Operationalizing and Examining Family Planning Vigilance in Adult Women With Type 1 Diabetes

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OBJECTIVE

Because unplanned pregnancies could cause maternal-fetal complications for women with diabetes, family planning vigilance (FPV) is imperative. The aims of this article are to operationalize and describe FPV and examine the associations among FPV behaviors and diabetes self-care management (DSM) and health outcomes of women with type 1 diabetes (T1D).

RESEARCH DESIGN AND METHODS

Retrospective data were used from a follow-up study of adult women with T1D who participated as adolescents in a preconception counseling (PC) intervention trial and matched comparison women with T1D who did not receive the adolescent PC intervention. Participants completed online questionnaires regarding family planning behaviors, DSM, and clinical and reproductive health outcomes.

RESULTS

Participants ($N = 102$) were, on average, 23.7 years old (range 18–38) and 98.0% were white, 82.2% had some college, 25.8% were married, and 11.8% had biological children. Of those sexually active ($n = 80$, 78.4%), 50% were contraceptive vigilant and 11% were FPV (i.e., being contraceptive vigilant, receiving PC, and initiating discussions with health care professionals). Among FPV behaviors, only receiving PC and initiating discussion with health care professionals were correlated ($r = 0.29$, $P = 0.010$). Compared with nonvigilant women, contraceptive vigilant and FPV women used more effective contraceptive methods ($P = 0.025$) and experienced less diabetic ketoacidosis ($P = 0.040$) and hospitalizations ($P = 0.064$), whereas FPV women were aware of PC ($P = 0.046$) and younger when they received PC ($P < 0.001$). FPV components were associated with DSM and health outcomes ($P < 0.05$).

CONCLUSIONS

Women with diabetes should be FPV, but few were. FPV women were more likely to have PC earlier and better health outcomes, supporting early PC intervention.

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Women with diabetes are at risk for pregnancy-related complications (1). Preconception counseling (PC) can significantly lower the risks of complications (2). Therefore, women with diabetes avoiding pregnancies should be vigilant in using effective family planning.

The American Diabetes Association (ADA) recommends that PC should be included in the routine clinical care of all women with diabetes of child-bearing potential beginning at puberty (2,3). In 1999, our team developed an evidenced-based

theory-driven PC intervention called Reproductive-health Education and Awareness of Diabetes in Youth for Girls (READY-Girls) that was tailored for female adolescents with type 1 diabetes (T1D), later modified in 2005 for type 2 diabetes (T2D), to promote effective family planning decisions and empower them to seek preconception care when planning a pregnancy (4). This validated PC program was in DVD, CD, and book formats and was theoretically based on the expanded health belief model (5). To date, we have conducted three independent randomized controlled trials in 1999 (6), 2002 (7), and 2005 (8), with samples of adolescent females with diabetes from 13 to 19 years of age. These studies only provided 3–12 months of outcome data. From these studies, we found that READY-Girls was significantly associated with increased knowledge, improved attitudes, use of effective family planning, and initiation of PC discussion with health care professionals (6–8), especially if they received PC boosters (8,9). Given the need for long-term (>1 year) follow-up to evaluate behavioral, pregnancy, and clinical outcomes, we were uniquely positioned to recontact subjects who participated in one of the three READY-Girls trials (and we recruited matched control subjects with T1D who never received READY-Girls intervention as adolescents) from a single clinical site to evaluate whether receiving PC intervention (READY-Girls) during adolescence had long-term effects on preventing unplanned pregnancies (initiating discussion with health care professionals; using effective family planning, including abstinence), pregnancy planning behavior (seeking and receiving PC and preconception care), and pregnancy outcomes (preventing maternal and neonatal complications). To our knowledge, this is the first retrospective and prospective cohort study of adult women with T1D who received a PC intervention during their adolescent years that can provide insight into family planning vigilance (FPV) behavior in this cohort (9).

In the general literature on adolescent sexual behavior, the term vigilance is usually associated with only "contraceptive use" (10,11) or contraceptive decision making (12,13). Contraceptive vigilance has been measured as the frequency and efficacy of contraceptive

method use (10,11). For this investigation, contraceptive vigilance is defined as always using contraceptive methods when avoiding a pregnancy. But for young women with diabetes, vigilance must be expanded beyond just the use of contraceptive methods all of the time and should also include having received PC and initiated discussion with health care professionals. Thus, we broadened the term to FPV (9).

Therefore, the primary aims of the article are to operationalize and describe FPV, examine the associations among the components of behaviors of FPV (i.e., used contraceptive methods all of the time, received PC, and initiated discussion with health care professionals) and their associations with diabetes self-care management (DSM) and clinical outcomes in women with T1D. Additionally, we compared women with T1D based on their vigilance status (FPV vs. contraceptive vigilant vs. nonvigilant) on reproductive health behaviors, DSM, and clinical outcomes.

RESEARCH DESIGN AND METHODS

Participants and Procedure

Although both retrospective and prospective data were collected for this longitudinal follow-up cohort study, only baseline retrospective data were used in these analyses. Participants were adult women with T1D who were recontacted up to 12 years after their participation as adolescents in one of three sequential independent READY-Girls PC randomized controlled trials at a large tertiary hospital in an academic center in southwest Pennsylvania, along with a matched comparative group of women with T1D who did not receive the PC intervention as teens. For READY-Girls participants, data were able to be pooled across the studies from the clinical site, as the major study variables were measured and collected using similar procedures. The following critical features allowed us to pool these data: *1*) technical content of PC in the READY-Girls programs for T1D has remained consistent, *2*) major variables were collected the same way, *3*) the same eligibility criteria were used, *4*) participants from all three studies and patients in the registry are all from the same clinical site and therefore had the same standards of practice for university-based team-approach pediatric diabetes care,

and *5*) the same principal investigator and strong consistent teams of coinvestigators participated.

In the pooled recruited sample of 252 past READY-Girls participants, 248 (98.4%) were randomized to either an intervention (n = 129, 52.0%) or usual-care (n = 119, 48.0%) group in one of three consecutive independent clinical trials. For the current follow-up study, 143 (57.7%) past READY-Girls participants were approached; reasons for the remaining 105 (42.3%) past READY-Girls participants not being approached were out-of-date contact information (n = 29, 21.5%) and being too young (<18 years of age) (n = 76, 67.3%). From the 143 past READY-Girls participants approached, 52 (36.4%) enrolled in the follow-up study. On the basis of the existing demographic and clinical information from the READY-Girls studies, those that declined participation were similar to those that participated in terms of age, race, age at diabetes diagnosis, and years with diabetes (P < 0.05). Common inclusion criteria for all three earlier studies were adolescent patients <20 years of age, T1D duration for at least 1 year, and English fluency; exclusion criteria were a history of another chronic illness or intellectual disability or being pregnant at the time of recruitment. Because all intervention participants and the control participants at the completion of each READY-Girls study received the READY-Girls program, we recruited an age-matched comparison group (n = 50) who had not received the READY-Girls PC intervention during adolescence. Given the baseline survey in the follow-up study, only 1 (2.1%) woman in the comparison group reported having received some form of PC from health care professionals as an adolescent (<20 years of age). Individuals in the comparative group were identified from the hospital's diabetes research registry and diabetes clinic, received standard care only, and were frequency matched to the READY-Girls participants in terms of age (±2 years), age at T1D diagnosis (±2 years), and race (white, nonwhite). The diabetes research registry is a central repository of information comprised of all new-onset cases of T1D diagnosed since 1955 from the children's hospital and followed over time. It has two components based on pre- and post-HIPAA

regulations: cases from 1955 until early 1990s and cases since 1990. Inclusion criteria for comparison participants were being newly diagnosed and new patients with T1D at the children's hospital who are seeking treatment or who are being treated at the hospital's diabetes research center, at least 18 years of age, and discharged using insulin. Table 1 describes the characteristics of the total sample. This study was approved by the institutional review board.

Our READY-Girls program of research in PC (4) is unique in targeting adolescents and examining the cohort of participants into adulthood on long-term general family planning behaviors and clinical outcomes. Participants completed online questionnaires every 6 months over the 18-month follow-up period regarding DSM, family planning behaviors, and clinical and reproductive health outcomes. Many of the behavioral measures were used in the original READY-Girls studies. We also obtained medical record data for clinical and pregnancy outcomes and metabolic control.

Participants had their own log-in username and password to access the website to complete online questionnaires. Participants used any computer with high-speed Internet at home, school, or public library or the clinic site where there was a laptop for their use. They accessed the secure web portal utilizing the instructions, username, and temporary password provided by the project nurse. An individual user account was created for each participant.

Measurements
For ease of administration, a composite instrument called the Reproductive Health Attitudes and Behavior Questionnaire was condensed into a single questionnaire and used in the previous READY-Girls studies. Validity, reliability (e.g., internal consistency, based on Cronbach α), other psychometric properties, results, and scale scores have been established and published (14).

Pregnancy Planning Behaviors
Young women's intentions and actual behaviors for seeking PC and preconception care were measured by self-report at each time point. "Seeking PC" is a list of dichotomous items with a "yes or no" response. All subjects reported whether they have received any (or additional) PC from their health team and checked from a list based on the ADA PC recommendations (15,16) of actual components of PC received. Awareness, access, and barriers to receiving PC were evaluated. Both diabetes-specific (e.g., starting intensive insulin therapy) and general (e.g., taking folic acid) PC recommended behaviors were assessed. Another pregnancy planning behavior is the use of effective contraceptive methods to prevent a pregnancy until tight metabolic control is achieved. "Effectiveness of contraceptive methods used" was calculated as a weighted summary measure of the contraceptive methods most frequently used, considering whether the identified methods were used singly or combination. The weights that were used were derived using the annual failure rates for methods of contraception reported by Trussell (17). These rates were transformed into probabilities of contraceptive failure (Prob{Failure}) and ranged from 0 to 1, with values near 0 denoting no failure. The overall effectiveness of contraceptive methods used was computed as 1-Prob{Failure}. For those participants who used contraceptive methods in combination (two or more methods jointly), the probability of failure was computed as the product of the failure probabilities of the individual contraceptive methods. For participants identifying multiple methods, but used singly, the overall probability of failure was computed as the average of the failure probabilities of the individual contraceptive methods.

To enhance participant recall for retrospective data, questions were asked according to "ever in your life," "past year," "past 3 months," "last time," and "current now."

Contraceptive Vigilance
Contraceptive vigilance was assessed based on the frequency of contraception use when sexually active and not trying to become pregnant. Participants were classified as "contraceptive vigilant" if they used contraception every time (100%) they had sexual intercourse when not planning a pregnancy.

FPV
"FPV" derived a composite to measure the new construct; namely, preventing unplanned pregnancies (using contraceptive methods all the time when not planning a pregnancy, i.e., contraceptive vigilance), demonstrating pregnancy planning behaviors (receiving PC and preconception care), and initiating any discussion with health care professionals about PC-related topics (diabetes and pregnancy, diabetes and sexuality, contraception, and PC). Women were classified as 1) FPV (i.e., reporting using contraceptive methods every time they had sexual intercourse when not planning a pregnancy, receiving PC, and initiating any discussion with a health care professional), 2) contraceptive vigilant (using contraceptive methods every time they had sexual intercourse when not planning a pregnancy and either not receiving PC or initiating any discussion with a health care professional), or 3) nonvigilant (not contraceptive vigilant and not receiving PC or initiating any discussion with a health care professional).

Motivational Cues
"Initial awareness of PC" determined if participants had prior knowledge of PC

Table 1—Sample characteristics (total sample and by sexual activity status)[a]

		Sexual activity status		
	Total (N = 102)	Yes (n = 80)	No (n = 22)	P value
Age (years)	23.7 ± 4.5	24.6 ± 4.5	20.5 ± 2.9	<0.001
Age at T1D diagnosis (years)	9.5 ± 5.1	9.5 ± 4.9	9.2 ± 5.8	0.810
Duration of T1D (years)	14.1 ± 6.7	15.0 ± 6.7	11.1 ± 5.9	0.017
Non-Hispanic white	99 (98.0)	77 (97.5)	22 (100.0)	0.999
At least some college or trade school	83 (82.2)	69 (87.3)	14 (63.6)	0.170
Current boyfriend or husband	69 (69.7)	60 (77.9)	9 (40.9)	0.002
Currently married	25 (25.8)	25 (32.9)	0 (0.0)	0.002
Any biological children	12 (11.8)	12 (15.0)	0 (0.0)	0.065
Private health insurance	75 (86.2)	59 (85.5)	16 (88.9)	0.999
Income <$40,000/year	24 (29.3)	21 (29.6)	3 (27.3)	0.999
Identifies as Roman Catholic	44 (47.3)	34 (47.9)	10 (45.5)	0.173

Data are mean ± SD or n (%). [a]At the time the survey was completed online.

and from whom. We used only one dichotomous (yes, no) as to prior knowledge of PC.

Personal Health

"Personal health" included illness characteristics (duration of illness, age of onset, complications); history of family planning, sexual activity, family planning methods, pregnancy; and measures of clinical outcomes, such as A1C, hospitalizations, and diabetic ketoacidosis (DKA). Many of these are single items yielding nominal or ordinal data. This information is standard in large studies.

DSM

"DSM" with the diabetes regimen was measured through self-report by a 7-item scale with Likert-type scaling (1 = "not very well done" to 7 = "very well done") based on adhering to DSM behaviors (diet, blood glucose monitoring, insulin and treatment usage, exercise, and clinic visits). This scale has content and predictive validity and internal consistency (Cronbach α = 0.63) (18).

Demographic Characteristics

Age, race, education, income, health insurance, living arrangements, marital status, and religion were collected.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics (19). The level of statistical significance was set at 0.05 for two-sided hypothesis testing. Data were analyzed using descriptive statistics, exploratory analyses, group comparative statistics, and correlational analyses. Descriptive and exploratory analyses were conducted by the key grouping variables of sexual activity status and vigilance status to portray characteristics of the sample and identify any data anomalies (i.e., outliers, missing data, etc.). Missing data were limited (<1.0% overall), and the pattern of missing data was general and deemed missing completely at random. For categorical descriptive and outcome variables, contingency table analyses with χ^2 tests of independence were used; however, Fisher exact tests were applied if sparse cells (expected cell counts <5) were encountered. When two groups were compared (e.g., sexual activity status) for either interval- or ratio-scaled variables, independent samples t tests were used; if data were heavily skewed or had outliers yet group variances were similar,

Mann-Whitney U tests were used. Analysis of variance or Kruskal-Wallis procedures were applied when three or more groups were compared on interval- or ratio-scaled–dependent variables. As the age at first receipt of PC was right censored, Kaplan-Meier estimation was used to obtain the mean and SE for the age at first receipt of PC, and the log-rank test was used for group comparisons among levels of vigilance status. Correlational analyses using Pearson, Spearman, point-biserial, or contingency correlations were used to examine associations 1) among FPV components and 2) between FPV components and DSM and clinical outcomes.

RESULTS

Table 1 describes the characteristics of the total sample and by sexual activity status. The current sample (N = 102) consisted of 1) 51.0% (n = 52) past READY-Girls participants (57.7% [n = 30] intervention, 42.3% [n = 22] usual-care control) and 2) 49.0% (n = 50) matched comparison women. Participants were between 18 and 38 years of age (mean [SD] 23.7 [4.5]) and mostly non-Hispanic white (98.0%). On average, women had been diagnosed with T1D at 9.5 years of age (SD 5.1, range 0–28) and had T1D for 14.1 years (SD 6.7, range 0–30). Many (69.7%) reported having a current boyfriend or husband, but only 25.8% were currently married. A fraction of the sample (11.8%) had at least one biological child. Almost half of the sample was Roman Catholic. A majority of the sample (78.4%, n = 80) have ever been sexually active, with a mean age of sexual debut of 18.2 years (range 14–28). Compared with women who had never been sexually active, sexually active women tended to be older, have a longer duration of T1D, be currently married, and have either a current boyfriend or husband (P < 0.05).

Regarding the components of FPV (i.e., vigilance with contraceptive methods, receipt of PC, and initiating discussions with health care professionals) in the total sample (N = 102), only 22.0% reported having received PC and preconception care, all of whom were sexually active (27.8% vs. 0%, P = 0.006). Most women (76.5%) had initiated discussion with a health care professional, with a greater proportion of sexually active women having initiated discussions

with health care professionals compared with women who had never been sexually active (82.5% vs. 54.5%, P = 0.010). Almost all (98.7%) sexually active women had ever used some form of contraception, but just 50% were vigilant about using contraception every time they had sexual intercourse when not planning a pregnancy. Among the three FPV components, only receipt of PC was significantly associated with initiating discussions with health care professionals (r = 0.29, P = 0.010).

Tables 2 and 3 focus on the 77 (96.3%) women with T1D who identified as being ever sexually active and could be classified as to their vigilance status. Three (3.8%) women could not be classified as to their vigilance status as they did not provide information on whether they used contraceptive methods every time they had sexual intercourse when not planning a pregnancy. Of these sexually active women (n = 77), only 14.3% (n = 11) were FPV, most of whom (81.8%, n = 9) were past READY-Girls participants, and 37.7% (n = 29) were classified as contraceptive vigilant. Compared with nonvigilant women, contraceptive vigilant and FPV women reported using more effective family planning methods (P = 0.025). The contraceptive methods identified as most frequently used were oral contraceptive pills (62.3%, n = 48) and male condoms (64.9%, n = 50). Oral contraceptive pills and male condoms were the most frequently identified combination method (31.6%, n = 25). Participants identified other methods of contraception, some of which have poor contraceptive effectiveness based on the report by Trussell (17), at lower frequencies, including withdrawal (33.8%, n = 26), NuvaRing (6.5%, n = 5), Plan B (emergency contraception) (5.2%, n = 4), intrauterine device (coil, loop) (3.9%, n = 3), abstinence (2.6%, n = 2), hormone patch (1.3%, n = 1), spermicide (foam, creams, gels, vaginal suppositories, vaginal films) (1.3%, n = 1), diaphragm (1.3%, n = 1), rhythm/calendar (1.3%, n = 1), douching (1.3%, n = 1), tubal ligation (1.3%, n = 1), and vasectomy (1.3%, n = 1). No participants identified implants (Norplant) or injections (Depo-Provera) as contraceptive methods that they used most frequently. Compared with either contraceptive vigilant or nonvigilant women, greater proportions of FPV women reported being aware of PC (P = 0.046)

Table 2—Comparing vigilance status with other reproductive health behaviors in women who have ever been sexually active

		Vigilance status			
	Total (n = 77[c])	Nonvigilant (n = 37)	Contraceptive vigilant (n = 29)	FPV (n = 11)	P value
Age at sexual debut (years)	18.3 ± 2.4	18.0 ± 1.9	18.4 ± 2.9	18.6 ± 2.7	0.745
Contraceptive method frequently used					
Used nothing	4 (5.2)	4 (10.8)	0 (0)	0 (0)	0.192[a]
Oral contraceptive pills	48 (62.3)	19 (51.4)	22 (75.9)	7 (63.6)	0.123[a]
Male condoms	50 (64.9)	21 (56.8)	24 (82.8)	5 (45.5)	0.030[a]
Combination method	29 (41.4)	10 (32.3)	16 (57.1)	3 (27.3)	0.101[a]
Effectiveness of contraceptive methods used (probability)	0.89 ± 0.17	0.84 ± 0.23	0.93 ± 0.07	0.92 ± 0.07	0.025
Awareness of PC before study start	55 (72.4)	26 (72.2)	18 (62.1)	11 (100)	0.046
Actually received PC	21 (27.6)	10 (27.0)	0 (0)	11 (100)	<0.001
Age when PC first received (years) (n = 46)	26.6 ± 1.2[b]	29.9 ± 1.1[b]	—	18.4 ± 1.6[b]	<0.001[b]
Started a discussion about PC with a health care professional	64 (83.1)	33 (89.2)	20 (69.0)	11 (100)	0.034[a]
Past READY-Girls participant	44 (57.1)	21 (56.8)	14 (48.3)	9 (81.8)	0.173[a]

Data are mean ± SD or n (%). [a]P value based on Fisher exact test. [b]Mean and SE are based on Kaplan-Meier estimation, and P value is based on the log-rank test. [c]Three (3.8%) women could not be classified as to their vigilance status due to missing information on whether they used contraception every time they had sexual intercourse when not trying to become pregnant.

and having received PC ($P < 0.001$), and on average they were significantly younger when they first received PC ($P < 0.001$). Interestingly, none of the women classified as contraceptive vigilant reported having received PC, yet 20 (69.0%) did report initiating discussion with health care professionals about various PC-related topics (mostly about contraception, 58.6% [$n = 17$]). A greater proportion of FPV women initiated discussions with their health care professionals about PC-related topics than either nonvigilant or contraceptive vigilant women ($P = 0.034$). Table 2 summarizes the results of reproductive health behaviors by vigilance status in women who were ever sexually active.

Compared with nonvigilant women, a lower proportion of contraceptive vigilant and FPV women experienced DKA ($P = 0.040$); a similar trend was found for having any hospitalizations ($P = 0.064$). There were no significant differences among groups regarding DSM and A1C levels. Table 3 presents the results of DSM and clinical outcomes by vigilance status in women who were ever sexually active.

Each FPV component was associated with different outcomes with contraceptive vigilance being associated with any DKA and hospitalizations and their frequencies ($P < 0.05$), initiating discussions with health care professionals being correlated with self-reported A1C

values during the past 6 months ($P = 0.027$), and receipt of PC being associated with DSM ($P = 0.025$). Table 4 reports the correlations between FPV components and DSM and clinical outcomes.

CONCLUSIONS

This article is the first to operationalize and examine FPV for women with diabetes and the first to use this term in this context. We expanded beyond the simple definition of contraceptive vigilance of using contraception all of the time (10–13). The components of FPV behaviors include contraceptive vigilance, receiving PC, and initiating discussions about PC topics with health care professionals. All components are necessary to

Table 3—Comparing vigilance status with overall DSM and selected physiological outcomes in women who have ever been sexually active

		Vigilance status			
	Total (n = 77[b])	Nonvigilant (n = 37)	Contraceptive vigilant (n = 29)	FPV (n = 11)	P value
Adherence to diabetes regimen	23.9 ± 3.1	23.5 ± 3.4	24.2 ± 2.9	24.6 ± 2.1	0.445
Self-reported average A1C past 6 months (% [mmol/mol])	7.6 ± 1.0 [59.1 ± 11.4]	7.6 ± 1.0 [59.1 ± 11.1]	7.8 ± 1.1 [61.5 ± 12.1]	7.2 ± 1.0 [54.6 ± 10.6]	0.924
Checking blood glucose levels as recommended	5.0 ± 0.9	5.0 ± 1.0	5.0 ± 0.9	5.3 ± 0.6	0.581
DKA					
Ever	25 (33.8)	16 (45.7)	7 (25.0)	2 (18.2)	0.131[a]
Number of times	1.0 ± 4.2	1.9 ± 6.1	0.3 ± 0.5	0.3 ± 0.6	0.060
Hospitalized					
Ever	29 (39.4)	18 (50.0)	7 (24.1)	4 (44.4)	0.100[a]
Number of times	1.4 ± 5.9	2.5 ± 8.4	0.3 ± 0.7	0.6 ± 0.7	0.086

Data are mean ± SD or n (%). [a]P value based on Fisher exact test. [b]Three (3.8%) women could not be classified as to their vigilance status due to missing information on whether they used contraception every time they had sexual intercourse when not planning a pregnancy.

Table 4—Correlations among FPV components and overall self-care management and selected physiological outcomes

	DSM	Checking glucose levels	Average A1C past 6 months	Ever have DKA	Number of episodes with DKA	Ever been hospitalized	Number of times hospitalized
Used contraceptive methods all the time							
r	0.137	0.024	0.008	−0.239	−0.263	−0.216	−0.258
P	0.235	0.833	0.951	0.040	0.026	0.065	0.026
Any discussion with health care professional							
r	0.113	0.117	−0.274	0.080	0.189	0.164	0.178
P	0.318	0.303	0.027	0.491	0.107	0.158	0.123
Received PC							
r	0.251	0.163	−0.247	−0.073	−0.064	0.106	0.083
P	0.025	0.151	0.049	0.528	0.591	0.365	0.478

prevent an unplanned pregnancy and to plan a pregnancy that is safe and wanted with tight metabolic control. The conceptual and clinical associations among the components of FPV were examined through correlational analyses. Receipt of PC was correlated with initiating discussions about PC topics with health care professionals.

We also examined the association among the components of behaviors of FPV with DSM and clinical outcomes of women with T1D and compared differences between FPV, contraceptive vigilance, and nonvigilance. Although there were no significant differences among the groups regarding current DSM and A1C levels, vigilant women were more likely to have had better clinical outcomes. Compared with nonvigilant women, contraceptive vigilant and FPV women had less DKA and hospitalizations. FPV components were also associated with DSM and clinical outcomes.

Although all women with T1D should be vigilant regarding contraceptive use, receiving PC, and initiating discussions with health care professionals, very few women in our study were. Participants who received PC earlier during adolescence were more likely to have been FPV, which was associated with better health outcomes. These findings are supported by the *Standards of Medical Care in Diabetes* from 2009 (3) to 2014 (2), which recommend that PC be included in the routine clinical care of all women with diabetes of child-bearing potential beginning "at puberty." The phrase "beginning at puberty" should be reconsidered for future ADA's recommended guidelines on PC in their Standards.

To prevent unplanned pregnancies, PC should begin at puberty, prior to sexual activity, and aim to postpone sexual debut. In the current study, compared with less vigilant women, vigilant

women tended to be older at sexual debut. The mean age of sexual debut for women in this study was 18.3 years, which is older than the 15 years for the general U.S. population (20–22).

We found that vigilant women were more likely to have had PC earlier, to use more effective family planning, and to report better health outcomes. The association between receiving PC and the use of contraception has been examined in previous studies (23). Although the effects of PC on pregnancy outcomes are well documented (1,24,25), fewer studies have explored PC's effects on reproductive health behaviors in women preparing for pregnancy (9,23). In these studies, women having received PC were more likely to plan their pregnancies and have less adverse health outcomes (23). Moreover, PC has been shown to be cost-effective (24,26), providing a net cost savings of approximately $34,000 per patient (24). Few preventive health care measures are as inexpensive and effective as PC (15,26).

FPV has implications for all women with diabetes (T1D and T2D). Preventing unplanned pregnancies is relevant to both groups of women (27). Yet the majority of our sample was not FPV, and only half of sexually active women were contraceptive vigilant. These results are similar to other studies of women with diabetes (23,28). Whereby, two-thirds of women with diabetes have unplanned pregnancies (2,15,23), with up to 10% having maternal and/or fetal complications, such as preeclampsia or congenital anomalies (1,29). Some women may believe that having diabetes causes infertility (22,30) and thus become less adherent with their contraception.

The following limitations must be considered when generalizing these results. The homogeneous sample was

reflective of women with T1D (>95% non-Hispanic white and average age at onset of diabetes was 9.5 years) (16). The adolescent age of the participants in the original READY-Girls studies made it more difficult to recontact them for participation for the follow-up study due to their transition from living with parents to either college and/or adult life separate from parents (i.e., out-of-date contact information due to change in addresses/telephone numbers). Recall of self-reported data could be an issue when only a fourth of the sample reported having received PC and preconception care, but half had received the READY-Girls program as teens. They may not have realized that READY-Girls was a formal PC program. Finally, when operationalizing the construct of FPV to include all the components for analyses, only 11 women met all of the criteria for being FPV, and the size of this subsample was small.

For women with diabetes, vigilance must include pregnancy planning behavior (receives PC and preconception care) and initiation of discussion with health care professionals, along with the use of effective family planning behavior (frequency and level of contraceptive effectiveness). Further analyses are warranted to determine the association between FPV and pregnancy outcomes and the most effective delivery of PC to enhance FPV in women with diabetes.

References

1. Kitzmiller JL, Buchanan TA, Kjos S, Combs CA, Ratner RE. Pre-conception care of diabetes, congenital malformations, and spontaneous abortions. Diabetes Care 1996;19:514–541

2. American Diabetes Association. Standards of Medical Care in Diabetes—2014. Diabetes Care 2014;37(Suppl. 1):S14–S80

3. American Diabetes Association. Standards of Medical Care in Diabetes—2009. Diabetes Care 2009;32(Suppl. 1):S13–S61

4. Charron-Prochownik D, Downs J. *READY-Girls*. Pittsburgh, PA, Univ. of Pittsburgh Press, 2009

5. Burns AC. The expanded health belief model as a basis for enlightened preventive health care practice and research. J Health Care Mark 1992; 12:32–45

6. Charron-Prochownik D, Ferons-Hannan M, Sereika S, Becker D. Randomized efficacy trial of early preconception counseling for diabetic teens (READY-Girls). Diabetes Care 2008;31: 1327–1330

7. Fischl AF, Herman WH, Sereika SM, et al. Impact of a preconception counseling program for teens with type 1 diabetes (READY-Girls) on patient-provider interaction, resource utilization, and cost. Diabetes Care 2010;33:701–705

8. Charron-Prochownik D, Sereika SM, Becker D, et al. Long-term effects of the booster-enhanced READY-Girls preconception counseling program on intentions and behaviors for family planning in teens with diabetes. Diabetes Care 2013;36: 3870–3874

9. Sereika S, Schmitt P, Powell AB, et al. Long-term effects of initiating preconception counseling (PC) during adolescence on family planning vigilance (FPV) in adult women with type 1 diabetes (T1D): 15 year follow-up. Diabetes 2014; 63(Suppl. 1):A198

10. Manlove J, Ryan S, Franzetta K. Patterns of contraceptive use within teenagers' first sexual relationships. Perspect Sex Reprod Health 2003; 35:246–255

11. Speier PL, Mélèse-D'Hospital IA, Tschann JM, Moore PJ, Adler NE. Predicting contraceptive vigilance in adolescent females: a projective method for assessing ego development. J Adolesc Health 1997;20:14–19

12. Picavet C, van der Leest en Ciel Wijsen L. Contraceptive decision-making: background and outcomes of contraceptive methods [article online], 2011. Available at http://www.rutgers .nl/sites/rutgersnl/files/PDF/Contraceptive_ Decisions_Report-def.pdf. Accessed 22 July 2016

13. Commendador K. The relationship between female adolescent self-esteem, decision making, and contraceptive behavior. J Am Acad Nurse Pract 2007;19:614–623

14. Charron-Prochownik D, Wang SL, Sereika SM, Kim Y, Janz NK. A theory-based reproductive health and diabetes instrument. Am J Health Behav 2006;30:208–220

15. American Diabetes Association. Preconception care of women with diabetes. Diabetes Care 2004;27(Suppl. 1):S76–S78

16. American Diabetes Association. Standards of Medical Care in Diabetes—2010. Diabetes Care 2010;33(Suppl. 1):S11–S61

17. Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404

18. Hess GE, Davis WK, Harrison RV. A diabetes psychosocial profile. Diabetes Educ 1986;12: 135–140

19. IBM SPSS Statistics, version 24. Armonk, IBM Corp., 2016

20. Abma JC, Martinez GM, Mosher WD, Dawson BS. Teenagers in the United States: sexual activity, contraceptive use, and childbearing. Vital Health Stat 23 2004;24:1–48

21. Mosher WD, Chandra A, Jones J. Sexual behavior and selected health measures: men and women 15-44 years of age, United States, 2002. Adv Data 2005;362:1–55

22. Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006-2010 national survey of family growth. Vital Health Stat 23 2011;31:1–35

23. Janz NK, Herman WH, Becker MP, et al. Diabetes and pregnancy. Factors associated with seeking pre-conception care. Diabetes Care 1995;18:157–165

24. Herman WH, Janz NK, Becker MP, Charron-Prochownik D. Diabetes and pregnancy. Preconception care, pregnancy outcomes, resource utilization and costs. J Reprod Med 1999;44: 33–38

25. American Diabetes Association. Management of diabetes in pregnancy. Sec. 12. In S*tandards of Medical Care in Diabetes–2016*. Diabetes Care 2016;39(Suppl.1):S94–S98

26. Coustan DR. Preconception counseling - debate: is preconception counseling for women with diabetes cost effective? Diabetes Spectr 1997;10:195–200

27. Downs JS, Arslanian S, de Bruin WB, et al. Implications of type 2 diabetes on adolescent reproductive health risk: an expert model. Diabetes Educ 2010;36:911–919

28. Perritt JB, Burke A, Jamshidli R, Wang J, Fox M. Contraception counseling, pregnancy intention and contraception use in women with medical problems: an analysis of data from the Maryland Pregnancy Risk Assessment Monitoring System (PRAMS). Contraception 2013;88: 263–268

29. Pettitt DJ, Jovanovic L. The vicious cycle of diabetes and pregnancy. Curr Diab Rep 2007;7: 295–297

30. Charron-Prochownik D, Sereika SM, Wang SL, et al. Reproductive health and preconception counseling awareness in adolescents with diabetes: what they don't know can hurt them. Diabetes Educ 2006;32:235–242