

Policy and Ethical Obligation for Postpartum Sterilization

Abstract

Underserved women face many barriers in their attempt to access postpartum tubal ligation as a means of contraception. The Federal policy regarding Medicaid sterilization funding hinders these women from exercising the same degree of reproductive healthcare autonomy as their more socio-economically advantaged counterparts.

The two main barriers are

- 1) The Medicaid form must be signed 30-180 days prior to the procedure and brought to the hospital on the procedure day and
- 2) The reading level and design of the consent form is not appropriate for the patient population.

In addition to the consent form that needs to be signed and verified before the procedure, other barriers include the age of the woman, in which some hospitals restrict sterilization procedures to woman who are more than 30 years of age, even though Medicaid funds sterilization for woman over 21 years of age. Additional restrictions arise when obstetric care is provided by Catholic affiliated hospitals where sterilization is not permitted, and any health care institution reporting a shortage of operating room facilities or resources. We suggest there is urgent need to revise Federal sterilization regulations in support of clinical and legal practice that adheres to ethical standards of medical practice.

Keywords: Access to Postpartum Sterilization; Contraception; Contraceptive Counseling; Ethics; Federal Medicaid Title XIX; Federally Funded Sterilization; Healthcare Justice; Health Policy; Medicaid Policy on Sterilization; Medicaid sterilization Consent Regulations; Medicaid Sterilization Consent Regulations; Medicaid XIX Sterilization Consent Form (XIX-SCF); Postpartum Bilateral Tubal Ligation; Postpartum Contraception; Postpartum IUD placement; Postpartum Period; Postpartum Sterilization Legislation; Tubal Sterilization; Unfulfilled Sterilization; Underserved Women

Opinion

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Introduction

Unintended pregnancies are associated with increased rates of perinatal morbidity and mortality and result in children who are likely at risk for developmental delays [1-6]. The direct costs of unintended pregnancies to the healthcare system are reported to be in the billions of dollars each year [1,2,7] and therefore, family planning is important.

The minority groups make up 60% of the Medicaid recipients, 51% of this group identify them-selves as being African American or Hispanic. Data from the National Survey of Family Growth from 2006-2010 was used to analyze the outcomes among different women over the age of 21 the outcome for women over the age of 21, who were having at least their second child and who were publically versus privately insured. 20,497 births from 2006-2010 data illustrated that white women with Medicaid insurance, were more likely to receive PPTS (postpartum tubal sterilization) in comparison to African Americans or Hispanics. However, African Americans and Hispanics who were privately insured were more likely to receive requested PPTS.

Women who have postpartum tubal sterilization are more likely to be a documented U.S. resident, married, of lower parity, have private or any medical insurance and received prenatal care [8]. Annually, there are 62,000 unfulfilled requests for the women who wanted postpartum tubal ligation, which leads to a reported 29,000 unintended pregnancies that resulted in 10,000 abortions and 19,000 unintended births.. This is estimated to cost society 215 million dollars a cost that could be significantly reduced by revising the Medicare policy [9,10].

A discussion with the family explaining the risks, benefits, and alternatives to sterilization is an important conversation when postpartum sterilization is desired. The next most important discussion is about the patient's insurance. Those who have Medicaid are required to complete a "Consent to Sterilization" from the section Medicaid Title XIX form at least 30 days and no more than 180 days prior to undergoing the procedure. This consent imposes a barrier to patients who desire permanent sterilization [1,2,4,11,12]. In comparison "Women who have private insurance are allowed to consent for tubal ligation at anytime, including active labor," which violates the principle of

autonomy since the underserved women are unable to make an independent decision [11].

Brief history

Sterilization has been a part of society for centuries beneficent sterilization could facilitate avoidance of a pregnancy by women affected by a life-threatening illness, which could be associated with significant perinatal morbidity and mortality. Regrettably, some sterilization procedures were used by eugenicists to prevent procreation by those believed to be “unfit”, intellectually deficient people, mentally ill individuals and interracial couples [3,13].

One example occurred in California between 1971 and 1974 when health care providers coerced 10 Mexican-American women to submit to sterilization procedures. During the litigation proceedings, these women testified against the hospital stating that the hospital staff pressured them to agree to become sterilized while they were in labor. The cause was attributed to the patients’ limited ability to speak English. This, among other similar cases, led to a revision of the sterilization guidelines that required consents be written in the patient’s preferred language and not obtained during labor or within 24 hours of delivery [14]. These consent revisions were enacted in 1978, which paved the way for Federal legislation resulting in creation of the present day Medicaid Title XIX sterilization regulations.

Current

Female sterilization is the second most popular form of contraception and is the most commonly used method by married women over 30 years of age [15]. Postpartum sterilization is a fairly routine procedure. Postpartum sterilization is performed after 10% of all hospital deliveries [1,16]. However, only 50% of those who reported electing to have postpartum sterilization actually had the procedure performed [1,17,18].

A cohort study conducted in 2010, discovered that nearly 47% became pregnant within a year of their index delivery [5]. A conversation about planning future pregnancies is important, because short inter-pregnancy interval, less than 18 months between deliveries, is associated with adverse perinatal outcome. Reported reasons for not performing the planned postpartum procedure included, lack of available operating rooms and/or anesthesia, receiving care in a religiously affiliated hospital, lack of Medicaid Title XIX mandated consent document and provider concern that patients with low parity or less than 30 years of age and may regret their decision to be sterilized [16]. Provider concerns about subpopulation regret continue to persist, even though most women voiced no regret after postpartum sterilization [1,3].

Summary of the current Title XIX consent for sterilization [1,3,7,12,19]

- i. Federal funds cannot be used to cover the sterilization costs for individuals who are under 21 years of age, institutionalized, or mentally incompetent.
- ii. The consent must be signed between 30 and 180 days before the procedure is performed.

- iii. The original or copy of the signed consent form must be present or verified before the procedure is performed.
- iv. Exemption for the 30-day wait period is made in case of emergency or premature delivery. However, for these unexpected deliveries there remains a required 3-day waiting period after the consent was signed before the procedure is performed.

Not complying with any of the Title XIX is often barrier to having the desired postpartum sterilization performed [2,3]. Producing a copy of the valid consent form may be complicated by delivery occurring at times when ambulatory sites are closed. Even though patients are often provided a copy of the consent form, it may have been forgotten amidst urgent travel to the hospital or misplaced which may be a particular relevant barrier for women who are homeless. These situations are a source of frustration for the clinician and patient who may know the appropriate measures have been taken but do not have access to the necessary documentation.

Only 12.8% to 20.3 % of publicly insured women attend their postpartum clinic appointments [5]. The low attendance percentages correlated with the unintended short pregnancy intervals that appear to be related to the human error and technical complications associated with the Title XIX sterilization consent form regulation [5].

Obstacles underserved women face to access postpartum sterilization [1-5,9,18]

Sterilization is not permitted in catholic health institutions, one of the largest health nonprofit institutions in the United States [1,3,4,6,19]. These factors combined with the time limitation of 30 to 180 days during which the signed consent is valid and the frequent limited access to operation room facilities and anesthesia to be reasons postpartum sterilizations were not performed [1,3].

Temporal solution for underserved women

Until the Medicaid policy is modified or changed, underserved women may have few options for reliable long-term methods of postpartum contraception. Postpartum intrauterine devices or contraceptive implants might be viable options. As ACOG Practice Bulletin No. 121 and Cochrane Database of Systematic Reviews describe: Immediate postpartum IUD insertion seems safe and effective [20,21]. Post-placental delivery insertion and insertion between 10 minutes and 48 hours after delivery results in higher expulsion rates than after 6 weeks postpartum which could be as high as 24 % [20-22]. However, some investigators have reported that benefits of immediate postpartum insertion may outweigh the risk of expulsion [20-24]. Another recent review article provides evidence that insertion of an intrauterine contraceptive within the first 48 hours of vaginal or caesarean delivery is safe and effective [25].

Contraception implants are safe, highly effective and can be used long-term (3 years). Insertion of the implant has been reported to be safe at any time in non-breastfeeding women after childbirth. However, several studies showed no differences

in rates of breastfeeding success with contraception implant between 1-3 days versus the standard 4-8 weeks postpartum insertion, including lactogenesis, which is the risk of lactation failure or an impact on infant health [26-28].

Moral & ethical mandate obligation

Federal Medicaid Title XIX was created to foster greater equality between those with government insurance and those with private insurance. The law is the same today as it was when it was created in 1978, but the population has changed. Medicaid Title XIX family planning regulations are doing the opposite of its original purpose; it is restricting underserved women access to appropriate reproductive healthcare and thus violating the basic principles of medical ethics, autonomy, beneficence, nonmaleficence, and justice [1,3,11,10,29,30].

The 30 day waiting period violates the 4 principles of medical ethics:

- a) Autonomy-limiting women's free choice of contraception methods.
- b) Beneficence and nonmaleficence - preventing women's from accessing family planning services.
- c) Justice- treating privately insured women differently than publicly insured underserved women.

The four pillars of ethics do not currently apply to postpartum sterilization of underserved women. The 30-day mandatory waiting period for tubal sterilization instilled by Medicaid, creates a burden on women to produce the required consent forms at the time of delivery. Nonetheless, in most jurisdictions the same burden does not apply to underserved women who are privately insured; these women are able to consent to tubal sterilization at any time, even at active labor [11]. The burden only applies to women who are funded by federal insurance often implying minority and poorer individuals. The notion that poorer underserved women are not able to make their own choice on tubal sterilization at the time of delivery violates autonomy as well as justice standards. According to the National Survey of Family Growth, 69% of unintended pregnancies were among African American women and 54% were among Hispanic women compared to only 20% among White women [31] Low economic status as well as education was also associated with an increase in unintended pregnancies; "62% of pregnancies were unintended among those earning <100% of the Federal Poverty Level (FPL), compared to 38% of pregnancies in those earning >200% of the FPL" [31]. However, in New York City, the 30 day sterilization consent form applies to everyone, including men and women, as well as those privately and publicly insured.

Thus a multi-class reproductive healthcare delivery system is created, which limits contraception options to one group. In doing so, this system violates the fundamental basic ethical rights of recipients of public health insurance to have access to postpartum sterilization procedures [1-3, 11,12,29,30].

Zite and her colleagues had several publications regarding the Medicaid Title XIX, which concludes that the Federal consent form

is neither readable nor understandable [32-35]. As a result, the consent form has been simplified for everyone, regardless of their language and reading level. To address these deficiencies, Zite [15] conducted a randomized controlled trial of a low-literacy version of the consent form and found it increased understanding of sterilization [36].

We join other commentators who recommend a modification of the Title XIX consent regulations [1,3,12]. In the American Journal of Obstetrics & Gynecology written by Moaddab & McCullough et al. [35] the 30- day mandatory waiting period for elective tubal ligation for Medicaid beneficiaries is addressed. The discrepancies between recipients of private versus public insurance violates the concept of health care justice, which protects the informed consent process as well providing clinical management to all patients based on their clinical needs [10].

Darney [37] supports the notion that the concept of justice is violated by 30-day waiting period for women with Federally funded insurance that prevents access to sterilization that are available to women (or men) who are self pay or have private insurance [38]. We add our voices to other authors and authority to stress the critical need to revise regulations concerning the XIX sterilization consent form requirements [1-3,39-42].

Conclusion [1-3,39-44]

We suggest the following to address the reproductive health care barrier:

- a. Mandatory comprehensive informed consent prior to sterilization that includes an explanation of the procedure's risks, benefits and alternative procedures.
- b. Rapid retrievable sterilization consents and secure accessible site. In the Internet era, national access to a drive with data base containing signed Federal sterilization forms is realistic and can eliminate the necessity for patient to produce a hard copy of the consent form.
- c. Since a valid Title XIX consent form is time limited, it should be a hospital priority to ensure the procedure is done before discharge. Consideration should be given to scheduling the procedure in main operating room rather than convenience scheduling on the labor and delivery unit.
- d. As patient advocates all members of the intrapartum team, obstetric provider, nurses, anesthesiologist, should help overcome the barriers to the patient receiving requested reproductive health services.
- e. Modification of 30-day waiting period and 180-day expiration rules. We suggest that consideration should be given to restoring the original 7-day waiting period and having no expiration date for valid consent forms.

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The Authors did not report any potential conflicts of interest. The Authors have previously published a discussion focused on the ethical and legal issues surrounding this subject matter. This current submission is a review of the clinical consequences and

available interventions associated with the obstacles concerning federal sterilization regulation as they affect undeserved women, who are classified as having low social economic status, receive welfare, and/or have no insurance.

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