

The Quality of Periconception Medical Care in Women With Diabetes Needs Improvement

Shlomit Riskin-Mashiah,¹ Ron Auslander,¹
and Ronit Almog²

OBJECTIVE

We evaluated the quality of periconception medical care in pregnant women with diabetes and assessed the influence of sociodemographic characteristics.

RESEARCH DESIGN AND METHODS

The study was based on retrospective data collection from electronic database on cohort of Israeli women at Clalit Health Services (CHS) with pre-existing diabetes who gave birth in 2008–2011. It included data on A1C and other laboratory test results, prescription fillings, diet and ophthalmology consultations, and sociodemographics extracted from CHS computerized systems. The performance of each of nine recommended measures in the periconception period and a composite quality score was evaluated; the score ranged from 0–8. Multivariate logistic regression was used to examine independent sociodemographic predictors of low-quality overall scores.

RESULTS

A total of 166 women gave birth to 180 infants; the performance of the different quality parameters ranged from 81% for A1C and kidney function tests to only 30% for dietary consultation and 41.1% for ophthalmology exam. Forty-nine percent of women had A1C <7.0% (53 mmol/mol). Only 45% took folic acid, whereas 13.9% continued the use of potentially teratogenic drugs in the first trimester. One-third of women were in the low-quality (0–3) overall score. In the multiple logistic regression analysis, the only significant variables to predict lower composite quality scores were multiparity odds ratio of 3.43 (95% CI 1.66–7.10; $P = 0.001$), Arabian ethnicity 3.76 (1.78–7.92; $P = 0.001$), and immigrant 3.73 (1.25–11.16; $P = 0.018$).

CONCLUSIONS

The periconception medical care of diabetic women is suboptimal. More intensive and targeted care is needed in order to optimize periconception care of diabetic patients, especially in the high-risk subpopulations.

Diabetes Care 2014;37:678–685 | DOI: 10.2337/dc13-2143

¹Department of Obstetrics and Gynecology, The Lady Davis Carmel Medical Center, Rappaport Faculty of Medicine, Technion, Haifa, Israel

²School of Public Health, Faculty of Health and Social Sciences, University of Haifa, Haifa, Israel
Corresponding author: Shlomit Riskin-Mashiah, shlomitri@gmail.com.

Received 10 September 2013 and accepted 3 November 2013.

© 2014 by the American Diabetes Association. See <http://creativecommons.org/licenses/by-nc-nd/3.0/> for details.

Diabetes is a complex chronic disease with increasing incidence in recent years in parallel with the obesity epidemic. The increasing prevalence of diabetes in general and the increasing age of pregnant women has led to an increasing number of pregnancies with this complication (1). Pre-existing diabetes increases the risk of pregnancy complications to the mother, fetus, and newborn infant. The duration and type of diabetes, its severity, the occurrence of chronic complications, and glycemic control are major factors influencing pregnancy outcome (1,2). Poorly controlled diabetes substantially increases the risk of spontaneous abortion and congenital malformations (1–3). Many studies (2,3) and meta-analyses (4,5) have showed that women who get appropriate preconception care have significantly lower risk for adverse pregnancy outcomes, including spontaneous abortions, congenital malformation, and prolonged hospitalizations for mothers and neonates. Yet providing high-quality care for women with diabetes remains a challenge.

Recognizing that gaps exist between recommended and actual care, there is an increasing interest in quality improvement. There is substantial evidence and consensus on what constitutes high-quality diabetes care, and societies around the world have published guidelines for preconception counseling and care for women with diabetes (6–9). All these guidelines recommend daily use of folate supplementation from preconception in order to prevent neural tube defects; to achieve good metabolic control, preferably with A1C below 6–7% (42–53 mmol/mol) by appropriate insulin therapy and dietary consultation; to assess for systemic complications, including diabetic nephropathy, retinopathy, and thyroid disease; and to review medication use and discontinue, preconceptionally, the use of potentially hazardous drugs. Despite this, suboptimal care and poor patient outcomes continue. Too many pregnancies are still unplanned, and many diabetic women get pregnant without proper preparation and with poor glycemic control and have high

rates of pregnancy complications (10–13).

Most studies in the past evaluated mainly preconception glycemic control and pregnancy outcome (3,10,11,14). Very few studies evaluated systematically the whole spectrum of recommended preconception care (12) and looked at the influence of sociodemographic characteristics on preconception medical care (12,15). Therefore our goal was to evaluate the quality of preconception medical care in women with pre-existing diabetes mellitus and to assess the influence of sociodemographic characteristics on the quality of medical care.

RESEARCH DESIGN AND METHODS

The study was approved by the ethics committee of Clalit Health Services (CHS), a nonprofit HMO covering more than half of the Israeli population. The study population included women with pre-existing diabetes who gave birth during 2008–2011 in Haifa and Western Galilee District of CHS in Israel. Women with diabetes were identified from the chronic disease registry in CHS computerized systems (16). Women who gave birth during 2008–2011 in Haifa and Western Galilee District of CHS were identified by their newborns, who are also registered in CHS. Database integration using the unique identity number assigned to all Israeli residents was used to identify the patients with diabetes who gave birth during 2008–2011. Data were retrieved retrospectively from CHS computerized systems on the following parameters for all women between 2007 and 2012: sociodemographic data, including date of birth for both mother and her child, ethnicity, marital status, number of previous children, immigration year, and primary care clinic address; date and results of all A1C, kidney, and thyroid function tests as well as urine assessment for microalbumin and protein; date of clinic dietary consultation and ophthalmology evaluation; as well as all prescription fillings they made during the study period, including name of drug, dosage, quantity, and date of prescription filling. The CHS laboratory database contains data on all laboratory results done in

CHS clinics as well as CHS hospitals, and the CHS pharmacy computerized database contains data on all prescription fillings in CHS pharmacies and affiliated pharmacies, including over-the-counter (OTC) drugs such as vitamins.

Diabetes diagnosis was verified by either an A1C $\geq 6.5\%$ (48 mmol/mol) according to the American Diabetes Association recommendation for diabetes diagnosis (17) or prescription filling for oral hypoglycemic drug or insulin in the year before the index pregnancy. This criteria was used to exclude women with gestational diabetes only. Type of diabetes mellitus, either type 1 or type 2, was determined by CHS chronic disease registry and based on the antidiabetic treatment in the year before and after the index pregnancy; women with insulin-only treatment were considered to have type 1 diabetes, whereas women without medication or those with oral hypoglycemic therapy either alone or in combination with insulin were considered to have type 2 diabetes. Maternal ethnicity was defined as Arabian, Israeli-born Jewish, or immigrant Jewish (if she was not born in Israel), and maternal socioeconomic class was determined based on her primary care clinic address.

The preconception period extends from approximately 3 months before to 3 months after conception. Since the average pregnancy lasts approximately 270 days, for the purpose of this study, the preconception period was calculated as the period between 180 and 360 days prior to child's date of birth. The quality of medical care in the preconception period was defined according to the following recommended measures (6–9) for women with pre-existing diabetes: evaluation and level of A1C, evaluation of kidney and thyroid function, urine assessment for microalbumin and protein, dietary consult and ophthalmology evaluation, folic acid prescription fillings, use of potentially hazardous drugs, and type of diabetes medication.

A composite score for the quality of medical care in the preconception period was created (based on the

following parameters as recommended in the literature). The composite quality score contains nine items, with a maximum score of eight points as outlined below. One point was given for each of the following parameters: evaluation of A1C level, kidney function test (creatinine or urea level), thyroid function test (thyrotropin or free T4 level), urine assessment for microalbumin or protein (either as spot urine for microalbumin-to-creatinine ratio or 24 h urine collection), dietary consultation, and ophthalmology evaluation. Women who did not have a recorded test result in the periconception period were given a zero score for that item. A1C level in the periconception period represents glycemic control at the time of fetal organogenesis and is of paramount importance for spontaneous abortion and congenital malformation risk. Thus women with A1C <7.0% (53 mmol/mol) were given one point, whereas women with A1C >9.0% (75 mmol/mol) were deleted one point; women with A1C level between 7.0 and 9.0% or no recorded A1C level were given zero points.

Folic acid consumption was calculated based on folic acid prescription fillings (at any dose, including in multivitamins or in combination with iron) in the periconception period. Prescription fillings were calculated per month, according to the pill quantity in each prescription. Some folic acid formulas can be bought as an OTC drug, yet all OTC purchases are also recorded in the CHS pharmacy's computerized database. Folic acid consumption was assumed if a woman filled more than one folic acid prescription in the periconception period; these women were given one point for folic acid intake. Use of potentially teratogenic drugs (i.e., ACE inhibitors, angiotensin-II receptor blockers, and statins) in the first months of pregnancy is dangerous. Thus women who filled prescription for any of these medications at that time (i.e., between 180 and 270 days before the child's date of birth) were deleted one point.

Most women with type 2 diabetes get oral hypoglycemic drugs before pregnancy, whereas those with type 1

diabetes are treated with insulin. However, during pregnancy, insulin is the drug of choice (6,9), thus we assessed type of diabetes medication but did not include it in the quality score.

Data were tested for normal distribution (Kolmogorov–Smirnov test), and χ^2 , Mann–Whitney test, one-way ANOVA, and Kruskal–Wallis one-way ANOVA on ranks were used to examine the associations between sociodemographic characteristics and the quality measures. The overall composite quality score was assessed in tertiles; significant differences between the composite quality score low tertile and sociodemographic characteristics were assessed by multivariate binary logistic regression analysis. Analyses were conducted using SigmaStat version 2.03 and Minitab version 12.23. Statistical significance was defined as a two-tailed $P < 0.05$.

RESULTS

A total of 166 women gave birth to 180 babies. Average maternal age at delivery was 33 ± 6 years, 81.7% of women were married, 30.6% were primiparous (Table 1), 46.1% were Arabian, 40% were Israeli-born Jewish, 13.9% were immigrant Jewish, and 62.2% were of low socioeconomic class. Overall, 58.9% of women had type 2 diabetes mellitus. As shown in Table 2, there were significant sociodemographic differences between women with type 2 and type 1 diabetes mellitus. Women with type 2 diabetes were older, less were primipara, and more were Arabian and of low socioeconomic class.

The performance of the different quality parameters (Table 1) ranged from 81% for A1C and kidney function tests to only 30% for dietary consult and 41.1% for ophthalmology evaluation. Notably, 48.9% of women had reasonable glycemic control with A1C <7.0% (53 mmol/mol), only 26% had A1C <6.0% (42 mmol/mol), and 8.3% had poor glycemic control with A1C >9.0% (75 mmol/mol). Only 45% of women took some folic acid, and 25 women (13.9%) continued the use of potentially dangerous drugs in the first trimester. Overall, there were no significant

differences in the performance of the different quality parameters between women with type 2 and type 1 diabetes (Table 2), although women with type 2 diabetes had significantly lower median A1C (6.4 vs. 7.1%, 46 vs. 54 mmol/mol; $P = 0.02$).

All women with type 1 diabetes used insulin; 43 used multiple daily injection (mainly human NPH insulin with regular insulin [18] or with rapid-acting insulin analogs [insulin lispro or insulin aspart (16)]), 2 women used Levemir, and 9 women used insulin glargine (Lantus), which is not recommended in pregnancy due to safety concerns (18), although a recent meta-analysis did not find increased adverse fetal outcomes with its use (19). Thirty-one women used continuous insulin pump with either rapid-acting insulin analogs (27) or regular insulin (4).

Among women with type 2 diabetes, only 50 (47.2%) received insulin, whereas 31 (29.2%) received oral hypoglycemic agents, mainly Metformin either alone (6 women) or in combination with insulin (25 women). Most women with type 2 diabetes used multiple daily injection (mainly human NPH insulin with regular insulin [51] or with rapid-acting insulin analogs [11]), 2 women used Levemir, and 1 woman used insulin glargine. Ninety-five percent of women with type 2 diabetes who received insulin (71 women) had A1C measurement, and 61.3% of them had A1C <7.0% (53 mmol/mol). Twenty-five women were treated with diet and did not take medication, and 10 of them (40%) had good glycemic control, with A1C <7.0%. However, 13 women did not have any A1C recording.

As shown in Table 2, there were significant sociodemographic differences between the quality score groups; notably more women in the lower composite quality score groups were multipara, were Arabian or immigrant Jewish, and of low socioeconomic class; however, there were no differences in women's age or type of diabetes. There was a significant gradual better performance of each of the quality measures between the low-, middle-, and high-quality score groups ($P < 0.0001$) (Table 1).

Table 1—Maternal characteristics and performance of quality measures by composite quality score

Maternal characteristics	All women	Composite quality score group (points)			P value
		Low (0–3) n = 60	Middle (4–5) n = 65	High (6–8) n = 55	
Maternal age (years)*	33.0 ± 6.0	32.5 ± 5.7	32.9 ± 6.2	33.6 ± 6.2	0.586
Married†	147 (81.7)	81.7	86.2	76.4	0.385
Primipara†	55 (30.6)	28.3	18.5	47.3	0.003
Socioeconomic class†					
Low	112 (62.2)	73.3	63.1	49.1	0.027
High middle	68 (37.8)	26.7	36.9	50.9	
Ethnicity†					0.006
Arabian	83 (46.1)	56.7	50.8	29.1	
Israeli-born Jewish	72 (40)	26.7	35.4	60.0	
Immigrant Jewish	25 (13.9)	16.7	13.9	10.9	
Diabetes type†					0.333
Type 1	74 (41.1)	48.3	35.4	40.0	
Type 2	106 (58.9)	51.7	64.6	60.0	
Quality measures performance					
A1C evaluation†	146 (81.1)	51.7	92.3	100	<0.001
A1C level‡	6.7 (6.2–7.7)	8.3 (7.3–9.2)	6.6 (6.2–7.6)	6.3 (6.0–6.9)	<0.001
A1C level†					<0.001
<7.0%	88 (48.9)	10.0	56.9	81.8	
7.0–9.0%	43 (23.9)	21.7	30.8	18.2	
>9.0%	15 (8.3)	20.0	4.6	0	
Not done	34 (18.9)	48.3	7.7	0	
Kidney function test†	147 (81.7)	51.7	93.9	100	<0.001
Urine test for protein†	101 (56.1)	21.7	56.9	92.7	<0.001
Thyroid function test†	133 (73.9)	40.0	86.2	96.4	<0.001
Ophthalmology exam†	74 (41.1)	20.0	32.3	74.6	<0.001
Dietary consultation†	54 (30.0)	10.0	20.0	63.6	<0.001
Folic acid use†	81 (45.0)	25.0	33.9	80.0	<0.001
Use of potential teratogenic drugs†	25 (13.9)	20.0	13.9	7.3	0.143

All data are n (%) or % unless otherwise indicated. *One-way ANOVA, mean ± SD. † χ^2 test. ‡Kruskal–Wallis one-way ANOVA on ranks, median (interquartile range).

In the multiple logistic regression analysis, the only significant variables to predict lower composite quality scores were multiparity adjusted odds ratio = 3.43 (95% CI 1.66–7.10; $P = 0.001$), Arabian women adjusted odds ratio = 3.76 (95% CI 1.78–7.92; $P = 0.001$), and immigrant Jewish adjusted odds ratio = 3.73 (95% CI 1.25–11.16; $P = 0.018$).

CONCLUSIONS

We found that a high proportion of women with diabetes had suboptimal preconception care with poor glycemic control and inadequate diabetic pharmacotherapy and dietitian consultation; many did not use folic acid and too many continued the use of potentially harmful medications in the first trimester of pregnancy. Moreover, diabetic retinopathy might worsen during pregnancy (6), and proteinuria is associated with increased risk for

preeclampsia (6). However, despite widespread recommendations for screening patients with diabetes for microvascular complications (17), only 41.1% had an ophthalmic evaluation, and 43.9% did not have any urine test for proteinuria evaluation. We also found that Arabian women and immigrant Jewish women had even worse preconception care. We did not find significant differences in the quality of preconception medical care between women with type 1 and type 2 diabetes except that women with type 2 diabetes had significantly lower median A1C.

Our findings are similar to the only other study that evaluated all aspects of preconceptional medical care provided to women with pre-existing diabetes in the U.K. (12). They found that women with diabetes were poorly prepared for pregnancy: less than half were recorded

to take folic acid supplements prior to pregnancy or to have had preconception counseling regarding glycemic control, diet, or diabetes complications. Only one-third had a test of glycemic control in the 6 months before pregnancy, and two-thirds had evidence of suboptimal glycemic control before conception and in the first trimester of pregnancy. Approximately 40% did not have retinal examination or renal function test in the year before pregnancy, and these women were more likely to have a poor pregnancy outcome. They concluded that suboptimal preconception care, suboptimal glycemic control before and during pregnancy, as well as maternal social deprivation (based on postcode of residence) were all associated with poor pregnancy outcome. Based on their recommendation, Murphy et al. (15) evaluated the effectiveness of a regional prepregnancy care program on

Table 2—Maternal characteristics and quality measures by maternal type of diabetes

	Diabetes		P value
	Type 1 n = 74	Type 2 n = 106	
Maternal age at delivery*	28.6 (26.4–33.1)	35.6 (30.9–39.3)	<0.001
Married†	78.4	84.0	0.341
Primipara†	39.2	24.5	0.036
Socioeconomic class†			0.028
Low	52.7	68.9	
High middle	47.3	31.1	
Ethnicity†			0.286
Arabian	39.2	50.9	
Israeli-born Jewish	45.9	35.9	
Immigrant Jewish	14.9	13.2	
A1C evaluation†	79.7	82.1	0.692
A1C level*	7.1 (6.2–8.3)	6.4 (6.1–7.3)	0.019
A1C level†			0.095
<7.0%	39.2	55.7	
7.0–9.0%	32.4	17.9	
>9.0%	8.1	8.5	
Not done	20.3	17.9	
Kidney function test†	81.1	82.1	0.865
Urine test for protein†	54.1	57.6	0.642
Thyroid function test†	74.3	73.6	0.912
Ophthalmology exam†	46.0	37.8	0.271
Dietary consultation†	21.6	35.8	0.06
Folic acid use†	47.3	43.4	0.605
Use of potential teratogenic drugs†	12.2	15.1	0.576

All data are % unless otherwise indicated. *Mann–Whitney rank sum test, median (interquartile range). † χ^2 test.

pregnancy preparation, glycemic control, and pregnancy outcomes in women with type 1 and type 2 diabetes. They found that women with prepregnancy care were significantly more likely to have type 1 diabetes, to take preconception folic acid, and to use insulin. They had lower A1C levels (6.9 vs. 7.6%), although only 53% achieved A1C <7.0% (53 mmol/mol). Fewer women conceived while taking potentially harmful drugs. Importantly, these women also had fewer adverse pregnancy outcomes (1.3 vs. 7.8%).

Good glycemic control prior to and in the beginning of pregnancy is crucial in order to reduce the rate of congenital malformations and spontaneous abortions among patients with diabetes (2–5,9). Therefore most other studies evaluated mainly the glycemic control prior to pregnancy and its effect on pregnancy outcome. For example, a French multicenter survey (10) and a large Danish study (11) found that women with higher first trimester A1C

had increased risk for adverse perinatal outcome. Similarly, in a population-based study in Northern England, only 53% of diabetic patients had a preconception A1C record, and of those with records, 74% had suboptimal glycemic control, with A1C above 7.0% (53 mmol/mol). They also found that diabetic women who received preconception counseling (40.8%) had significantly higher rate of good glycemic control prior to pregnancy, 63.8% compared with only 36.3% in women without such care (14). In a previous study by our group (20), we found that even women with diabetes who undergo repeat fertility treatments lack proper preconception care. Less than two-thirds had A1C recoding within 3 months of fertility treatment, and only one-third of them had evidence of good glycemic control with A1C <7.0% (53 mmol/mol). These findings were similar to diabetic women with spontaneous pregnancy. We also showed that women with diabetes who

attended high-risk pregnancy clinics prior to fertility treatment achieved significantly better glycemic control (21).

There are many studies in the general population on folic acid intake before pregnancy. For example, the Centers for Disease Control and Prevention reported that in 2007, only 40% of women of childbearing age in the U.S. took vitamin supplements containing folic acid (22). However, there are only scant data about the use of folic acid before pregnancies in patients with diabetes. A study from the Netherlands (23) among pregnant women with type 1 diabetes found relatively high preconception folic acid intake of 70%. In contrast, in a study from England, only 45% of women with diabetes took folic acid in the preconception period (14). They also found that prepregnancy folic acid use was significantly higher among women who received preconception counseling (68.4 vs. only 31.6%). Furthermore, Nilsen et al. (24), in a large survey from Norway, found that overall only 10.2% of women used folic acid supplement in the preconception period. Folic acid use was somewhat higher among women with diabetes (17.3%). Our findings are in agreement with above results; we found that only 45% of patients took folic acid supplementation in the preconception period. Our findings are also in agreement with a previous survey from Israel in which 34% of postpartum women stated that they used folic acid in the preconception period (25).

Drug use in the preconception period and early pregnancy is very common, including drugs that are teratogenic or potentially hazardous. Studies from the U.S. (26), the U.K. (27), and Finland (28) have demonstrated that up to 4.0% of pregnancies are exposed to potentially teratogenic class D or X medications in the preconception period. However, very little is known about medication use in pregnant diabetic women (15). Some potentially hazardous drugs are commonly indicated in diabetic patients (e.g., statins and ACE) and are thus expected to increase the problem. In a recent study by our group (20), we also found that some diabetic patients who undergo fertility treatments continue

the use of these drugs in the beginning of pregnancy and after fertility treatment. In this study, we found that similar to the general pregnant population, too many women with diabetes continue the use of potentially harmful drugs in the beginning of pregnancy. In a literature review, we could not find any other articles that dealt with preconception screening for microvascular complications in women with diabetes.

The current study also demonstrated disparities in the quality of preconception medical care among diabetic patients. Mainly, women of lower socioeconomic class and Arabian and immigrant Jewish women had less favorable diabetes care and control. Previous studies found similar results. A recent study from Israel among nonpregnant diabetic patients found that low socioeconomic status, Arabian ethnicity, and immigrants were associated with less favorable diabetes care and control (29). Also in a population-based study in Northern England (14), diabetic women of white British ethnicity and those of higher socioeconomic status were more likely to receive preconception counseling. Similarly, Murphy et al. (15) found that women who attended prepregnancy care were more likely to be white and less likely to live in a deprived area.

We did not find significant differences in the quality of preconception medical care between women with type 1 and type 2 diabetes except that women with type 2 diabetes had significantly lower median A1C; however, it is possible that our study was underpowered to demonstrate small differences between the two groups. In contrast, a large survey from the U.K. (12) found that women with type 2 diabetes were less likely than women with type 1 diabetes to have retinal assessment or test for albuminuria in the year prior to pregnancy. However, folic acid intake and A1C evaluation rates were similar in both groups. They also found that women with type 1 diabetes were more likely to have suboptimal preconception glycemic control; only 24% of women with type 1 diabetes had a median A1C <7.0% prior to pregnancy compared with 41% of women with type

2 diabetes. In a meta-analysis (30) of almost 12,000 women with diabetes, compared with women with type 1 diabetes, women with type 2 diabetes had lower rates of diabetic retinopathy but higher rates of chronic hypertension. Similar to our results, this meta-analysis found that A1C at booking was lower in women with type 2 diabetes (7.20 vs. 8.06%, 55 vs. 65 mmol/mol), although less had prepregnancy care. However, despite a milder glycemic disturbance, women with type 2 diabetes had no better perinatal or maternal outcomes than those with type 1 diabetes.

There are several limitations to our work. We assessed only women with live birth deliveries, and we do not have data on pregnancy outcomes or complications. Thus we cannot assess the correlation between proper preconception care and pregnancy outcome; however, this was not the aim of this study. Also, women who had either a spontaneous abortion or termination of pregnancy due to fetal anomaly or for maternal reasons were not included. Nevertheless, it is highly unlikely that these women had a significantly better preconception care than women with diabetes who had a live-birth child, and therefore the inadequate quality that was observed in our results can be even better estimation of the real practice quality. Also, due to the retrospective study design, we cannot assess barriers for better care.

Women with diabetes were identified from the chronic disease registry in CHS computerized systems. Pre-existing diabetes diagnosis was verified by either an A1C $\geq 6.5\%$ or prescription filling for oral hypoglycemic drug or insulin in the year before the pregnancy. It is possible that we did not identify a small number of patients with diabetes, for example, those who had very good diabetic control and treatment with diet only. Also, women with undiagnosed diabetes and thus no A1C tests or antidiabetic treatment were not accounted for. Still we probably identified most women with diabetes, especially those with clinically significant disease, and the few unidentified patients probably could not change significantly our findings.

We calculated performance of the various laboratory tests as well as dietary and ophthalmology consultations based on data in CHS administrative electronic database. It is possible that some women made these tests or consultations in private clinics. Yet since these women have medical insurance through CHS, which has readily available clinics as well as hospitals throughout the country, and most women were of low socioeconomic class, it is doubtful that a substantial number of these women with diabetes had private medical care outside CHS. The internal consistency between the separate measures to the overall quality score also supports the validity of the information.

We calculated folic acid use based on prescription fillings in CHS pharmacies. It is possible that some women purchased folic acid or other multivitamins including folic acid as OTC drugs in other pharmacies. However, since these women purchased their diabetic drugs in CHS pharmacies and the cost of the vitamins is similar in all pharmacies, it is unlikely that this would change substantially our calculations of folic acid use. Moreover, most studies on folic acid use (12,14,22–25) are based on questionnaires or interviews of pregnant or postpartum women. Thus while our study might have underestimated preconception folic acid use, women's self-report on preconception daily folic acid use is probably over-reported. To the best of our knowledge, there is no study that evaluated preconception folic acid intake by pill counting, which is more accurate.

As for the potentially teratogenic drugs, we chose to examine only the use of drugs that are commonly used by diabetic women and for whom there is firm recommendation to stop using before conception. One might argue that women can fill a prescription and not use the medication, thus prospective evaluation of harmful medication use might be lower than what we reported. However, these women should have received the guidance to stop using these drugs prior to conception and should not have filled a prescription for potentially

teratogenic drugs. Use of potentially harmful medications in early pregnancy should be negligible.

In conclusion, we found that the periconceptional medical care of women with diabetes is suboptimal and needs improvement. Preconception care and counseling is a form of primary prevention that includes three components: risk assessment, health promotion, and intervention in order to improve pregnancy outcome. If we want to achieve the goals of the St. Vincent Declaration (31) and improve pregnancy outcomes of women with diabetes to the level of the nondiabetic population, we need to understand that for women with diabetes, prepregnancy care is as essential as antenatal care. Probably a multidisciplinary team approach is needed with a specialized clinic that can give optimal preconception evaluation and care for patients with diabetes prior to pregnancy. The service should be highly accessible and culturally oriented to the specific target population that was found in this and other studies to have the least qualified service. All women with either type 1 or type 2 diabetes should have a thorough medical assessment with special attention to risk factors, glycemic control, chronic diseases, medications, and family history before pregnancy. Appropriate treatment of all medical conditions, optimization of glycemic control, and cessation (before pregnancy) of use of potentially teratogenic medications can improve women's health status and reduce pregnancy-related complications. Also, culturally appropriate diabetes care and education is needed in order to improve diabetes care and ensure better pregnancy outcomes in the high-risk subpopulations.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. S.R.-M. designed the study, collected and analyzed the data, and wrote the manuscript. R.Au. contributed to the discussion and reviewed the manuscript. R.Al. contributed to the design of the study, the interpretation of the results, and the discussion and edited the manuscript. S.R.-M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

References

- Langer O. Type 2 diabetes in pregnancy: exposing deceptive appearances. *J Matern Fetal Neonatal Med* 2008;21:181–189
- Macintosh MC, Fleming KM, Bailey JA, et al. Perinatal mortality and congenital anomalies in babies of women with type 1 or type 2 diabetes in England, Wales, and Northern Ireland: population based study. *BMJ* 2006;333:177–183
- Kitzmilller JL, Gavin LA, Gin GD, Jovanovic-Peterson L, Main EK, Zigrang WD. Preconception care of diabetes. Glycemic control prevents congenital anomalies. *JAMA* 1991;265:731–736
- Ray JG, O'Brien TE, Chan WS. Preconception care and the risk of congenital anomalies in the offspring of women with diabetes mellitus: a meta-analysis. *QJM* 2001;94:435–444
- Wahabi HA, Alzeidan RA, Bawazeer GA, Alansari LA, Esmaeil SA. Preconception care for diabetic women for improving maternal and fetal outcomes: a systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2010;10:63
- Kitzmilller JL, Block JM, Brown FM, et al. Managing preexisting diabetes for pregnancy: summary of evidence and consensus recommendations for care. *Diabetes Care* 2008;31:1060–1079
- National Collaborating Centre for Women's and Children's Health (Great Britain); National Institute for Clinical Excellence (Great Britain). Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. London, RCOG Press, 2008
- Mahmud M, Mazza D. Preconception care of women with diabetes: a review of current guideline recommendations. *BMC Womens Health* 2010;10:5
- Israel Society of Obstetrics and Gynecology. Management of pregnancy and delivery in women with preconception diabetes. Position statement number 17 [article online], 2008. Available from http://www.obgyn.org.il/niarEmda_info.asp?info_id=54186. Accessed 9 March 2013
- Boulout P, Chabbert-Buffet N, d'Ercole C, et al.; Diabetes and Pregnancy Group, France. French multicentric survey of outcome of pregnancy in women with pregestational diabetes. *Diabetes Care* 2003;26:2990–2993
- Jensen DM, Korsholm L, Ovesen P, et al. Peri-conceptional A1C and risk of serious adverse pregnancy outcome in 933 women with type 1 diabetes. *Diabetes Care* 2009;32:1046–1048
- Modder J, Fleming KM, Acolet D. Diabetes in pregnancy: are we providing the best care? Findings of a National Enquiry [article online], 2007. Available from <http://www.publichealth.hscni.net/sites/default/files/Diabetes%20in%20Pregnancy-%20are%20we%20providing%20the%20best%20care.pdf>. Accessed 22 February 2013
- Persson M, Norman M, Hanson U. Obstetric and perinatal outcomes in type 1 diabetic pregnancies: A large, population-based study. *Diabetes Care* 2009;32:2005–2009
- Tripathi A, Rankin J, Aarvold J, Chandler C, Bell R. Preconception counseling in women with diabetes: a population-based study in the north of England. *Diabetes Care* 2010;33:586–588
- Murphy HR, Roland JM, Skinner TC, et al. Effectiveness of a regional prepregnancy care program in women with type 1 and type 2 diabetes: benefits beyond glycemic control. *Diabetes Care* 2010;33:2514–2520
- Goldfracht M, Levin D, Peled O, et al. Twelve-year follow-up of a population-based primary care diabetes program in Israel. *Int J Qual Health Care* 2011;23:674–681
- American Diabetes Association. Standards of medical care in diabetes—2013. *Diabetes Care* 2013;36(Suppl. 1):S11–S66
- Kurtzhals P, Schäffer L, Sørensen A, et al. Correlations of receptor binding and metabolic and mitogenic potencies of insulin analogs designed for clinical use. *Diabetes* 2000;49:999–1005
- Pollex E, Moretti ME, Koren G, Feig DS. Safety of insulin glargine use in pregnancy: a systematic review and meta-analysis. *Ann Pharmacother* 2011;45:9–16
- Riskin-Mashiah S, Auslander R. Quality of medical care in diabetic women undergoing fertility treatment: we should do better! *Diabetes Care* 2011;34:2164–2169
- Paz M, Auslander R, Riskin-Mashiah S. [Medical treatment of diabetic patients in high risk pregnancy clinic improves glycemic control prior to fertility treatment]. *Harefuah* 2011;150:820–823, 877
- Centers for Disease Control and Prevention (CDC). Use of supplements containing folic acid among women of childbearing age—United States, 2007. *MMWR Morb Mortal Wkly Rep* 2008;57:5–8
- Evers IM, de Valk HW, Visser GH. Risk of complications of pregnancy in women with type 1 diabetes: nationwide prospective study in the Netherlands. *BMJ* 2004;328:915–920
- Nilsen RM, Vollset SE, Gjessing HK, et al. Patterns and predictors of folic acid supplement use among pregnant women: the Norwegian Mother and Child Cohort Study. *Am J Clin Nutr* 2006;84:1134–1141
- Amitai Y, Fisher N, Meiraz H, Baram N, Tounis M, Leventhal A. Preconceptional folic acid utilization in Israel: five years after the guidelines. *Prev Med* 2008;46:166–169

26. Andrade SE, Gurwitz JH, Davis RL, et al. Prescription drug use in pregnancy. *Am J Obstet Gynecol* 2004;191:398–407
27. Hardy JR, Leaderer BP, Holford TR, Hall GC, Bracken MB. Safety of medications prescribed before and during early pregnancy in a cohort of 81,975 mothers from the UK General Practice Research Database. *Pharmacoepidemiol Drug Saf* 2006;15:555–564
28. Malm H, Martikainen J, Klaukka T, Neuvonen PJ. Prescription of hazardous drugs during pregnancy. *Drug Saf* 2004;27:899–908
29. Wilf-Miron R, Peled R, Yaari E, et al. Disparities in diabetes care: role of the patient's socio-demographic characteristics. *BMC Public Health* 2010;10:729–737
30. Balsells M, García-Patterson A, Gich I, Corcoy R. Maternal and fetal outcome in women with type 2 versus type 1 diabetes mellitus: a systematic review and metaanalysis. *J Clin Endocrinol Metab* 2009;94:4284–4291
31. Diabetes care and research in Europe: the Saint Vincent Declaration. *Diabet Med* 1990;7:360