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Obstacles Underserved Women Face to Access Postpartum Sterilization: Ethical Obligation for Modification

Abstract

Postpartum tubal ligation is an effective, safe method of sterilization. Underserved women face many barriers in their attempt to access this time sensitive postpartum contraception. A major barrier for many of these women who are without the means of availing themselves of this procedure is the Federal policy regarding Medicaid sterilization funding.

The two main barriers are

a) The Medicaid form must be signed 30-180 days prior to the procedure and brought to the hospital on the procedure day and

b) The reading level and design of the consent form is not patient friendly.

Barriers enacted by Federal regulations may prevent disenfranchised women from exercising the same degree of reproductive healthcare autonomy as their more socio-economically advantaged counterparts. 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 on woman younger than 30, even though Medicaid funds sterilization for woman over 21, restrictions from Catholic affiliated hospitals where sterilization is not permitted, and the shortage of operating rooms and resources. We suggest change in clinical and legal practice fostered by revised Federal regulations is urgently needed to adhere 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

Commentary

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Introduction

Routine appointments to the obstetrician are often filled with excitement and anticipation of the birth of a new child. Amidst preparation for a healthy delivery, family planning is often a component of prenatal care. 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. 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]. Additionally, the direct costs of unintended pregnancies to the healthcare system are reported to be in the billions of dollars each year [1,2,7].

The ethnic makeup of Medicaid recipients is 60% are member of minority groups 51% of which identify them selves as being African American or Hispanic [8]. Researchers studied data from the National Survey of Family Growth from 2006-2010 analyzing women over the age of 21, who were having at least their second child, who were publically or privately insured. From the 20,497 births from 2006-2010, white women with Medicaid insurance, were more likely to receive PPTS than African Americans or Hispanics [9]. However, African Americans and Hispanics who were privately insured were more likely to receive requested PPTS. In 2002-2003 a retrospective chart review concluded that Medicaid-insured woman (46.7%) did not receive postpartum tubal sterilization (PPTS) compared with 42.7% of privately insured women; 37.3% of the Medicaid insured women did not receive the PPTS due to the lack of Medicaid consent form [10].

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 had prenatal care [11]. Every year, there are 62,000 unfulfilled requests for the women who wanted postpartum tubal ligation, Annually; these denied tubal ligations requests are reported to have lead to 29,000

unintended pregnancies that resulted in 10,000 abortions and 19,000 unintended births in the subsequent year. This is estimated to cost society 215 million dollars a cost that could be significantly reduced by revising the Medicare policy [12,13].

Postpartum contraceptive use, including the use of more effective methods, is highest when contraceptive counseling is provided during both prenatal and postpartum time periods. Women with Medicaid or no health insurance before pregnancy receive the most benefit from this family planning counseling [14].

When postpartum sterilization is desired, before the patient signs the informed consent, a detailed discussion should occur to provide the patient with the risks, benefits and alternatives to sterilization as a family planning option. When the patient has made her choice, the next question is, "what type of insurance do you have?" In most jurisdictions, those patients who have Medicaid or other government insurance are required to complete the "Consent to Sterilization" section of the Medicaid Title XIX form at least 30 days and no more than 180 days prior to undergoing the procedure. This consent has a historical background that is not unfounded, but currently often imposes a barrier to patients who desire permanent sterilization [1-3,15,16]. "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 [15].

Brief history

Sterilization of both men and women has occurred for centuries. Sometimes the sterilization occurred with the person's voluntary consent, more often, however, without any consent. One would like to believe that these procedures have always been performed for the betterment of woman's health. Perhaps by allowing those with life-threatening illness avoid a pregnancy that could lead to significant morbidity or mortality to mother and/or the baby. However, some sterilization procedures were occasionally used by eugenicists to prevent the procreation by those believed to be "unfit", intellectually deficient people, mentally ill individuals and interracial couples [3,17].

One such example occurred in California between the 1971 and 1974 when health care providers coerced 10 Mexican-American women to submit to sterilization procedures. During litigation proceedings, these women testified that hospital staff pressured them to agree to become sterilized while they were in labor. The cause was ultimately largely attributed to the patients' limited ability to speak English. This, among other 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 [18]. These consent revisions paved the way for Federal legislation that resulted in the creation of the present day Medicaid Title XIX sterilization regulation, which was enacted in 1978.

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 [19]. Postpartum sterilization is a fairly routine procedure, because the puerperal changes in the pelvic and abdominal anatomy makes the fallopian tubes more accessible combined with the fact that the woman is already being observed in the hospital. In fact, postpartum sterilization is performed after 10% of all hospital deliveries [1,20]. However, only 50% of those who reported electing to have postpartum sterilization actually had the procedure performed [1,21,22].

The chief reproductive health concern related to the lower numbers of requested versus performed postpartum tubal ligations is documented in a report by Thurman and colleagues. In its selected population, this cohort study found that women who requested, but did not receive postpartum sterilization, nearly 47% became pregnant within a year of their index delivery [5]. As discussed previously, a short inter-pregnancy interval pregnancy has been associated with many adverse consequences. 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 Title XIX mandated consent document and provider concern that patient with low parity or is less than 30 years of age and may regret their decision to be sterilized [20]. 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: [1-3,15,16,23-25]

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.

Thus, the patient may thus not be able to receive her tubal ligation in the near postpartum period. The likelihood of attending scheduled postpartum visits is known to be lower for women who are recipients of public insurance when compared to women who have private insurance coverage. According to one investigator, 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] (Figures 1, 2 & 3).

Obstacles underserved women face to access postpartum sterilization: [1-3,15,16,20,25]

Even though most women voiced no regret after postpartum sterilization, many physicians are reluctant to preform sterilization for women who are less than 30 years of age because of belief that the young women may regret the finality of the decision [25]. Sterilization is restricted or not permitted in catholic health institutions, one of the largest health nonprofit institutions in US [1,3,20,23,26]. 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 [1,4].

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 [27,28]. 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 % [27,29,30], However, some investigators have reported that benefits of immediate postpartum insertion may outweigh the risk of expulsion [27,29,28,31]. 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 [32].

An additional postpartum option for women is contraceptive implants. They are safe, highly effective and longterm (3 years) methods of contraception. 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. This included lactogenesis, the risk of lactation failure or an impact on infant health [33-35].

According to The European Journal of Contraception and Reproductive Health Care, women living in the United States have increased their use of IUD utilization in recent years. The percentage of women using contraception has increased from 1.3% in 1995 to 5.5% in 2006-2008 [19]. Unfortunately, there has not been significant activity from any state and federal legislatures regarding alternative contraception for underserved women. Unfortunately, there has been no significant state or federal activity regarding this topic.

Moral & ethical mandate obligation

As a social safety net, 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 in such a way that Medicaid Title XIX family planning regulations are now effectively doing the opposite of what was its original purpose; it is restricting the access underserved women have to appropriate reproductive healthcare. The consent procedure violates the basic principles of medical ethics, autonomy, beneficence, nonmaleficence, and justice, as it restricts and limits the effected individuals' access to healthcare [1-3,15,16,36,37]. 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 (Figures 1, 2 & 3). Nonetheless, 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 [15]. The burden only applies to women who are funded by federal insurance, which assumes 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. In 2005, a retrospective study showed that 46.9% of women who had Medicaid did not receive the desired tubal sterilization. As a result, more than half of the underserved women on Medicaid (64%) had unintended pregnancies when compared to only 48% of unintended births among women with private insurance [38]. 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 [39]. 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" [39].

Women insured through Medicaid are more likely to experience unintended births than women who have private insurance due to the unjust 30-day waiting period for a voluntary tubal sterilization; violating the standards of beneficence and nonmaleficence.

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 [1-3,15,16,36,37].

In addition, the consent form has to be simplified in a language that is understandable for women with limited literacy (Figure 4). Zite and her colleagues had several publications regarding

the Medicaid Title XIX, which concludes that the Federal consent form is neither readable nor understandable [40-43]. To address these deficiencies, Zite conducted a randomized controlled trial of a low-literacy version of the consent form and found it increased understanding of sterilization [44]. Furthermore, a postpartum sterilization questionnaire was designed to asses the understanding of the postpartum sterilization process (Figure 5). The study, which was also conducted by Zite, was found to be reliable and a valid measure of the Medicaid recipient's understanding of postpartum tubal sterilization process as well as the Medicaid sterilization process (Appendix).

We join other commentators who recommend a modification of the Title XIX consent regulations [1,3,16]. In the American Journal of Obstetrics & Gynecology written by Moaddab et al. [13] addresses the 30- day mandatory waiting period for elective tubal ligation for Medicaid beneficiaries. This mandatory waiting period does not apply to women with a private source of payment; solely to Medicaid beneficiaries. These discrepancies violate 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 [13]. Instead, underserved woman who are funded by Medicaid, are unable to receive the procedure they desire and as a result, the risks of unwanted pregnancies increase.

Darney [45] 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 [45].

We add our voices to other authors and authority to stress the critical need to revise regulations concerning the XIX sterilization consent form requirements [1-3,13,15,16,23,45,46]

Conclusion [1-3,15,23,16]

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

1) Mandatory comprehensive informed consent prior to sterilization that includes an explanation of the procedure's risks, benefits and alternative procedures.

2) Rapid retrievable sterilization consents and secure accessible site. In the Internet era, national access to a drive that contains Federal sterilization forms is realistic and can eliminate the necessity for patient to produce a hard copy of the consent form.

3) 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.

4) 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.

5) 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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