

# Preconception Counseling and Type 2 Diabetes

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*Editor's note: This is the first article in our newly revamped "Evidence-Based Clinical Decision Making" department. For more information about our new format and its rationale, please see the editorial on p. 69 of this issue.*

## Background and Clinical Problem: Preconception Counseling

Diabetes has been associated with pregnancy-related complications.<sup>1,2</sup> Rates of spontaneous abortion and perinatal mortality and the incidence of congenital anomalies in offspring of women with diabetes remain significantly higher than that of the background population. It is well accepted that achieving a level of glycemic control comparable to the nondiabetic population can decrease the incidence of adverse pregnancy outcomes. The American Diabetes Association (ADA)<sup>1</sup> and the American College of Obstetricians and Gynecologists<sup>2</sup> both recommend preconception counseling (PC) for all women with diabetes who have child-bearing potential.

The ADA<sup>1</sup> recommends that PC include the risks of congenital malformations associated with poor metabolic control and the use of effective contraception unless the woman is in good metabolic control. The goal for glycemic management is to obtain the lowest possible hemoglobin A<sub>1c</sub> (A1C) level without undue risk of hypoglycemia, preferably an A1C that is < 1% above the normal range. It is also recommended that providers identify and treat complications of diabetes, such as nephropathy, retinopathy, hypertension, coronary artery disease, and neuropathy, before conception.<sup>3</sup>

The majority of women with diabetes, however, do not obtain PC and continue to have unplanned pregnancies. The majority of studies (Table 1)<sup>4,5,7-19</sup> report that up to 62% of women with type 1 diabetes received PC, whereas < 36% of women with type 2 diabetes received PC. In studies by Gunton et al.,<sup>4,5</sup> the rate of women with type 1 diabetes having received PC

improved significantly over time (from 18.9 to 62.5%), but a downward trend was noted in the rate for women with type 2 diabetes (from 52.6 to 36.4%). With the rising rates of obesity and type 2 diabetes in the United States and throughout the world,<sup>6</sup> there is a rising number of women of childbearing age with type 2 diabetes.

**Characteristics of women seeking PC.** As shown in Table 1, generally < 30% of women with type 2 diabetes present for preconception care. The differences between women with type 1 and those with type 2 diabetes who obtain PC are consistent throughout all studies reviewed. Women with type 2 diabetes are significantly older, are more obese, have higher parity, and are non-Caucasian. They have a shorter duration of diabetes and present for prenatal care later in pregnancy.

In Hillman et al.'s<sup>19</sup> study, women with type 2 diabetes had similar rates of PC and lower A1C levels at presentation for care compared with women with type 1 diabetes, and no significant differences in perinatal mortality or major congenital malformations were found. They concluded that women with type 2 diabetes who received intensive medical treatment preconceptually and during pregnancy have better pregnancy outcomes.

Holing et al.<sup>20</sup> found that women who planned their pregnancies had a significantly lower A1C at their first prenatal visit, were married, were older, had more education, and were more likely to have seen a diabetes specialist for care of their diabetes. Women with unplanned pregnancies were poorer, were more likely to belong to an ethnic or racial minority, were less likely to have private health insurance, and had poor relationships with health care providers. Similarly, in a prospective observational study by Janz et al.<sup>21</sup> that looked at the differing characteristics of women with type 1 and type 2 diabetes who sought PC and those who did not, women who sought PC were more likely to be mar-

ried, college graduates, and employed and have type 1 diabetes. They reported having discussed PC with their health provider and were encouraged by their provider to receive it. These women were also more likely to perceive benefits from receiving PC for themselves and their infants.

## Case Study

P.H. is a 33-year-old African-American woman who has had two pregnancies resulting in live births. Three years ago, she was diagnosed with type 2 diabetes by her primary care provider. She was started on metformin, and 6 months later, glipizide was added. Last year, pioglitazone was added to her regimen. She has been testing fasting and predinner glucose levels, which range from 200 to 300 mg/dl. Her A1C is 10.2%, and her BMI is 36 kg/m<sup>2</sup>. She also has chronic hypertension, for which she takes captopril, 25 mg twice daily, and hypercholesterolemia, for which she takes atorvastatin, 10 mg daily. At a routine medical visit, she asks, "Can I still get pregnant?"

## Clinical Question

In women with type 2 diabetes, how effective is PC in improving clinical outcomes?

## PICO Format

The patient **population** to be examined is women with type 2 diabetes. The **intervention** to be investigated is PC. A **comparison** will be made between women with type 2 diabetes who attend PC and those who do not attend PC. The **outcomes** of interest are metabolic control, spontaneous abortion, perinatal mortality, congenital anomalies, pregnancy/delivery complications, macrosomia, and neonatal hypoglycemia.

## Search Strategy

The literature search included any study that compared outcomes in women with type 2 diabetes who did

Table 1. Rates of PC

Authors	Year	Type 1 (n)	Type 1 (%)	Type 2 (n)	Type 2 (%)	Pregestational* (n)	Pregestational (%)
Kitzmilller et al. <sup>7</sup>	1991					194	43
Willhoite et al. <sup>8</sup>	1993					185	34
Hawthorne et al. <sup>9</sup>	1997					113	50
Garcia-Patterson et al. <sup>10</sup>	1997	152	36.1	33	9.1		
Gunton et al. <sup>4</sup>	2000	74	18.9	12	52.6		
Brydon et al. <sup>11</sup>	2000	196	18.0	57	5		
Schaefer-Graf et al. <sup>12</sup>	2000			416	< 5		
Gunton et al. <sup>5</sup>	2002	24	62.5	11	36.4		
DPG Study <sup>13</sup>	2003	289	48.5%	146	24%		
Clausen et al. <sup>14</sup>	2005	240	~70%	61	<5%		
McElduff et al. <sup>15</sup>	2005	81	27.8%	99	12%		
Roland et al. <sup>16</sup>	2005	389	40.5%	146	28.7%		
Wender-Ozegowska et al. <sup>17</sup>	2005					198	6%
Galindo et al. <sup>18</sup>	2006					126	11.9%
Hillman et al. <sup>19</sup>	2006	532	22.6% (ns)	93	16.1%(ns)		

\*Pregestational = type 1 and type 2 combined.

Table 2. Studies Comparing Outcomes in Women Receiving and Not Receiving PC

Authors, Year	Purpose	Design	Type 2 diabetes; total (n)	Diabetes type	Outcome, variables	Results
Kitzmilller et al., 1991 <sup>7</sup>	Determine whether intensive blood glucose management improves outcome	Prospective	71; 194	PGD	MCM	PC ↓ MCM, mean fasting and postprandial blood glucose
Willhoite et al., 1993 <sup>8</sup>	Determine whether PC improves outcome	Prospective	65; 185	PGD	PM, MCM	PC ↓ PM, MCM
Garcia-Patterson et al., 1997 <sup>10</sup>	Assess impact of PC on perinatal outcomes	Prospective	33; 185	PGD	Multiple perinatal and neonatal	Same rate SAB and MCM; ↑ C/S rate, ↓ A1C with PC
Gunton et al., 2000 <sup>4</sup>	Assess outcomes, pregnancy planning	Retrospective	19; 93	1, 2	Multiple perinatal and neonatal	PC ↓ A1C, C/S rate
Gunton et al., 2002 <sup>5</sup>	Evaluate improvement in PC	Prospective	11; 35	1, 2	Multiple perinatal and neonatal	PC ↓ A1C, C/S rate, GA at delivery
*DPG Study, 2003 <sup>13</sup>	Evaluate perinatal outcomes, PC	Cross-sectional	146; 435	1, 2	PM, MCM, PGD	↑ rate PM, MCM; Higher A1C, ↑ rate
Galindo et al., 2006 <sup>18</sup>	Effects of PGD on pregnancy outcomes	Prospective	28; 126	PGD	SAB, PM, MCM, rate of PC	Higher A1C, ↑ SAB, MCM; PC ↓ A1C

\* The only article that compared outcomes in women with type 2 diabetes who received or did not receive PC. C/S, cesarean section; GA, gestational age; MCM, major congenital malformation; PGD, pregestational diabetes (type 1 and type 2 diabetes combined); PM, perinatal mortality; SAB, spontaneous abortion.

and did not receive PC. An integrative review was conducted using Medline and Ovid electronic databases for articles published between January 1990 and October 2006. Key words used in the search were “preconception counseling,” “preconception care,” “type 2 diabetes and pregnancy,” and “NIDDM and pregnancy.” Studies were reviewed based on statistically ( $P < 0.05$ ) and clinically significant outcomes.

## Results and Critical Appraisal

**Description of studies.** From ~ 1,500 citations, 74 articles were retrieved through Women & Infants’ Hospital and Rhode Island Hospital Library system. Only articles published in English were reviewed. Reference lists of articles located were also reviewed for other studies that met the inclusion criteria. Studies in women with type 1 diabetes were eliminated. Studies that compared outcomes in women with pregestational diabetes (type 1 and type 2 diabetes combined) were included. All studies were retrospective, prospective, or population-based cohort studies. Although 15 studies reported rates of PC, only seven were found that compared outcomes in women with diabetes who received or did not receive PC (Table 2). Only one compared outcomes in women with type 2 diabetes who received or did not receive PC.<sup>13</sup> The number of subjects with type 2 diabetes in the seven studies used for analysis ranged from 11 to 71 for a total of 373 subjects.

**Metabolic control.** Because the goal of preconception care is to achieve euglycemia before conception, all seven of these studies focused on metabolic control as an outcome. Only one study, from the Diabetes and Pregnancy Group of France (DPG),<sup>13</sup> compared metabolic control separately in women with type 2 diabetes who received or did not receive PC. In this cross-sectional study of 146 women with type 2 diabetes, only 1 (2.9%) of the women who received PC had a first trimester A1C > 8% compared to 31 women (27.9%) of those without PC. The other six studies combined outcomes of women with pregestational diabetes who had PC and compared them to outcomes of women with pregestational dia-

betes who did not have PC. Three studies (Table 3) reported improved A1C values in women who had PC. A fourth study<sup>10</sup> also reported lower A1C’s in the PC group, but actual means of A1C values were not provided. Kitzmiller et al.<sup>7</sup> reported lower mean fasting and postprandial glucose values in women who received PC. Galindo et al.<sup>18</sup> separated women into those with fair versus those with poor control at presentation and found that 17% of women in fair control had PC, whereas only 5.5% of women in poor control had PC. Overall, the studies suggest that women who seek PC have improved metabolic control.

**Spontaneous abortion.** Women with diabetes have a significantly higher rate of spontaneous abortion (SAB) than women without diabetes.<sup>22,23</sup> It has been established that good metabolic control at conception can decrease the rate of miscarriage in women with diabetes.<sup>23</sup> Three of the seven articles reported spontaneous abortion as an outcome, but no studies compared this outcome separately in women with type 2 diabetes who received PC versus those who did not receive PC. Garcia-Patterson et al.<sup>10</sup> found no difference in the rate of SAB in women with pregestational diabetes who had PC compared to those who did not have PC. Kitzmiller et al.<sup>7</sup> reported a 13.7% SAB rate in women who received PC and a rate of 10% in women who did not receive PC. Conversely, Galindo et al.<sup>18</sup> found a threefold increase in SAB in women who had poor metabolic control at conception. Therefore, based on these three studies, the effects of PC on SAB are inconsistent.

**Perinatal mortality.** Perinatal mortality (stillbirth and neonatal death) remains significantly elevated in women with pregestational diabetes compared to the background popula-

tion.<sup>9,24,25</sup> A threefold increase in perinatal mortality has been reported in women with type 2 diabetes compared to women with type 1 diabetes.<sup>14,26,27</sup>

Three of the seven articles compared rates of perinatal mortality in women who had PC to those of women who did not have PC. The DPG study<sup>13</sup> was the only one to compare this outcome separately in women with type 2 diabetes who received or did not receive PC. Researchers found a 5.7% rate of perinatal mortality in women who had PC and a 3.6% rate in women who did not have PC, which was not a statistically significant difference. In the two studies that combined outcomes for women with type 1 and type 2 diabetes, Garcia-Patterson et al.<sup>10</sup> found no difference in the rate of perinatal mortality in women who received PC (1.85% for PC vs. 1.92% for no PC, which was not a significant difference), whereas Willhoite et al.<sup>8</sup> found less perinatal mortality in women with diabetes who received preconception care (6.4% with PC vs. 21.1% without PC). Similarly, Galindo et al.<sup>18</sup> found a higher rate of perinatal mortality in women who had poor metabolic control at conception. Therefore, based on these three studies, there is a trend toward less perinatal mortality in women who had PC compared to women who did not have PC.

**Congenital anomalies.** Women with pregestational diabetes continue to have infants with congenital anomalies at a much higher rate than the background population.<sup>9,13,24,28</sup> Dunne et al.<sup>29</sup> found that women with type 2 diabetes had a rate of congenital malformations that was 11 times greater than the background population.

Four of the seven articles compared the rate of congenital anomalies in women who had PC to those of women who did not have PC. Only

**Table 3. Mean A1C Values With and Without PC**

Authors	Year	A1C With PC	A1C Without PC	P
Gunton et al. <sup>4</sup>	2000	6.6 ± 2.8	8.4 ± 5.4	0.01
Gunton et al. <sup>5</sup>	2002	6.0 ± 1.4	8.1 ± 1.8	0.0035
Galindo et al. <sup>18</sup>	2006	5.84 ± 0.98	6.61 ± 1.72	0.02

*Data are A1C ( %) means ± SD.*

the DPG study<sup>13</sup> compared this outcome separately in women with type 2 diabetes who received or did not receive PC. Researchers found a 2.9% rate of congenital malformations in women who had PC and a 3.6% rate in women who did not have PC, which was not statistically significant. Three studies<sup>7,8,10</sup> that combined outcomes of women with type 1 and type 2 diabetes and compared rates of major congenital malformations in women who had PC to those in women who did not all found lower rates of congenital malformations in women who had PC (1.2 vs. 10.9%,  $P = 0.01$ ; 1.6 vs. 6.5%, not significant; and 3.6 vs. 8.8%, not significant). These studies indicate that PC does have a positive effect in preventing major congenital malformations, although the differences did not reach statistical significance in all studies.

**Pregnancy/delivery complications, macrosomia, and neonatal hypoglycemia.** Five of the seven studies compared other outcomes in women with pregestational diabetes who had PC to those in women who did not have PC. No studies were found that compared these outcomes exclusively in women with type 2 diabetes. The DPG study<sup>13</sup> found a positive association between preterm delivery and first trimester A1C  $> 8\%$ .

Gunton et al.<sup>5</sup> reported a later gestational age at delivery in women who had PC (38.2 weeks vs. 36.2 weeks,  $P = 0.0318$ ), whereas Willhoite et al.<sup>8</sup> found no significant difference. Gunton et al.<sup>4,5</sup> found significantly lower rates of cesarean section in women who had PC (13.6 vs. 48%,  $P < 0.05$ ; 31.6 vs. 72.7%,  $P = 0.0295$ ), and Garcia-Patterson et al.<sup>10</sup> found a significantly higher rate of cesarean section in women who had PC (71 vs. 54.9%,  $P < 0.05$ ). Willhoite et al.<sup>8</sup> also reported a higher cesarean section rate in women who received PC (81 vs. 66%) that did not reach statistical significance.

Gunton et al.<sup>5</sup> found a lower rate of large-for-gestational-age (LGA) infants in women who had PC (26.3 vs. 36.4%), whereas Garcia-Patterson et al.<sup>10</sup> found a higher rate of LGA infants in women who had PC (33.9 vs. 25.2%, not significant) and a lower rate of small-for-gestational-age babies in women who had PC (1.8 vs. 8.7%,  $P < 0.05$ ). Willhoite et al.<sup>8</sup>

found no significant difference in birth weight. Garcia-Patterson et al.<sup>10</sup> found no significant difference in the incidence of neonatal hypoglycemia between women who had PC and those who did not (21.8 vs. 25.5%). Again, these outcomes, comparing women who had PC to those who did not, were inconsistent.

### Summary and Evidence Grading System for Clinical Practice Recommendations

Based on the ADA's evidence grading system,<sup>3</sup> in which A designates clear evidence from randomized control trials, B is supportive evidence from well-conducted cohort studies, C is evidence from poorly controlled studies, and E is expert consensus or clinical experience, the overall level of evidence for the studies in this integrative review on the effects of PC in type 2 diabetes ranged from B to C. Most studies were well-conducted retrospective and prospective cohort studies (B). However, conflicting evidence was found, with the weight of the evidence supported by clinical recommendations (E).<sup>1,3</sup>

### Case Study Revisited

P.H. told her provider that she would like to have another child, but did not know if she could conceive now that she has diabetes. Given the overall evidence on the effects of PC in improving clinical outcomes in women with diabetes, she will receive PC. Based on ADA's "Standards of Medical Care in Diabetes,"<sup>3</sup> she should be counseled about the effects of diabetes and her other medical conditions on a pregnancy and the effects that a pregnancy could have on her diabetes. She should be offered contraception until glycemic control has been achieved and the following goals have been met. She should be seen by a team experienced in the management of diabetes and pregnancy. This should include a physician, dietitian, diabetes educator, social worker, and other specialists as necessary.

The number and type of oral antidiabetic agents available for the treatment of type 2 diabetes is growing at a rapid pace. Schaefer-Graf et al.<sup>12</sup> found that women who had taken sulfonylureas (the only group of oral agents available in 1995) during the

first 8 weeks of pregnancy had a significantly higher incidence of infants with congenital anomalies than women who had not taken sulfonylureas. In the 2005 study by Roland et al.,<sup>16</sup> 14 women were taking two antidiabetic agents and two women were taking three agents. Medications used included sulfonylureas, thiazolidinediones, repaglinide (pregnancy Category C), metformin, and acarbose (pregnancy Category B). Sixty-one percent of infants with congenital malformations in this study were born to women taking oral antidiabetic agents at conception. Treatment with oral antidiabetic agents was found to be independently associated with congenital anomalies.<sup>16</sup> Thus, her metformin, glipizide, and pioglitazone should be discontinued, and insulin therapy should be initiated with the goal of achieving an A1C  $< 1\%$  above the upper limits of normal.

She should be evaluated for retinopathy, neuropathy, nephropathy, and coronary artery disease, any of which should be treated before pregnancy. Statins and fibrates for dyslipidemias, as well as ACE inhibitors and ACE receptor blockers for hypertension, are contraindicated in pregnancy because they increase the risk of congenital anomalies.<sup>30</sup> Her captopril should be changed to an antihypertensive agent that is safe to use during pregnancy, and atorvastatin should be discontinued. When these goals have been reached, contraception can be discontinued and pregnancy can be attempted. P.H. states that she would like to begin PC to improve her chances for a healthy pregnancy and child.

### Clinical Question Revisited

In women with type 2 diabetes, how effective is PC in improving clinical outcomes? Only one study<sup>13</sup> was identified that compared outcomes exclusively in women with type 2 diabetes who did and did not have PC. In this study, which was conducted in France, there were 146 women with type 2 diabetes, and only 35 of them had PC. This small subsample does not allow for generalization. For some outcomes evaluated in the studies of women with type 2 diabetes, inconsistent findings and small sample sizes made it difficult to draw general conclusions,



and thus there is a paucity of strong empirical evidence.

### Implications for Practice

Based on the current state of evidence, including ADA's recommendations as outlined in "Standards of Medical Care in Diabetes"<sup>3</sup> and "Preconception Care of Women with Diabetes,"<sup>1</sup> PC is recommended for all women of childbearing age with type 1 or type 2 diabetes. Because rates of obesity and the incidence of type 2 diabetes are rising in the United States and throughout the world, more women of childbearing age are being diagnosed with type 2 diabetes. The number of women with type 2 diabetes complicating pregnancy now exceeds the number of women with pregnancies complicated by type 1 diabetes.<sup>31</sup>

The DPG study<sup>13</sup> demonstrated that women with type 2 diabetes who had PC had a significantly lower incidence of A1C > 8% in the first trimester than did women who did not have PC. However, women with type 2 diabetes generally do not get PC as often as women with type 1 diabetes (Table 1).

Women with type 2 diabetes may have more barriers to receiving PC than women with type 1 diabetes. Health care providers and patients may think that type 2 diabetes is more benign than type 1 diabetes. Terms like "borderline diabetes" and "mild diabetes" may give the impression to women and providers alike that type 2 diabetes is not as serious as type 1 diabetes. Women may believe that because their diabetes is controlled with medical nutrition therapy or a pill, it is less severe than diabetes requiring insulin. Women with type 2 diabetes may also believe that because their diabetes care is managed (in the vast majority of cases) by primary care physicians, it is less severe. Because minority populations have a higher incidence of type 2 diabetes, there may be disparities including less access to health care.

Health care professionals need to find solutions to alleviate these barriers. PC must be available for all women of childbearing potential who have either type 1 or type 2 diabetes. Because type 2 diabetes represents ~ 8–45% of patients diagnosed with diabetes in U.S. pediatric centers,<sup>32</sup> PC should begin at puberty.<sup>33,34</sup> Preconception counseling is

a topic that pediatric endocrinologists may be unfamiliar or uncomfortable discussing with teenaged girls. The ADA<sup>33</sup> has published a book and interactive CD-ROM that were designed especially for teens about sexuality, pregnancy, and diabetes and provide fundamental PC. Because women can conceive anytime between puberty through menopause, they should receive PC at every routine visit with a health care provider.

The ADA's standards of care<sup>3</sup> for all people with diabetes recommend treatment to achieve an A1C < 7% in most patients and an A1C as close to normal (< 6%) as possible without significant hypoglycemia. If this goal were attained in women of childbearing age, the rates of adverse outcomes could be substantially reduced.

Following are a summary of the ADA's<sup>1,3</sup> recommendations for PC for women with type 2 diabetes:

1. Counseling about the risks of malformations associated with poor glycemic control
2. Effective contraception until glycemic control is achieved
3. A1C < 1% above the normal range
4. Nutrition counseling
5. Discontinuation of oral antidiabetic agents and institution of insulin therapy to achieve target A1C
6. Evaluation and treatment of complications of diabetes, such as retinopathy, neuropathy, nephropathy, and coronary artery disease
7. Assessment of medications taken for other conditions, such as hypertension, and change of agents to those that is safe for use during pregnancy or discontinuation of medications that are contraindicated during pregnancy

Our challenge will be to educate all health care providers and women with type 2 diabetes that 1) type 2 diabetes is not a benign condition, and women who have it have the same or greater risk of poor pregnancy outcomes than women with type 1 diabetes, and 2) every encounter with a postpubescent woman with type 2 diabetes who is of childbearing potential is an opportunity for PC, regardless of her age, race, body size, socioeconomic status, number of children, or level of education. The key is PC. What she doesn't know can hurt her!<sup>34</sup>

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