

# Provision of Contraceptive Services to Women with Diabetes Mellitus

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**BACKGROUND:** Women with diabetes mellitus who delay pregnancy until glycemic control is achieved experience lower rates of adverse pregnancy outcomes.

**OBJECTIVE:** To compare rates of provision of contraceptive services among women with diabetes mellitus and women without chronic medical conditions.

**DESIGN:** A retrospective cohort study of 459,181 women aged 15–44 who had continuous membership and pharmacy benefits in a managed care organization in Northern California between January 2006 and June 2007. Rates of documented provision of contraceptive counseling, prescriptions, and services were compared between women with diabetes and women without chronic medical conditions.

**RESULTS:** Among 8,182 women with diabetes and 122,921 women without any chronic conditions, women with diabetes were less likely than women without a chronic condition to have documented receipt of any contraceptive counseling, prescriptions, or services (47.8% vs 62.0%,  $p < 0.001$ ). After controlling for age and race, women with diabetes were more likely to have undergone tubal sterilization compared to women without a chronic condition (OR=1.41, 95% CI 1.30–1.54), but less likely to have received highly effective, reversible methods of contraception such as intrauterine contraception (OR=0.68, 95% CI 0.61–0.75). In addition, more women with diabetes had undergone hysterectomy, which is rarely performed solely for contraceptive purposes.

**CONCLUSIONS:** Women with diabetes were less likely to receive highly effective reversible contraception and more likely to undergo sterilization procedures. Increasing the use of highly effective reversible contraceptives may help diabetic women who want to retain their fertility to delay pregnancy until glycemic control is achieved.

**KEY WORDS:** diabetes mellitus; pregnancy; contraception; preconception counseling; women.

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## INTRODUCTION

Women with diabetes who become pregnant during a period of poor glycemic control face increased risks of adverse pregnancy outcomes.<sup>1</sup> With tight glycemic control before and during pregnancy, rates of congenital malformations and birth trauma can be minimized.<sup>2</sup> Unfortunately, approximately half of all pregnancies in the United States are unintended,<sup>3</sup> and pregnancies conceived by diabetic women may be more likely to be unplanned.<sup>4,5</sup> When unplanned pregnancies occur to diabetic women, they are more likely to result in fetal malformation, stillbirth, or perinatal death.<sup>6</sup> Given the prevalence of unplanned pregnancies conceived by women with poor glycemic control, 9% of the offspring of women with diabetes are affected by birth defects,<sup>7</sup> which is two to three times the rate of birth defects experienced by the general population.<sup>7,8</sup>

Traditionally, obstetric and gynecologic clinicians have provided the majority of preconception counseling and contraception services. Recently, the United States Center for Disease Control and Prevention (CDC) recommended that preconception care be considered an essential part of routine primary and preventive care for women of reproductive age,<sup>9</sup> including women who are at high risk for pregnancy-related morbidity and mortality, such as women with diabetes. National<sup>9</sup> and international<sup>10</sup> guidelines regarding preconception care for women with diabetes are consistent in recommending that preconception care include a discussion about the risk of congenital malformation related to uncontrolled blood sugars and ensuring adequate contraception until glycemic control is achieved. However, the degree to which these guidelines for preconception care have been implemented remains unclear.<sup>11,12</sup> The goal of this study, therefore, was to compare the prevalence of documented provision of preconception and contraceptive

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counseling, and provision of contraceptive prescriptions and services to reproductive-aged women with diabetes compared to women without a chronic medical condition.

## METHODS

Kaiser Permanente Northern California (KPNC) is the largest integrated managed care organization in Northern California, serving approximately one third of the region's population with a focus on providing cost-effective and preventive care; contraceptive prescriptions and services are covered benefits. We conducted a retrospective cohort study of 459,181 women aged 15–44 years, who had continuous membership and received their medications through KPNC pharmacies between January 2006 and June 2007. Women with diabetes were identified using the Chronic Conditions Data Warehouse (CCW), which includes data from clinical care registries<sup>13</sup> maintained by the KPNC department of Quality and Operations Support. The KPNC diabetes registry includes women of all ages with two or more inpatient, outpatient or emergency department diagnoses for either type 1 or type 2 diabetes mellitus over the past 5 years, excluding diagnoses of gestational diabetes mellitus. Among the women with diabetes, we identified a subset that had at least one other selected chronic medical condition identified within the CCW (e.g., hypertension, cardiovascular disease, breast cancer, HIV). For purposes of comparison, we identified a cohort of women without any documented chronic conditions (a “healthy” cohort); this group of women included KPNC members with at least one preventive health visit made to a primary care or obstetric/gynecologic clinic within the 3 years prior to the index date of December 31, 2006. This time period was chosen to confirm that clinicians had an opportunity to assess women's medical history, and offer preconception/contraceptive counseling, prescriptions, or services, and because KPNC's cervical cancer screening guidelines recommend that women of reproductive age be screened for cervical cancer at least once every 3 years. Women were excluded from the “healthy” cohort if they had ICD-9 documentation of any of the chronic medical conditions identified by the World Health Organization (WHO) as potentially affecting decisions regarding the use of contraception<sup>14</sup> or were in any of the KPNC disease registries<sup>15–17</sup> that identify individuals with asthma, chronic pain, diabetes, hypertension, cardiovascular disease, heart failure, cancer, or HIV. Women with ICD-9 codes indicating an ongoing pregnancy were also excluded from this analysis.

All contraceptive prescriptions dispensed or administered in the 3 months prior or up to 6 months after the index date of the study were identified using KPNC pharmacy databases. Outpatient visit and procedure databases were also searched for evidence of provision of contraceptive procedures or services using the parameters listed in Appendix 1. As per WHO convention,<sup>18</sup> we grouped contraceptive methods by efficacy as follows: “highly effective” methods included tubal sterilization, transcervical sterilization, hysterectomy, intrauterine contraceptives (levonorgestrel, copper-T, and unknown type), and contraceptive implants. “Effective” methods included contraceptive pills,

patches, rings, and injections. “Less effective” prescription methods included diaphragms and cervical caps. Lack of documented receipt of any of these methods was classified as receipt of “no” method. When considering “highly effective” contraceptive methods we further distinguished between those methods that are reversible (e.g., intrauterine contraceptives and contraceptive implants) and those that are permanent.

We identified clinical encounters in which preconception counseling, contraception counseling, oral contraceptive management, or family planning counseling was provided by reviewing ICD-9 codes in the Outpatient Services Clinical Record System for the 2 years prior to the study period (2005–2006) or 6 months after the study period.

Two sets of analysis were performed, one examining rates of sterilization among all women in the “diabetes” and “healthy” cohorts, and a second, examining the subset of women who had not been surgically sterilized. We also examined the effect of disease burden, by comparing diabetic women with and without one or more chronic medical conditions in the CCW to the “healthy” women. Differences in rates of receipt of contraceptive services were examined using chi-square tests among women of different ages. To examine the association between a diagnosis of diabetes and tubal sterilization or the placement of intrauterine contraception (IUC), multivariable logistic regression was used to control for age and race when estimating odds ratios and predicted percentages.

To validate the results of the data from the electronic databases, we conducted a detailed review of the medical records of a randomly selected subset of 240 women who had no database evidence of receipt of preconception or contraceptive counseling, prescriptions, or services. Specifically, we assessed use of non-prescription contraceptives (e.g., condoms), provision of counseling that was not documented with ICD-9 codes, history of sterilization performed outside of KPNC, or reasons for no use of contraception (e.g., planning pregnancy, abstinence, same sex partner). In addition, patients' problem lists were examined for evidence of chronic medical conditions that might not have been identified by an ICD-9 code. This detailed medical record review also identified the number of visits each study subject made to each clinical department during the study period. All analyses were conducted using SAS (version 9.1, SAS Institute, Cary, NC). This study was approved by the Institutional Review Boards of Kaiser Permanente Northern California and the University of Pittsburgh.

## RESULTS

In 2006, 459,181 women of reproductive age had continuous membership and uninterrupted pharmacy benefits with KPNC. Of these women, 122,921 women were identified as “healthy,” and 8,182 had diabetes; 3,191 (39%) of the diabetic women had one or more additional chronic medical conditions. Women with diabetes were older than the “healthy” women (mean age 36.5 vs 31.5,  $p < 0.0001$ ) and more likely to be African American (10.9% vs 4.6%,  $p < 0.0001$ ) or Hispanic (29.9% vs 19.5%,  $p = 0.001$ ) when compared to the “healthy” women (Table 1).

Table 1. Demographic Characteristics of Study Participants

	Women with diabetes mellitus N=8,182	Women with no chronic condition N=122,921	p-value
Age (years) mean (SD)	36.5 (7.1)	31.5 (7.7)	<0.0001
Race/ethnicity (%)			0.0001
White, non-Hispanic	31.6	35.9	<.0001
African-American, non-Hispanic	10.9	4.6	
Asian/Pacific Islander, non-Hispanic	15.6	24.9	
Hispanic	29.9	19.5	
Native American/multiracial/other/unknown, non-Hispanic	11.9	15.1	

Women with diabetes were less likely than women without a chronic condition to have documented receipt of contraceptive services. Specifically, no documented receipt of contraceptive counseling, prescriptions, or services was identified for 52.2% of women with diabetes vs. 38.0% of healthy women,  $p < 0.001$  (Table 2). Among women who had documented receipt of a contraceptive method, women with diabetes were more likely to have received a highly effective contraceptive than “healthy” women (21% vs 11%,  $p < 0.001$ , Table 2). However, this was largely due to the fact that women with diabetes were more likely to have had tubal sterilization or undergone hysterectomy (Table 2).

When the analyses were repeated excluding women who had been sterilized, 12.1% of women with diabetes who had no documented receipt of a contraceptive method had documented receipt of counseling compared to 17.9% of “healthy” women ( $p < 0.001$ , Table 3). Similarly, the proportion of non-sterilized

diabetic women that had no evidence of receipt of either contraceptive counseling or a contraceptive method was 61.3% compared to 39.7% among “healthy” women ( $p < 0.001$ , Table 3).

After controlling for age and race, women with diabetes (with or without additional chronic conditions) were more likely to have undergone tubal sterilization than women without a chronic condition (OR=1.41, 95% CI: 1.30–1.54). The predicted percentages for each age group showed higher percentages of tubal sterilization among the diabetic women compared to the “healthy” women. In contrast, women with diabetes, both overall and within each age group, were less likely than “healthy” women to have documented receipt of highly effective reversible contraception such as IUC (OR=0.68, 95% CI: 0.61–0.75). Within each age group, women with diabetes had a significantly higher predicted percentage for having tubal sterilization and lower predicted percentages of IUC use compared to women without chronic conditions (Table 4).

Table 2. Proportion of Non-pregnant Women Receiving Contraceptive Counseling, Prescriptions or Services, by Age and Disease History (%)

	Women with diabetes mellitus				Women with no chronic condition			
	Age 15–24 N=716	Age 25–34 N=1,678	Age 35–44 N=5,788	Total N=8,182	Age 15–24 N=27,124	Age 25–34 N=47,227	Age 35–44 N=48,570	Total N=122,921
<b>Highly effective</b>	1.5	14	24.8	20.6	2.47	10.1	15.6	10.6
Irreversible	0.7	7.2	19.0	14.9	0.07	2.4	8.0	4.1
Sterilization*	0.6	5.8	11.6	9.4	0.06	2.3	6.9	3.6
Hysterectomy	0.1	1.4	7.4	5.5	0.01	0.2	1.1	0.5
Reversible	0.8	6.8	5.8	5.7	2.4	7.7	7.6	6.5
Intrauterine	0.8	6.7	5.8	5.6	2.3	7.7	7.6	6.5
Subdermal implant	0	0.1	0.03	0.05	0.06	0.03	0.02	0.03
<b>Moderately effective</b>	32.6	26.5	11.6	16.5	50.4	36.6	19.6	32.9
Injectable	5.5	3.9	2.6	3.1	4.3	2.1	0.9	2.1
Pill, patch, or ring	27.1	22.6	9.0	13.4	46.1	34.5	18.7	30.8
<b>Less effective</b>	1.3	1.1	0.4	0.6	1.8	1.4	1.0	1.4
Barrier†	0	0.2	0.2	0.2	0.1	0.4	0.5	0.4
Emergency contraception	1.3	0.9	0.2	0.4	1.7	1.0	0.5	1.0
Counseling without prescriptions‡	13.3	16.9	8.0	10.3	17.3	21.5	12.9	17.1
No contraceptive prescriptions, no counseling§	51.4	41.5	55.3	52.2	28.2	30.4	51.0	38.0

\*Tubal sterilization including trans-cervical sterilization

†Prescribed barrier methods include diaphragms and cervical caps

‡Contraceptive counseling without provision of contraceptive prescriptions or services including surgical sterilization

§No contraceptive counseling, provision of contraceptive prescriptions, or services including surgical sterilization

**Table 3. Proportion of Non-pregnant Women Who Had Not Undergone Surgical Sterilization Who Received Contraceptive Counseling, Prescriptions or Services, by Disease History (%)**

	Women with diabetes mellitus			Women with no chronic conditions
	No other chronic condition* (n=4,258)	Another chronic condition* (n=2,703)	Total (N=6,961)	Total (N=124,838)
Highly effective and reversible	6.3	7.0	6.6	6.8
Intrauterine	6.3	6.9	6.6	6.7
Subdermal implant	0.02	0.1	0.06	0.03
Moderately effective	21.2	16.4	19.4	34.3
Injectable	3.5	3.9	3.6	2.2
Pill, patch, or ring	17.8	12.5	15.7	32.1
Less effective	0.7	0.7	0.7	1.4
Barrier†	0.1	0.3	0.2	0.4
Emergency contraception	0.6	0.4	0.5	1.0
Counseling without contraception	12.7	11.1	12.1	17.9
No contraception, no counseling	59.1	64.8	61.3	39.7

\*Selected chronic conditions included hypertension, cardiovascular disease, breast cancer, or HIV infection

†Barrier methods available by prescription include diaphragms and cervical caps

When we compared use of highly effective contraception among women with diabetes alone or diabetes plus selected chronic conditions, we found that women aged 35–44 years had significantly higher percentages of IUC use if they only had diabetes ( $p=0.002$ ). When we compared rates of tubal sterilization, we found that in each age group women who only had diabetes were more likely to have had tubal sterilization than women with diabetes and additional chronic conditions ( $p<0.001$  for all age groups).

On detailed review of the medical records of women who had no database evidence of provision of contraceptive counseling, prescriptions, or services, evidence was found of either abstinence or use of condoms for 56% (95% CI 50%–62%). However, documentation of receipt of any contraceptive counseling or services was still less frequent for diabetic

women than “healthy” women (10.3% vs 17.1%,  $p<0.001$ ). Among the women who had documented receipt of pre-conception or contraceptive counseling on detailed chart review, 74% received this counseling from a clinician in an obstetric or gynecologic (ObGyn) clinic, while only 10% received such counseling from a primary care clinician (trained in internal medicine, family practice, or pediatrics). Contraception or pre-conception counseling occurred during 59% of 265 visits to an ObGyn clinician vs. 2% of 845 visits to primary care clinicians. Visits to primary care clinicians were three times as common as visits to ObGyn clinicians; 58% of women whose medical records were reviewed in detail visited an ObGyn clinician.

## DISCUSSION

Although diabetes is affecting a growing number of women of reproductive age<sup>19</sup> and poses an increased risk of adverse birth outcomes if pregnancy occurs while glucose levels are not tightly controlled,<sup>20</sup> this study found that clinicians provided contraceptive or pre-conception counseling less frequently to women with diabetes than women without any chronic medical conditions. These findings are supported by previous work that has shown that, nationally, diabetic women receive less contraceptive counseling<sup>4</sup> and are less likely to use contraception than non-diabetic women.<sup>5</sup> Results from the Translating Research into Action for Diabetes (TRIAD) study, a large multicenter prospective cohort study, found that only 52% of women recalled pre-conception counseling about the importance of glycemic control and only 37% recalled receiving family planning advice.<sup>12</sup> Similarly, results from the National Ambulatory Medical Care Survey of 3,000 office-based US physicians showed that only 4% of visits by women with diabetes documented contraceptive counseling unless family planning was the primary reason for the visit.<sup>5</sup> In addition, pregnancies affected by diabetes result in higher rates of miscarriage, congenital anomalies, preeclampsia, large for gestational age infants, and birth trauma;<sup>1</sup> maternal hyperglycemia also increases risks for child obesity, metabolic syndrome, and diabetes in offspring.<sup>21</sup> Thus, the significant

**Table 4. Predicted Percentages of Use of Intrauterine Contraception and Tubal Sterilization by Age Group and by Chronic Condition Status**

	Predicted percentages* of IUC use	Predicted percentages* of tubal sterilization
Age 15–24		
Women with diabetes mellitus	1.6	0.13
Women with no chronic condition†	2.2	0.07
Age 25–34		
Women with diabetes mellitus	6.0	4.8
Women with no chronic condition†	7.7	2.3
Age 35–44		
Women with diabetes mellitus	5.9	13.4
Women with no chronic condition†	7.6	6.8

\*Predicted percentages were calculated from logistic regression, adjusted for age group and race/ethnicity.  $P$ -values from all  $t$ -tests comparing women with DM to women with no chronic conditions were  $<0.0001$

†No chronic conditions tracked by registries or identified by the World Health Organization’s Medical Eligibility Criteria as affecting decision regarding contraceptive use



societal costs of unintended pregnancy<sup>22,23</sup> are even greater when women have diabetes.

Of further concern, since regret following surgical sterilization is relatively common, especially when women are sterilized before 30 years of age,<sup>24</sup> we found that young women with diabetes were more likely to undergo surgical sterilization than women without chronic conditions. However, it remains possible that these differences are due to patient preferences and that women with diabetes may be less likely to regret sterilization than other women, especially as many women with diabetes who had been sterilized had undergone hysterectomy, which is rarely performed for contraceptive purposes. Interestingly, women with diabetes and additional chronic conditions were less likely to have tubal sterilization within each age group than women who only had diabetes. This may be due to less sexual activity among women with additional chronic conditions or perceptions among primary care providers that gynecological procedures such as tubal sterilization or IUC placement posed unnecessary risk.

Women who have had diabetes for less than 20 years, and have no end organ disease, may safely use all reversible methods of contraception, according to both the World Health Organization<sup>14</sup> and the US Centers for Disease Control (CDC) and Prevention.<sup>25</sup> For diabetic women with vascular complications, estrogen should be avoided,<sup>14,25</sup> and contraceptive options are more limited. Nevertheless, it is particularly important for women with diabetes and end organ damage to avoid unintended pregnancies, and to delay desired pregnancy until glycemic control is achieved.

Highly effective reversible contraceptives, which do not contain estrogen, may be ideal methods for delaying or avoiding pregnancy for women with diabetes, especially those with end organ damage. Intrauterine and implantable contraceptives are safe, reversible options that do not increase the risk of clotting<sup>26</sup> or other vascular disease, and are as effective as tubal sterilization.<sup>27,28</sup>

The reasons why diabetic women may receive less contraceptive counseling than healthier women likely include the challenges clinicians face in ensuring that diabetic women receive all recommended diabetes care (e.g., eye exams, foot exams) within the time constraints of usual practice and the lack of any quality indicators related to provision of preconception care. In addition, the lack of reimbursement for provision of contraceptive counseling and limited physician training in contraceptive care have also been identified as barriers to the provision of contraceptive care.<sup>29</sup> For instance, some clinicians may have inaccurate perceptions that all available contraceptives increase women's vascular risk. In response to the results of this study as well as the call to action by the CDC to improve preconception care for women with chronic medical conditions, KPNC has initiated a region-wide effort to raise awareness and improve provider education about the importance of incorporating contraceptive counseling as part of preconception care for women with diabetes. This advocacy and support comes in the form of KPNC regional prevention guidelines for reproductive age women as well as continuing medical education (CME) sessions on preconception health for primary care clinicians.

Strengths of this study include the ability to examine large cohorts of women both with diabetes and without any chronic medical conditions who receive integrated medical and pharmacy services, and the use of detailed medical record review to

validate the findings of the data abstracted from electronic databases. In addition, KPNC's validated chronic disease registries<sup>13,15-17</sup> allowed reliable identification of women with diabetes as well as women with multiple other chronic conditions. Previous studies have found that members of KPNC include slightly fewer people in the very lowest and highest socioeconomic classes, and tend to be slightly more educated than the general population,<sup>30</sup> otherwise, they are very similar to the general population of California in terms of other demographic characteristics such as race and ethnicity.

We acknowledge some limitations in our study. The electronic data sources used for this study do not include information about women's desire to conceive, sexual orientation, sexual activity, or use of condoms. In addition, we do not have information on the fertility of women's partners, women's glycemic control, or parity, which may affect desires for sterilization. This study considered only four additional chronic medical conditions, three of which (hypertension, cardiovascular disease, and breast cancer) are more common among women with diabetes. Some women may have undergone surgical sterilization, or had contraceptive implants or IUC placed outside of the KPNC system. Women may have received preconception or contraceptive counseling without documentation of this counseling appearing either in the coded databases or in clinician notes. However, we would not expect these factors to vary significantly by whether a woman had been diagnosed with diabetes. Nevertheless, the results of this study did demonstrate significant differences between documented provision of contraceptive services to women with diabetes as compared to healthy women.

In conclusion, this study found that insured women with diabetes were less likely than insured women without a chronic medical condition to have documented receipt of contraceptive counseling, prescriptions, or services; rates of contraceptive use among diabetic women who lack health insurance are likely much lower. In the interest of preventing pregnancy complications, women with diabetes may benefit from more discussion of reversible alternatives to sterilization, which are highly effective and safe for women with diabetes. Greater awareness among clinicians who care for women with diabetes of guidelines for the safe use of contraception by women with diabetes<sup>14,25</sup> may facilitate use of more effective reversible contraceptives and help more women with diabetes delay pregnancy until glycemic control is achieved.

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