregularity
- Non comparative study demonstrated with time after sterilization, negative menstrual symptoms increased

N Engl J Med. 2000;**343**:1681-7
Am J Epidemiol. 1992 Jun 15;135(12)

Barrier to obtaining desired procedure

- Women report that issues related to Medicaid policy prevented them from getting a desired sterilization
  - Requesting sterilization too late in pregnancy to fulfill the 30-day waiting period
  - Not having the form available at delivery
  - Delivering before the waiting period had elapsed

Potter: *Perspect Sex Repro Health*, 2012 (in press)
Thurman: *J Reprod Med*, 2009
Zite: *Contraception*, 2006
Borrero: *J Gen Intern Med*, 2009
Gilliam: *Contraception*, 2008

Form Approved: OMB No.
0937-0166 Expiration date: 3/31/2019

CONSENT FOR STERILIZATION

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

■ CONSENT TO STERILIZATION ■

I have asked for and received information about sterilization from _____ (*Doctor or Clinic*). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as Temporary Assistance for Needy Families (TANF) or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____ (*Specify Type of Operation*). The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on: _____ (*Date*)

I, _____, hereby consent of my own free will to be sterilized by _____ (*Doctor or Clinic*) by a method called _____ (*Specify Type of Operation*). My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services, or Employees of programs or projects funded by the Department but only for determining if Federal laws were observed.

I have received a copy of this form.

_____ (*Signature*) _____ (*Date*)

You are requested to supply the following information, but it is not required: *(Ethnicity and Race Designation) (please check)*

Ethnicity:
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Race (mark one or more):
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

■ INTERPRETER'S STATEMENT ■

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

_____ (*Interpreter's Signature*) _____ (*Date*)

HHS-687 (10/12)

■ STATEMENT OF PERSON OBTAINING CONSENT ■

Before _____ (*Name of Individual*) signed the consent form, I explained to him/her the nature of sterilization operation _____ (*Specify Type of Operation*), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent. I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

_____ (*Signature of Person Obtaining Consent*) _____ (*Date*)

_____ (*Facility*)

_____ (*Address*)

■ PHYSICIAN'S STATEMENT ■

Shortly before I performed a sterilization operation upon _____ (*Name of Individual*) on _____ (*Date of Sterilization*)

I explained to him/her the nature of the sterilization operation _____ (*Specify Type of Operation*), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(**Instructions for use of alternative final paragraph**: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

- ☐ Premature delivery
  Individual's expected date of delivery: _____
- ☐ Emergency abdominal surgery *(describe circumstances)*:

_____

_____

_____ (*Physician's Signature*) _____ (*Date*)

Title XIX-SCF form: Is it understandable?

- Readability and comprehension characteristics
  - scored in “poor” range on standardized assessment
  - reading level significantly higher than average literacy
  - women most likely to rely on publicly funded sterilization at high risk for limited literacy

- After reviewing the consent form, 34% of women incorrectly answered a question about the permanence of the procedure

Zite: *Contraception*, 2007
Zite: *Obstet Gynecol*, 2011

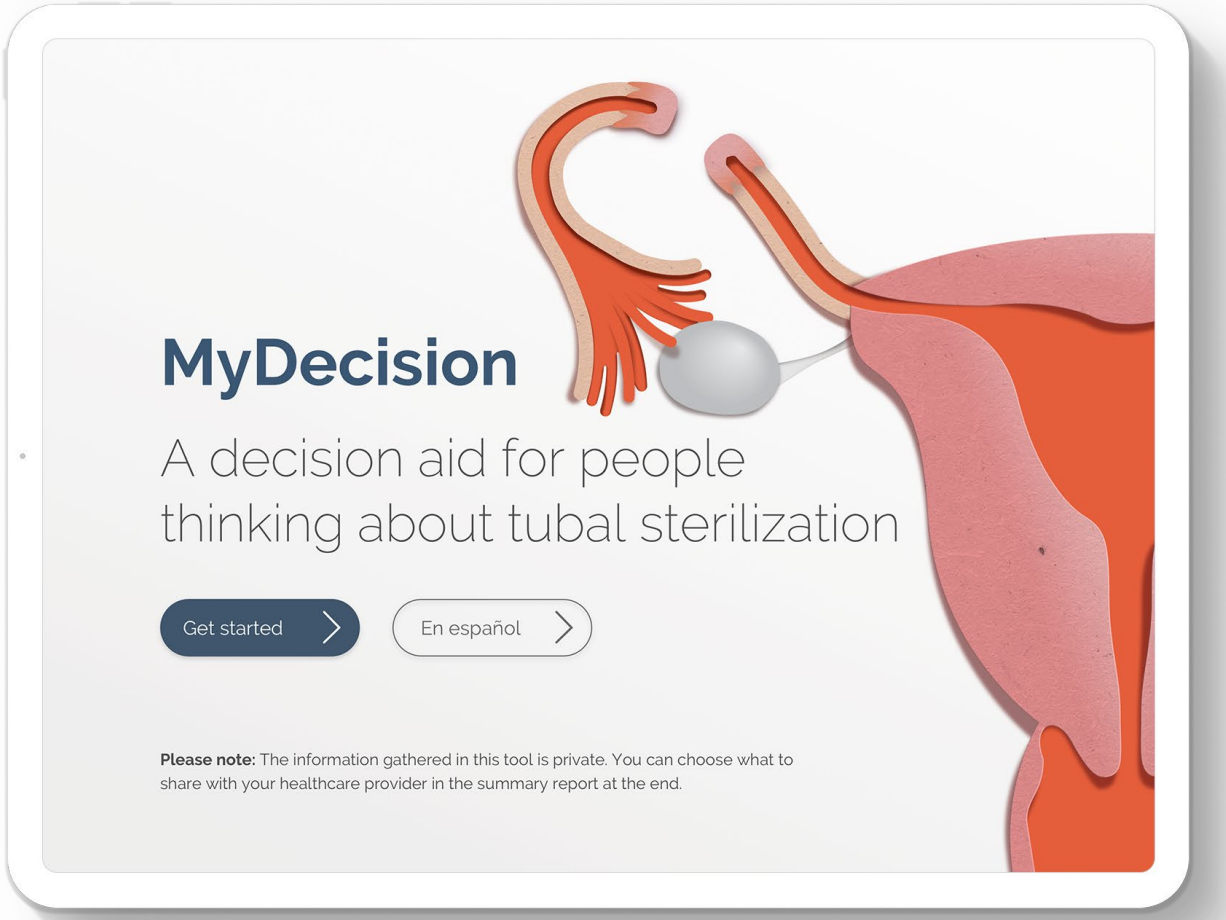
Unfulfilled sterilization requests are costly

- Decision tree model constructed from the health care payer perspective
- Compared the incremental cost of the current policy (no change since 1976/2013) with that of a hypothetical policy that maximized access to post-partum sterilization
- An ideal policy could:
  - **save $215 million/ year**
  - **Averting 29,000 unintended pregnancies/ year**

Contraception 2013/ NEJM 2014

MY DECISION/MI DECISIÓN DEVELOPMENT

- Informed by in-depth interviews with:
  - People living on lower incomes who had or had considered tubal sterilization
  - OBGYNS who perform tubal sterilization
- Guidance from a multi-disciplinary steering committee comprising:
  - Providers
  - Social scientists
  - Reproductive justice advocates
  - People with lived experience
- Cognitive interviews and beta testing with potential end users

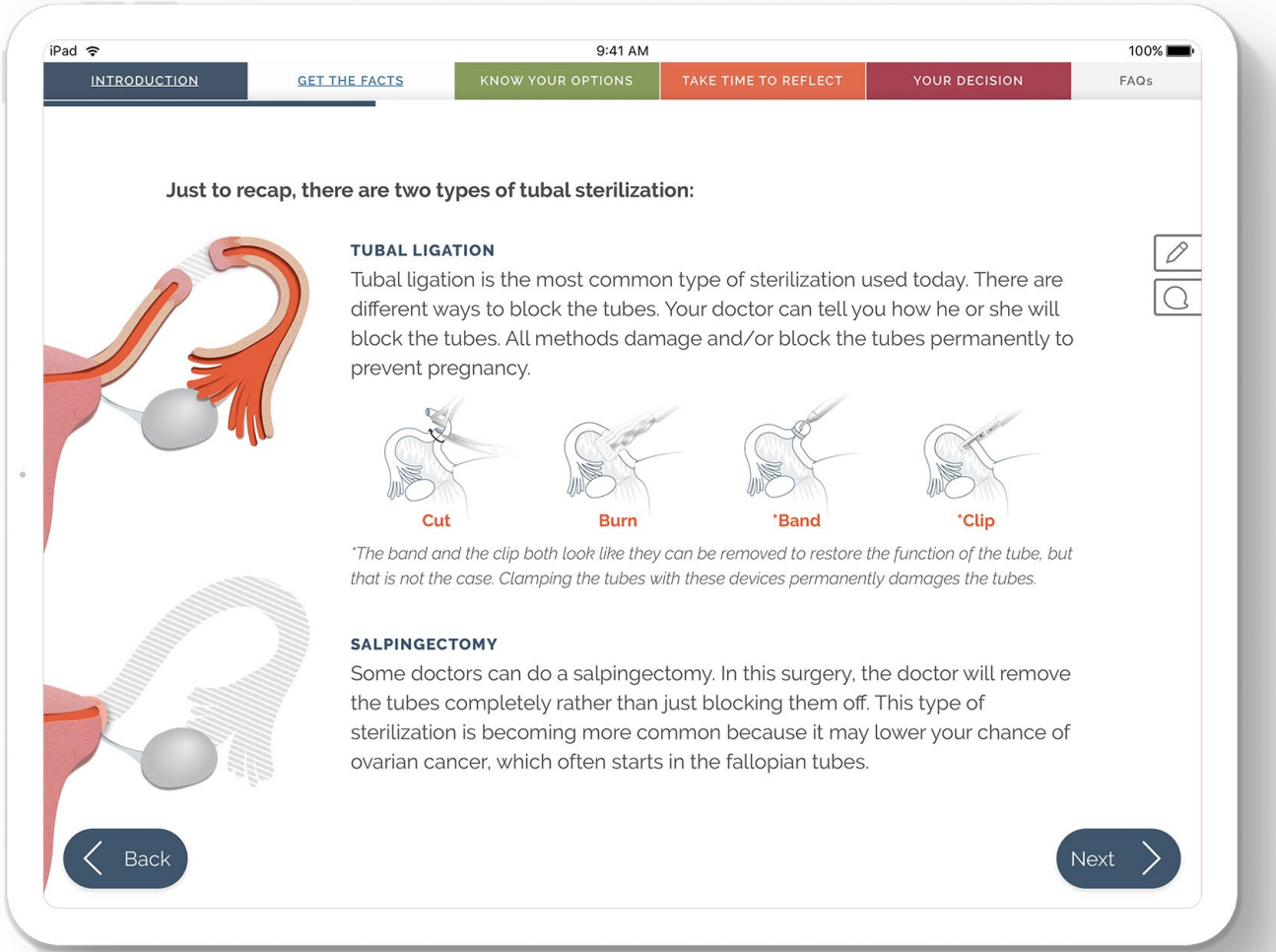


Mosley: *PEC Innovation*, 2023

THE TOOL

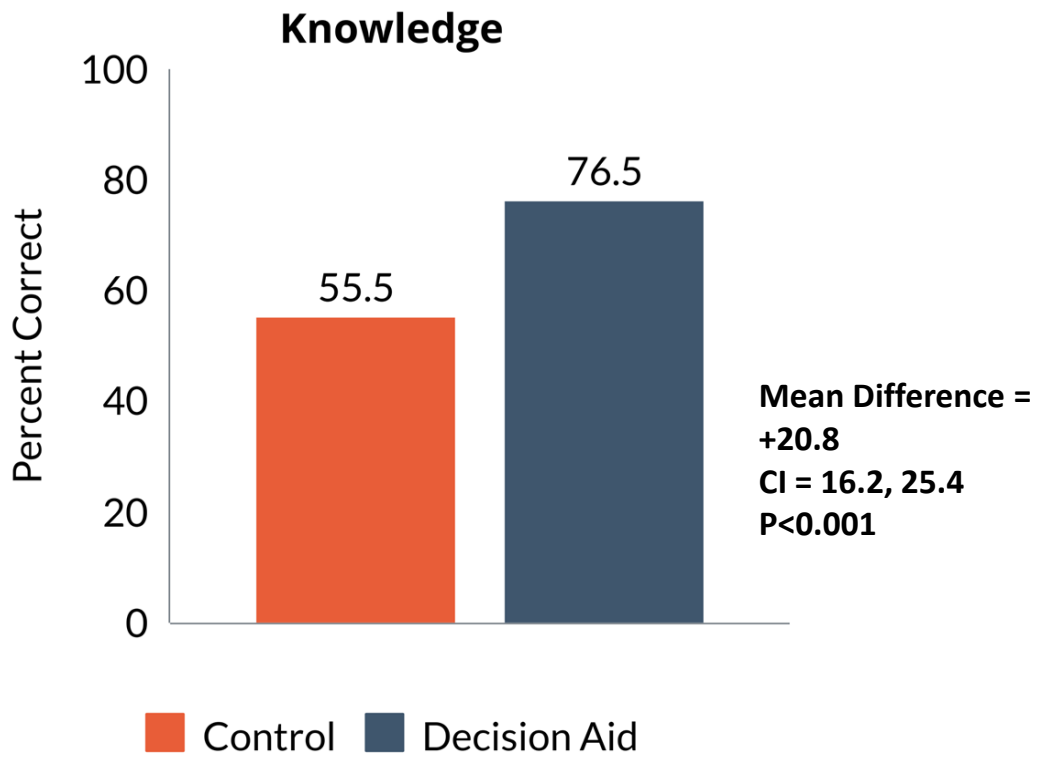
- The *My Decision/Mi Decision* tool includes:
  - written and video information about tubal sterilization procedures
  - an interactive table of contraception options
  - values clarification exercises
  - reflection and deliberation
  - knowledge checks
  - summary report (optional) to share with one's provider

- On average takes about 15 minutes to complete and patients overwhelmingly find the tool to be easy-to-use, informative, and valuable

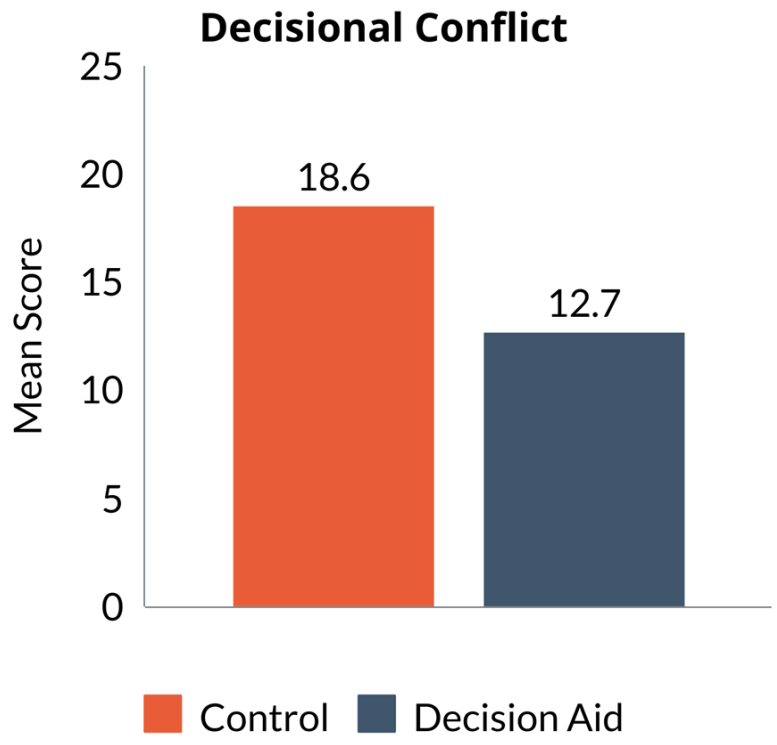


CONVERGE @Pitt
The Center for Innovative Research on Gender Health Equity

RESULTS – Time 1

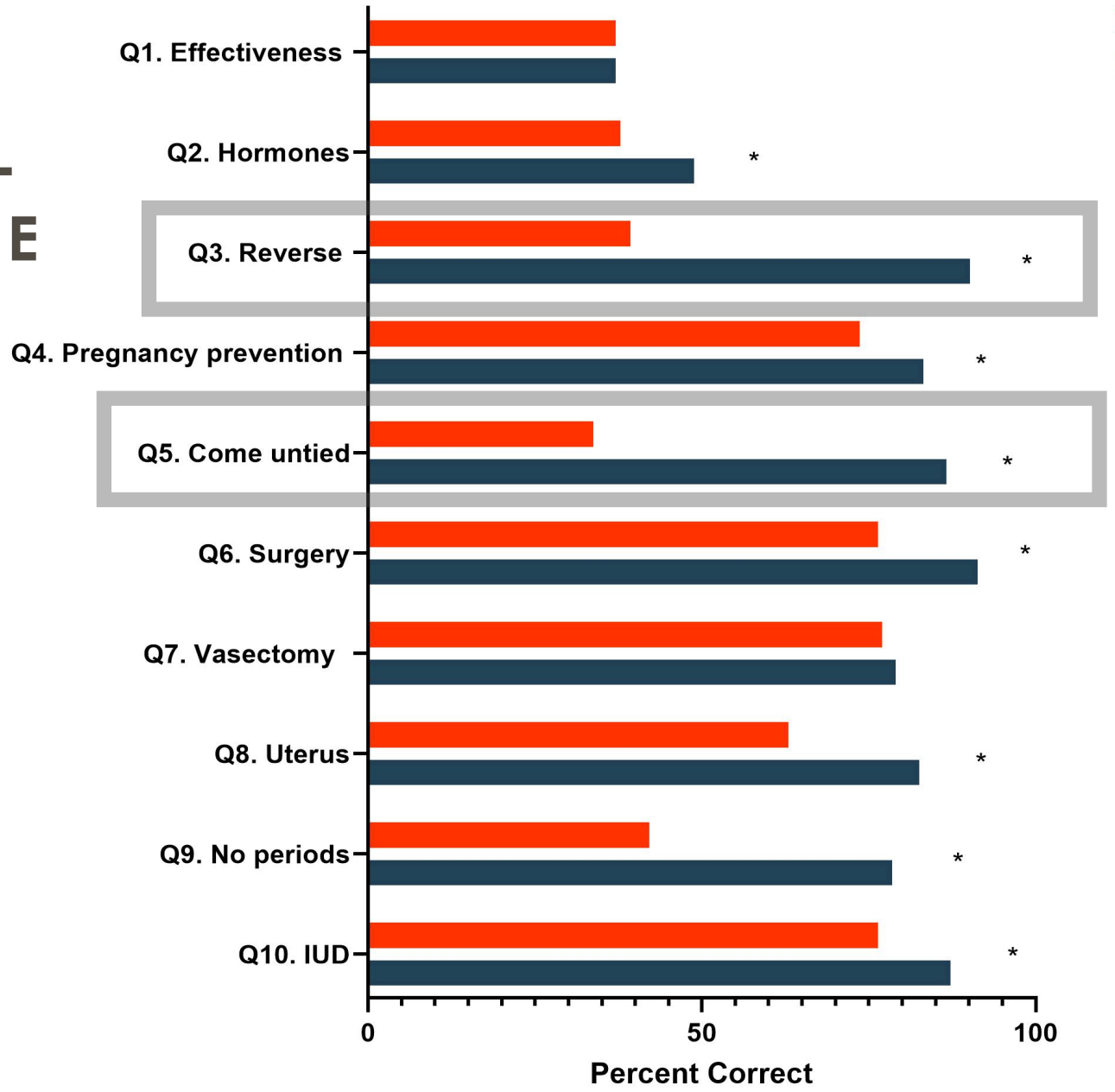


Mean Difference = +20.8
CI = 16.2, 25.4
P<0.001



Mean Difference = -5.77
CI = -10.0, -1.6
P<0.003

RESULTS: INDIVIDUAL KNOWLEDGE ITEMS

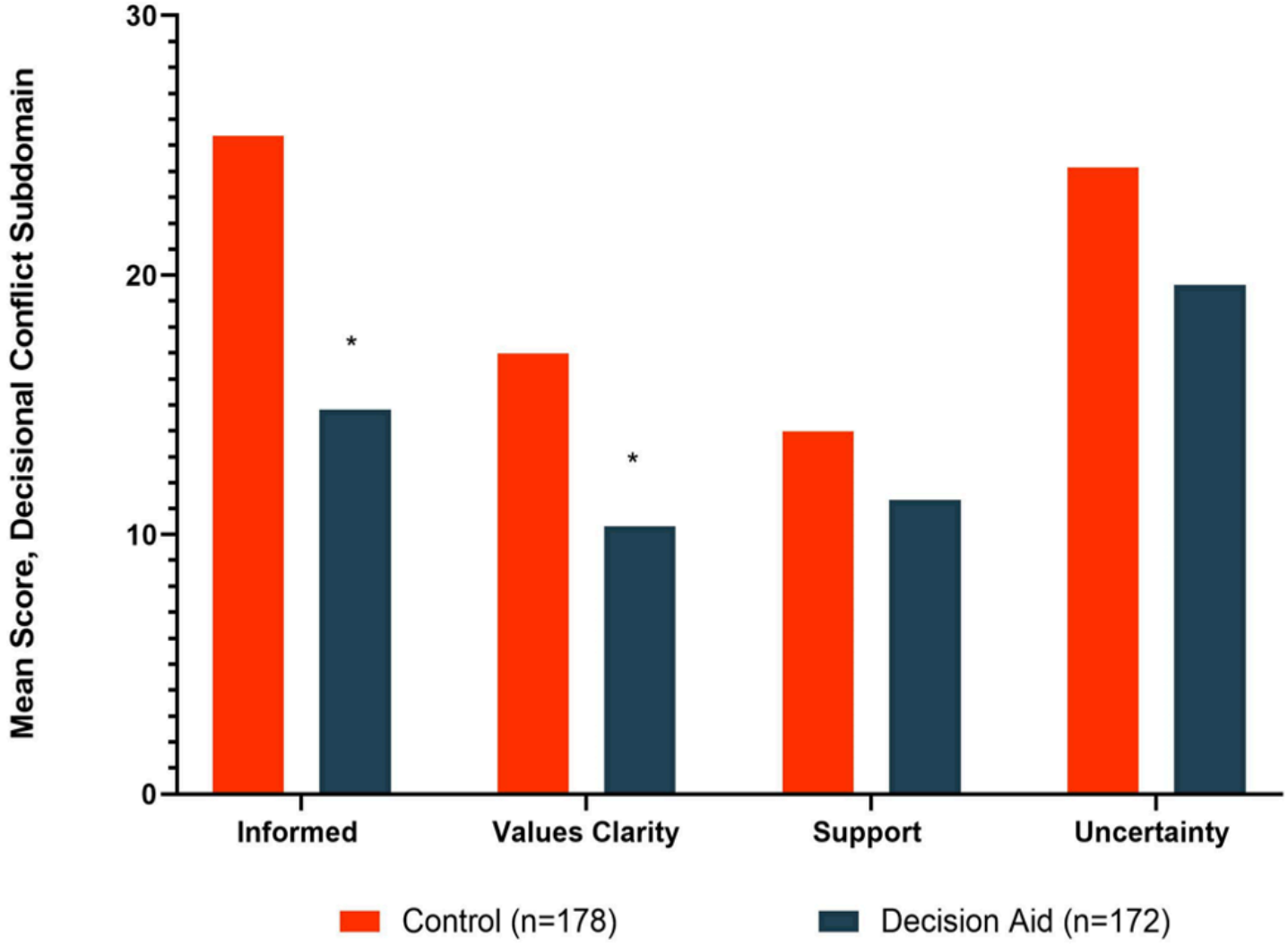


"After a woman has had her tubes tied, a doctor can easily reverse the procedure if she wants to get pregnant again." (90% vs 39%)

"After getting a tubal sterilization, the tubes are likely to come untied, grow back together, or unblock on their own." (87% vs 34%)

*Indicates a statistically significant difference between control and decision aid groups after adjustment for study site.

RESULTS: DECISIONAL CONFLICT SUBSCALES



*Indicates a statistically significant difference between control and decision aid groups after adjustment for study site

Decision Aid Conclusion

- Compared to usual care alone, My Decision improved decision quality regarding tubal sterilization in a sample of pregnant people enrolled in Medicaid
- The beneficial effects of the decision aid were observed across all age groups, racial/ethnic groups, education levels, sites, and for those who had and had not received provider counseling
- Findings underscore the potential of the decision aid to address observed challenges of provider counseling by offering an independent path to make informed and value-concordant decisions

JAMA NETWORK 2024 Mar4;7(3)

Vasectomy

- Office based
- Success higher than all but salpingectomy (with confirmation SA)
- Lower cost
- Lower complication risk

Summary

- Informed consent is more than the Medicaid form
  - Lots of misunderstanding
  - Vulnerable populations still utilize more often
    - Balance risk of regret, access to other methods and undesired pregnancy
- Movement towards Salpingectomy for permanent contraception
  - More effective, ovarian cancer risk reduction
- Vasectomy should always be part of discussion