Federally Funded Sterilization: Time to Rethink Policy?

In the 1970s, concern about coercive sterilization of low-income and minority women in the United States led the US Department of Health, Education, and Welfare to create strict regulations for federally funded sterilization procedures.

Although these policies were instituted to secure informed consent and protect women from involuntary sterilization, there are significant data indicating that these policies may not, in fact, ensure that consent is truly informed and, further, may prevent many low-income women from getting a desired sterilization procedure.

Given the alarmingly high rates of unintended pregnancy in the United States, especially among low-income populations, we feel that restrictive federal sterilization policies should be reexamined and modified to simultaneously ensure informed decision-making and honor women's reproductive choices. (*Am J Public Health*. 2012;102:1822–1825. doi:10.2105/AJPH.2012.300850)

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

FEMALE STERILIZATION HAS been a popular method of contraception since the 1970s. Despite the relatively high utilization of sterilization in the United States, there is considerable evidence that there is an unmet demand for the procedure among some segments of the US population.[1–5] In particular, low-income women may face significant system-level barriers to obtaining a desired sterilization procedure.[1,4–7] In this commentary, we argue that federal regulations on publicly funded sterilizations do not effectively serve their original purpose of ensuring informed consent and may even restrict women's reproductive autonomy. Given the unacceptably high rates of unintended pregnancy in this country, we feel that restrictive sterilization policies must evolve to address the current social need.

THE HISTORY OF SURGICAL STERILIZATION

Before the 1960s, the main reason for sterilization in the United States was either to prevent pregnancies with potentially severe medical consequences for the mother or to promote the eugenics movement. During the early 20th century, many states passed laws permitting involuntary sterilizations to advance eugenics principles. The main targets of these programs were women who were "mentally retarded" or otherwise considered "feebleminded."[8,9] At that time, sterilization was performed primarily using laparotomy, which carried a significant risk of morbidity and mortality. During the 1960s and 1970s, the birth control movement, the legalization of contraception, and the advent of safer, less invasive laparoscopic techniques brought about the use of elective sterilization as a method of contraception.

The US government played a significant role in the popularization of tubal sterilization during the 1970s by establishing family planning clinics and subsidizing payments for sterilization procedures.[10] However, numerous reports concerning coercive sterilization of minority and poor women began to emerge,[11–15] and a public outcry ensued alleging racist and classist applications of the federal family planning programs. In response, the Department of Health, Education, and Welfare developed protective regulations and a standardized consent form for all publicly funded sterilizations in 1976.[16] These regulations prohibited sterilization of persons younger than 21 years and of mentally incompetent or institutionalized persons and also required that women wait a minimum of 72 hours before sterilization. In 1978, the waiting period for sterilization was extended from 72 hours to 30 days between the time of written informed consent and the procedure, with exceptions for special circumstances such as preterm delivery and emergency abdominal surgery.[17]

FEDERAL REGULATIONS: DO THEY PROTECT OR IMPEDE CONTROL?

In compliance with the 1978 regulations, women currently requesting publicly funded sterilization must complete the "Consent to Sterilization" section of the Medicaid-Title XIX form (Title XIX-SCF) at least 30 days and no more than 180 days before undergoing the procedure. In addition, a signed copy of the consent form must be available or verified at the time of the procedure. In cases of premature delivery or emergency abdominal surgery, the 30-day waiting period requirement may be waived, but a minimum of 72 hours must have elapsed between the time of consent and the procedure. Although these policies were instituted to secure informed consent among low-income women and protect them from involuntary sterilization, there is significant data indicating that these policies may not, in fact, ensure that consent is truly informed and, further, may pose significant barriers to desired sterilization.

Although the current Title XIX-SCF includes language to confirm understanding of the risks, benefits, alternatives, and permanent nature of the procedure as well as information about the mandatory 30-day waiting period (Figure 1), readability and processability assessments indicate that the form is quite complex and significantly above the average literacy skills of American adults.[18] Women most likely to undergo publicly funded sterilization—low-income and minority women—are at particularly high risk for having average or below average health literacy skills.[19] Although it is unlikely that women sign the Title XIX-SCF form without counseling by a provider, data examining sterilization knowledge among women who had already undergone the procedure revealed a startlingly high level of misinformation, including misunderstandings about the

LDSS-3134 (2/01)

STERILIZATION CONSENT FORM

PATIENT NAME	CHART NO.	RECIPIENT ID NO.
HOSPITAL/CLINIC		

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 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 A.F.D.C. 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 know as a _____. 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 thirty 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 _____ Month Day Year

I, _____, hereby consent of my own free will to be sterilized by _____ (Doctor)

by a method called _____. 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, Education, and Welfare or Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

_____ Signature Date: _____ Month Day Year

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)

☐1 American Indian or Alaska Native ☐ 4 Hispanic

☐2 Asian or Pacific Islander ☐ 5 White (not of Hispanic origin)

☐3 Black (not of Hispanic origin)

■ 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 _____ Date

■ STATEMENT OF PERSON OBTAINING CONSENT ■

Before _____ Name of Individual signed the consent form, I explained to him/her the nature of the sterilization 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 knowlingly and voluntarily requested to be sterilized and appears to understand the nature and consequence 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 to be sterilized on _____ Date of sterilization, I explained to him/her the _____ Operation nature of the sterilization operation _____ Specify type of operation, the fact that it is intended to be a final 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 a 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 paragraphs: 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 thirty days have passed between the date of the individual's signature on this consent form and the date sterilization was performed.

(2) This sterilization was preformed 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 and fill in information requested):

☐ 1. Premature delivery
Individual's expected date of delivery: _____

☐ 2. Emergency abdominal surgery: _____
(describe circumstances): _____

_____ Physician _____ Date

THE FOLLOWING MUST BE COMPLETED FOR STERILIZATIONS PERFORMED IN NEW YORK CITY -- WITNESS CERTIFICATION

I, _____ (patient's name) do certify that on _____ I was present while the counselor read and explained the consent form to _____ and saw the patient sign the consent form in his/her handwriting.

SIGNATURE OF WITNESS	TITLE	DATE
X		

REAFFIRMATION (to be signed by the patient on admission for Sterilization)

I certify that I have carefully considered all the information, advice and explanations given to me at the time I originally signed the consent form. I have decided that I still want to be sterilized by the procedure noted in the original consent form, and I hereby affirm that decision.

SIGNATURE OF PATIENT	DATE	SIGNATURE OF WITNESS	DATE
X		X	

DISTRIBUTION: 1 – Medical Record File 2 – Hospital Claim 3- Surgeon Claim 4 – Anesthesiologist Claim 5 – Patient

FIGURE 1—Medicaid-Title XIX sterilization consent form: valid in 2012.

permanence of the procedure and ease of reversibility, suggesting that providers do not always do an adequate job of ensuring patient understanding.[20]

When a modified, low-literacy version of the Title XIX-SCF was compared with the current Title XIX form in a randomized trial with more than 200 women recruited from a general obstetrics and gynecology residency clinic waiting room, those in the modified consent group were found to be statistically more likely to understand the length of time required for the form to be valid, the time interval before expiration, and that nonpermanent contraceptive options as effective as sterilization are available, as assessed using the validated Postpartum Tubal Sterilization Knowledge Questionnaire.[21,22] Most notably, 81% of participants in the modified consent group correctly answered a question about the permanence of the procedure compared with 65% in the standard consent group ($P < .1$). Although patient-related content presented on both the standard and modified consent forms was essentially the same as the current Title XIX-SCF, which is written at a high school reading level, the modified version was written at the sixth grade level and met established guidelines for optimal formatting to enhance ease of reading, including using at least a 12-point font and more white space.[23,24] At the end of the study, all participants were given a copy of both versions of the consent to compare and contrast, and when asked which version of the consent they would prefer to use, 94% selected the modified version.

Given the high prevalence of poststerilization regret (up to 30% in some populations, including minority women and those younger than 30 years at the time of

the procedure),[25–27] the observation that regret is associated with preoperative misunderstanding of the permanence of the procedure and ease of reversibility,[28] studies that indicate that such misunderstandings are not uncommon,[20,22] and evidence that clinicians may not be particularly skilled at ensuring informed consent,[29–33] there is a need to ensure that sterilization consent forms effectively convey basic information (i.e., the permanent nature of the procedure). However, the existing data raise concerns about the current Title XIX-SCF's ability to do this effectively and, therefore, ensure informed consent.

Moreover, there are substantial data indicating that policies related to the Medicaid consent form have prevented a number of low-income women from getting a desired sterilization procedure.[1,4–7] In both quantitative and qualitative studies, women commonly report that requesting sterilization too late in pregnancy to fulfill the 30-day waiting period, not having the form available at delivery, or delivering before the waiting period had elapsed prevented them from having their sterilization requests fulfilled.[1,4–7]

Preventing women from using their contraceptive method of choice may put them at particularly high risk of unintended pregnancy. In one study, nearly half of all women who requested but did not obtain a postpartum sterilization became pregnant in the year following the index delivery, and this rate was significantly higher than among those women who did not request sterilization after their delivery (47% vs 22%; $P \leq .001$).[34] This is particularly concerning not only because many of these pregnancies were presumably unwanted (although this was not specifically assessed in the study) but also because short interpregnancy intervals are associated with adverse perinatal outcomes, including low birth weight, preterm birth, and infant mortality.[35,36]

Furthermore, there are no data indicating that the 30-day waiting period has prevented sterilization abuses or poststerilization regret, although we recognize that these associations are difficult to assess. In a study using nationally representative data, compared with women with private insurance, women with public or no insurance (who are likely to have had to sign the Title XIX consent form, although this was not assessed in the data set) were significantly more likely to express regret in unadjusted analysis (odds ratio [OR] = 2.0; 95% confidence interval [CI] = 1.2, 3.2) and trended toward higher regret in adjusted analysis although the odds did not reach statistical significance (OR = 1.4; 95% CI = 0.8, 2.5).[25]

In two different qualitative studies among women who had undergone or wanted sterilization, women reported that in addition to system-level barriers (lack of timely consent, absence of consent papers at time of delivery, and Catholic hospital prohibitions on sterilization), their providers acted as a barrier to getting a desired sterilization.[1,6] Many women reported that their doctors attempted to dissuade them from sterilization and in some cases simply refused to do the procedure, citing their young age or low parity as too highly correlated with subsequent regret.[1,6] Women felt that such system- and provider-level barriers thwarted their reproductive autonomy.[6] When women ask for sterilization, it is incumbent on providers to explore the social and psychological factors influencing the request (including who may be influencing her decision) and to make sure they understand the permanence of the procedure, the risk of complications including failure, the potential psychological consequences of permanently ending childbearing capacity including regret, and the availability of other long-acting, reversible methods, but then assist them in getting the procedure if they so choose.

Given that sterilization is a preference-driven decision and that each woman's knowledge base, sociocultural circumstances, and contraceptive experience is unique, presterilization counseling should vary according to individual patient context. To this end, the development of a female sterilization decision aid to ensure that patients receive high-quality, comprehensive information and make decisions that align with their personal values and goals may be helpful. Compared with usual care, decision aids have been shown to be helpful in increasing knowledge, producing more realistic expectations of potential risks and benefits, reaching decisions that are more congruent with values, increasing patient participation in decision-making, and reducing decisional conflict across a wide range of medical decisions, including for vasectomy decision-making.[37,38]

CONCLUSIONS

Although concerns about sterilization abuses are pertinent and important, so is the alarmingly high rate of unintended pregnancy in this country. We think that measures to promote informed sterilization decision-making, rather than stringent and restrictive policies for federally funded sterilizations, will prevent coercive practices as well as unintended pregnancy among low-income populations who are at risk. To this end, we feel that the current Medicaid-Title XIX sterilization consent form needs to be redesigned so that the pertinent information is presented in an easier-to-read, user-friendly format or replaced altogether by a validated decision aid that can more effectively ensure informed decision-making. We also feel that 30-day waiting periods are excessive and should be shortened significantly or eliminated. ■

About the Authors

Sonya Borrero is with the Department of Medicine and the Center for Research on Health Care at the University of Pittsburgh, Pittsburgh, PA. Nikki Zite is with the Department of Obstetrics and Gynecology at the University of Tennessee Graduate School of Medicine, Knoxville. Mitchell D. Creinin is with the Department of Obstetrics and Gynecology, University of California, Davis.

Correspondence should be sent to Sonya Borrero, MD, University of Pittsburgh, Center for Research on Health Care, 230 McKee Pl., Suite 600, Pittsburgh, PA 15213 (e-mail: borrerosp@upmc.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

This commentary was accepted April 5, 2012.

Contributors

S. Borrero conceptualized the idea and led the writing of this article. All authors contributed to critical revisions.

Acknowledgments

This article was made possible by the National Center for Research Resources (NCRR), a component of the National Institutes of Health ([NIH] grant 1 KL2 RR02415403 to S. B.) and NIH Roadmap for Medical Research.

Note. The content of this publication is solely the responsibility of the authors and does not necessarily represent the official view of NCRR or NIH.

References

1. Potter JE, White K, Hopkins K, et al. Frustrated demand for sterilization among low-income Latinas in El Paso, Texas. Paper presented at the Annual Meeting of the Population Association of America, Session 21, "On the Border: Understanding Family Planning;" March 31-April 2, 2011; Washington, DC.

2. Thurman AR, Harvey D, Shain RN. Unfulfilled postpartum sterilization requests. *J Reprod Med.* 2009;54(8):467–472.

3. Zite N, Wuellner S, Gilliam M. Failure to obtain desired postpartum sterilization: risk and predictors. *Obstet Gynecol.* 2005;105(4):794–799.

4. Zite N, Wuellner S, Gilliam M. Barriers to obtaining a desired postpartum tubal sterilization. *Contraception.* 2006;73(4):404–407.

5. Davidson A, Philliber S, Graves W, Rulin M, Cushman L. Sterilization decision making and regret: the determinants and consequences of unfulfilled sterilization plans. Paper presented at the Annual Meeting of the Population Association of America; May 3-5, 1990; Toronto, ON, Canada.

6. Borrero S, Nikolajski C, Rodriguez KL, Creinin MD, Arnold RM, Ibrahim SA. "Everything I know I learned from my mother. . . or not": perspectives of African-American and White women on decisions about tubal sterilization. *J Gen Intern Med.* 2009;24(3):312–319.

7. Gilliam M, Davis SD, Berlin A, Zite NB. A qualitative study of barriers to postpartum sterilization and women's attitudes toward unfulfilled sterilization requests. *Contraception.* 2008;77(1):44–49.

8. Rafter N. Claims-making and sociocultural context in the first U.S. eugenics campaign. *Soc Probl.* 1992;39(1):17–34.

9. Schoen J. Between choice and coercion: women and the politics of sterilization in North Carolina, 1929–1975. *J Womens Hist.* 2001;13(1):132–156.

10. Shapiro TM, Fisher W, Diana A. Family planning and female sterilization in the United States. *Soc Sci Med.* 1983; 17(23):1847–1855.

11. *Relf v. Weinberger,* Civ. a. Nos. 73-1557 (DC 1973).

12. American Civil Liberties Union. Reproductive Freedom Project, American Civil Liberties Union Foundation Legal Docket, June 18. Seeley G. Mudd Manuscript Library, Princeton University, box 387, folders 14, 15; 1980.

13. Schoen J. *Choice and Coercion: Birth Control, Sterilization, and Abortion in Public Health and Welfare.* Chapel Hill: University of North Carolina Press; 2005.

14. Washington H. *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans From Colonial Times to the Present.* New York, NY: Doubleday; 2006.

15. *Cox v Stanton,* 381 F Suppl 349 (1974).

16. US Department of Health, Education, and Welfare. 42 Code of Federal Regulations. 441.257; 1976.

17. US Department of Health, Education, and Welfare. 42 Code of Federal Regulations. 441.253; 1978.

18. Zite NB, Philipson SJ, Wallace LS. Consent to sterilization section of the Medicaid-Title XIX form: is it understandable? *Contraception.* 2007;75(4):256–260.

19. National Center for Education Statistics. *National Assessment of Adult Literacy: A First Look at the Literacy of America's Adults in the 21st Century;* 2005. NCES Publication No. 2006470.

20. Borrero S, Abebe K, Dehlendorf C, et al. Racial variation in tubal sterilization rates: role of patients-level factors. *Fertil Steril.* 2011;95(1):17–22.

21. Zite NB, Wallace LS. Development and validation of a Medicaid Postpartum Tubal Sterilization Knowledge Questionnaire. *Contraception.* 2007;76(4):287–291.

22. Zite NB, Wallace L. Use of a low-literacy informed consent form to improve women's understanding of tubal sterilization: a randomized controlled trial. *Obstet Gynecol.* 2011;117(5):1160–1166.

23. Doak C, Doak L, Root J. *Teaching Patients With Low Literacy Skills.* 2nd ed. Philadelphia, PA: J.B. Lippincott; 1996.

24. Centers for Disease Control and Prevention. *Simply Put: A Guide for Creating Easy-to-Understand Materials.* Atlanta, GA: Strategic and Proactive Communication Branch, Division of Communication Services; 2010.

25. Borrero SB, Reeves MF, Schwarz EB, Bost JE, Creinin MD, Ibrahim SA. Race, insurance status, and desire for tubal sterilization reversal. *Fertil Steril.* 2008;90(2):272–277.

26. Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol.* 1999;93(6):889–895.

27. Schmidt JE, Hillis SD, Marchbanks PA, Jeng G, Peterson HB. Requesting information about and obtaining reversal after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Fertil Steril.* 2000;74(5):892–898.

28. Moseman CP, Robinson RD, Bates GW Jr, Propst AM. Identifying women who will request sterilization reversal in a military population. *Contraception.* 2006;73(5):512–515.

29. Brezis M, Israel S, Weinstein-Birenshtock A, Pogoda P, Sharon A, Tauber R. Quality of informed consent for invasive procedures. *Int J Qual Health Care.* 2008;20(5):352–357.

30. Leclercq WK, Keulers B, Scheltinga M, Spauwen P, van der Wilt G. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World J Surg.* 2010;34 (7):1406–1415.

31. Touqmatchi D, Boret T, Nicopoullous J. The quality of operative consenting against RCOG advice as standard. *J Obstet Gynaecol.* 2010;30(2):159–165.

32. Braddock CH 3rd, Edwards K, Hasenberg N, Laidley T, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA.* 1999;282(24):2313–2320.

33. Braddock CH 3rd, Fihn S, Levinson W, Jonsen A, Pearlman R. How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. *J Gen Intern Med.* 1997;12(6):339–345.

34. Thurman AR, Janecek T. One-year follow-up of women with unfulfilled postpartum sterilization requests. *Obstet Gynecol.* 2010;116(5):1071–1077.

35. Institute of Medicine. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: National Academies Press; 2011.

36. Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta A. Birth spacing and risk of adverse perinatal outcomes—a meta-analysis. *JAMA.* 2006;295(15):1809–1823.

37. Labrecque M, Paunescu C, Plesu I, Stacey D, Legare F. Evaluation of the effects of a patient decision aid about vasectomy on the decision-making process: a randomized trial. *Contraception.* 2010;82:556–562.

38. Stacey D, Bennett C, Barry M, et al. *Decision Aids for People Facing Health Treatment or Screening Decisions.* Cochrane Database of Systematic Reviews; 2011:10. Article No. CD001431.