Federally Funded Sterilization: Time to Rethink Policy?

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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. In particular, low-income women may face significant system-level barriers to obtaining a desired sterilization procedure. 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.” 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. However, numerous reports concerning coercive sterilization of minority and poor women began to emerge, 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. 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.

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. 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. 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...
permanence of the procedure and ease of reversibility, suggesting that providers do not always do an adequate job of ensuring patient understanding.\textsuperscript{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, assessed using the validated Postpartum Tubal Sterilization Knowledge Questionnaire.\textsuperscript{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.\textsuperscript{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.

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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%; \(p \leq 0.001\)). \(^{24}\) 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. \(^{25,36}\)

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. \(^{37,28}\)

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.