

# Impact of a Preconception Counseling Program for Teens With Type 1 Diabetes (READY-Girls) on Patient-Provider Interaction, Resource Utilization, and Cost

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**OBJECTIVE** — To evaluate the impact of a preconception counseling program tailored for teens with type 1 diabetes on cognitive, psychosocial, and behavioral outcomes and to assess its cost-effectiveness.

**RESEARCH DESIGN AND METHODS** — A total of 88 teens with type 1 diabetes from two sites were randomized into the READY-Girls (Reproductive-health Education and Awareness of Diabetes in Youth for Girls) intervention (IG) ( $n = 43$ ) or standard care (SC) ( $n = 45$ ) groups. During three diabetes clinic visits, IG subjects viewed a two-part CD-ROM, read a book, and met with a nurse. Program effectiveness was measured by knowledge, attitudes, intentions, and behaviors regarding diabetes, pregnancy, sexuality, and preconception counseling. Assessments occurred at baseline, before and after viewing program materials, and at 9 months. Economic analyses included an assessment of resource utilization, direct medical costs, and a break-even cost analysis.

**RESULTS** — Age range was 13.2–19.7 years (mean  $\pm$  SD  $16.7 \pm 1.7$  years); 6% ( $n = 5$ ) were African American, and 24% ( $n = 21$ ) were sexually active. Compared with baseline and SC subjects, IG subjects demonstrated a significant group-by-time interaction for benefit and knowledge of preconception counseling and reproductive health: increasing immediately after the first visit ( $P < 0.001$ ) and being sustained for 9 months ( $P < 0.05$  benefits;  $P < 0.001$  knowledge). For IG subjects, preconception counseling barriers decreased over time ( $P < 0.001$ ), and intention and initiation of preconception counseling and reproductive health discussions increased ( $P < 0.001$ ). Costs of adverse reproductive outcomes are high. Direct medical costs of READY-Girls were low.

**CONCLUSIONS** — READY-Girls was beneficial and effects were sustained for at least 9 months. This low-cost self-instructional program can potentially empower young women with type 1 diabetes to make well-informed reproductive health choices, adding little time burden or cost to their diabetes management.

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Uncontrolled diabetes is a major cause of reproductive complications including congenital malformations (1,2). The incidence of major congenital malformations can be reduced from 9 to 2% with preconception counseling (1–3). In 2009, the American Diabetes Association recommended that all

women with diabetes of childbearing potential receive preconception counseling and that this counseling start at puberty (2). In a previous study, we developed a preconception counseling program called READY-Girls (Reproductive-health Education and Awareness of Diabetes in Youth for Girls), tailored for teens with diabetes, and conducted a one-session intervention with a 3-month follow-up evaluation (4–6). Immediately after the session, teens who received the intervention improved in knowledge, attitudes, and intentions related to diabetes and reproductive health. However, some of the effects were not sustained for 3 months. Booster sessions seemed warranted to sustain long-term effects (4). The specific aims of this study were to 1) evaluate the effects of a multiple session intervention of the READY-Girls preconception counseling educational program on cognitive, psychosocial, and behavioral outcomes over 9 months and 2) the economic impact of the READY-Girls intervention.

## RESEARCH DESIGN AND METHODS

This two-site study used an experimental randomized-controlled repeated-measures design. Adolescent girls with type 1 diabetes, between 13 and 19.9 years of age, were randomized into either a preconception counseling intervention group (IG) ( $n = 43$ ) or a standard care group (SC) ( $n = 45$ ). The study was reviewed and approved by the Institutional Review Boards at the sites, and consent was obtained from teens  $\geq 18$  years of age. Both assent from teens and consent from parents were obtained for individuals  $< 18$  years of age.

The intervention was READY-Girls (7), an evidenced-based, theory-driven preconception counseling program tailored for teens with diabetes. READY-Girls intervention raised awareness; provided information about the effects of diabetes on reproductive health, puberty, sexuality, and pregnancy; focused on the benefits of preconception counseling in

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preventing unplanned pregnancies; and enhanced communication skills.

The intervention involved viewing two CD-ROMs, reading a book version, and having a brief research nurse counseling session during three consecutive diabetes clinic visits over a 9-month period. The first CD session provided information on reproductive health and preconception care. The second included exercises to develop communication and decision-making skills concerning preconception counseling. During the third session, teens read a book with information that reinforced the information in the CDs. After sessions 2 and 3, IG teens had a brief one-on-one face-to-face counseling session with the research nurses to answer questions about reproductive health and preconception care.

During the first study sessions, teens in both the IG and SC groups read a March of Dimes brochure on preconception care. Teens in the SC group received the usual care provided in the pediatric diabetes clinics. The standard of care for diabetes at the sites involved quarterly (every 3 months) clinic visits. Both sites were major university-based diabetes clinics in the northeast section of the U.S. The clinics used similar educational programs and team-focused care concerning diabetes and pregnancy.

### Program effectiveness using cognitive and behavioral variables

Program effectiveness was measured by assessing cognitive, psychosocial, and behavioral outcomes based on the Expanded Health Belief Model (6,8,9). These included reproductive health and preconception counseling knowledge and attitudes (perceived susceptibility to an unplanned pregnancy and pregnancy complications, perceived severity of those consequences, perceived benefit of and barriers to prevent an unplanned pregnancy and seeking preconception counseling, self-efficacy to use effective family planning methods and in seeking preconception counseling, and motivational cues). In addition, we measured intentions and actual behaviors regarding both initiating preconception counseling discussion with the health care team and preventing unplanned pregnancies. For non-sexually active teens, preventing unplanned pregnancies meant remaining abstinent, whereas for the sexually active teens, target behaviors included the use of effective contraception to prevent unplanned pregnancies. These constructs

were measured by a composite instrument called the Reproductive Health Attitudes and Behavior (RHAB) Questionnaire, for which psychometric properties, results, and scale scores have been published previously (6). Outcomes were assessed at four sessions with paper-and-pencil self-administered questionnaires. The IG subjects were assessed at baseline and immediately after CD #1, at 3 months (before and after CD #2), at 6 months (before and after book), and at 9 months of follow-up. Subjects in the SC group completed the same battery of questionnaires at baseline, 3, 6, and 9 months.

Efficacy was analyzed using descriptive statistics, group comparative analyses, and repeated-measures mixed-modeling methods using SPSS (v16). Post hoc comparisons explored group main and group-by-time interaction effects.

Past research in educational behavioral interventions in this population has shown effects on the order of 0.20–0.40; results from our previous research, Reproductive Health Awareness for Teens with Diabetes (RHATD), showed similar medium-to-large effects for behavioral outcomes (4). A sample size of 135 was originally estimated to have sufficient power (0.80) at a two-tailed significance level of 0.05.

### Economic analysis

To evaluate the economic impact of the READY-Girls intervention, we prospectively assessed the resource utilization and cost of the intervention. We then modeled the likely reproductive health outcomes of the teens participating in the READY-Girls intervention to determine how effective the intervention would need to be to balance the costs of the intervention with the savings arising from preventing adverse reproductive outcomes. Finally, we described the short-term clinical outcomes of the READY-Girls intervention and projected likely long-term clinical outcomes.

Descriptive statistics (means, SDs, medians, and interquartile ranges) were calculated for each of the time components of the program after extensive exploration for data anomalies and outliers. For each group, the means for the total time across sessions were estimated for the participant, nurse, and doctor (1) using the data that were available and 2) weighted according to the number of subjects participating in each session.

To assess resource utilization, nurses at each research site prospectively completed logs recording the time they spent

delivering the intervention. Specifically, the time they spent for setup, training, and delivery of the READY-Girls intervention was assessed. Each participant's time was also assessed. Because participation in the intervention might also affect clinic time, we prospectively assessed clinic time for each of the three intervention sessions in both the intervention and standard care groups.

To calculate the direct medical costs of the intervention, the time required for the nurse to set up the computer, train the teen, and deliver the intervention was multiplied by the nurse educators' average compensation plus 25% for fringe benefits and 60% for clinic overhead. Although participant time was assessed, its value was not included in the calculation of direct medical costs.

As a sensitivity analysis, we also assessed differences in average clinic time for teens in the intervention and standard care groups over the course of the three visits and multiplied the difference in time by the mean salary of a pediatric endocrinologist plus 25% for fringe benefits and 60% for clinic overhead.

To determine how effective the intervention would need to be to offset the cost of the intervention, we performed a break-even cost analysis. Specifically, we assessed the downstream financial implications of one unplanned pregnancy in a teen <20 years of age in the U.S. and then estimated how many unplanned pregnancies would need to be prevented by the READY-Girls intervention to offset the cost of delivering the intervention to 100 teens with type 1 diabetes.

**RESULTS**— At two university-based diabetes clinics, 88 adolescent teens with type 1 diabetes, between 13.2 and 19.7 years of age (mean 16.6 years) were enrolled. Forty-three adolescent teens were randomized to the IG group and 45 to the SC group. Although all of the participants were encouraged to complete the program, one of the adolescent teens dropped out of the IG group.

Six percent ( $n = 5$ ) of subjects were African American and 78% ( $n = 67$ ) were Caucasian. The majority (96%,  $n = 85$ ) were living with their parents. Mean duration of diabetes was 7.2 years (range 1–17). Most subjects were in high school (64%,  $n = 54$ ), and some were in college (7%,  $n = 6$ ). Forty-seven percent ( $n = 42$ ) of the subjects' mothers were college graduates. Thirty-eight percent ( $n = 34$ ) of subjects reported having boyfriends.

Table 1—Group response profiles for outcome variables at baseline, immediately after intervention, and 9-month follow-up post-test values

	Intervention group (n = 42)		Control group (n = 45)		F	P
	Mean ± SE	Range	Mean ± SE	Range		
Diabetes and pregnancy knowledge*						
Group					32.34	<0.001
Time					37.44	<0.001
Group-by-time					32.3	<0.0001
Baseline	52.1 ± 3.6	45–59.3	46.7 ± 3.5	39.7–53.7		
Immediately after intervention	82.2 ± 3.1	76–88.4	48.3 ± 3.1	42.3–54.4		
9-Month follow-up	81.3 ± 3.5	74.3–88.3	53.5 ± 3.3	46.9–60		
Benefits†						
Group					9.70	0.0025
Time					14.02	<0.0001
Group-by-time					11.2	<0.0001
Baseline	16.5 ± 0.5	15.5–17.6	16 ± 0.5	15–17.1		
Immediately after intervention	19.3 ± 0.4	18.5–20.3	16.2 ± 0.4	15.5–17		
9-Month follow-up	18.3 ± 0.5	17.4–19.3	16.7 ± 0.5	15.8–17.6		
Intention to initiate discussion‡						
Group					1.06	0.31
Time					15.54	<0.0001
Baseline	8.71 ± 0.4	7.6–9.8	8.87 ± 0.69	7.75–9.97		
Immediately after intervention	11.11 ± 0.5	9.9–12.3	10.1 ± 0.33	9.0–11.3		
9-Month follow-up	11.2 ± 0.6	10.1–12.6	9.77 ± 0.46	8.8–11.2		
Group-by-time					1.56	0.21
Initiating discussion§						
Group					1.90	0.17
Time					14.6	0.0003
Baseline	0.7 ± 0.09	0.4–0.9	0.6 ± 0.09	0.3–0.9		
9-Month follow-up	1.4 ± 0.15	1.0–1.9	1.0 ± 0.15	0.5–1.4		
Group-by-time					1.83	0.18

\*Knowledge of diabetes and pregnancy, a summation of 12 dichotomous items (correct = 1, incorrect = 0, % correct). †Perceived benefits of seeking and using family planning, a summation of 5 Likert-type items (possible range 5–25). ‡Intention to initiate discussion with health care provider, a summation of 2 Likert-type items (possible range 2–14). §Actual initiation of discussion with health care provider, a summation of 4 dichotomous items (possible range 0–4), showing group change from baseline and at 9 months.

Twenty-one percent ( $n = 24$ ) reported having been sexually active, with half (12/24) having had at least one episode of unprotected sex. Mean debut of sexual intercourse was 15.6 years of age (range 13–19 years). Two participants reported a pregnancy. There were no significant differences in demographic variables between the two groups.

### Program effectiveness with cognitive and behavioral outcomes

Compared with baseline and control subjects (SC), significant group-by-time interaction effects were found with the IG teens for both perceived benefit and knowledge of preconception counseling content and reproductive health. The IG group increased significantly ( $P < 0.001$ ) in both of these outcomes at the immediate post-intervention time point, and the effect was sustained over 9 months ( $P < 0.05$  benefits;  $P < 0.001$  knowledge).

Although no significant group-by-time or group effect was observed, the IG had a significant decrease in barriers to preconception counseling over time ( $P < 0.001$ ). Only the IG significantly increased over time with intention to initiate discussion ( $P < 0.001$ ) and actual initiation of discussion about ( $P < 0.001$ ) preconception counseling and reproductive health with their diabetes health care team (Table 1). There was no significant difference between the groups over time for intention to use birth control. However, IG teens showed only a marginal effect in their consistency to use highly effective birth control methods over time compared with the SC teens ( $P = 0.10$ ). Twenty-two IG subjects requested additional preconception counseling resources and information during the nurse counseling sessions.

### Economic outcomes

Table 2 summarizes resource utilization in minutes for nurses, participants, and physicians, by treatment group and intervention session. Total time to deliver the intervention is shown for the nurse, physician, and participant, assuming that all participants attended all sessions (unweighted total sum of means) and weighted according to the proportion of each group that participated in each session (weighted total sum of means). Delivery of the READY-Girls intervention required ~20 min of nurse time over three sessions. As can be seen from Table 2, participation in the READY-Girls intervention did not increase clinic time: in fact, READY-Girls participants spent ~45 min less time in the clinic over the course of the three sessions. Compared with the SC group, READY-Girls participants devoted ~1 h to the intervention. Based on the information in supplemental Table 1

Table 2—READY-Girls: resource use (minutes) by treatment group

	Intervention group (n = 42)				Comparison group (n = 45)			
	% of sample	Nurse	Participant	Doctor	% of sample	Nurse	Participant	Doctor
Session 1 time								
Setup	100	3.31 ± 2.47 2.00 (4.00)	NA	NA	NA	NA	NA	NA
Training	100	3.06 ± 2.37 2.00 (4.00)	3.06 ± 2.37 2.00 (4.00)	NA	NA	NA	NA	NA
CD viewing	100	NA	36.34 ± 6.20 35.00 (8.00)	NA	NA	NA	NA	NA
Clinic‡	100	NA	50.81 ± 18.5 55.0 (15.00)	50.81 ± 18.5 55.0 (15.00)	100	NA	43.33 ± 31.5 30.0 (45.00)	43.33 ± 31.54 30.00 (45.00)
Session 2 time								
Setup	90	2.77 ± 1.91 2.00 (4.00)	NA	NA	NA	NA	NA	NA
Training	90	1.67 ± 1.46 1.00 (0.00)	1.67 ± 1.46 1.00 (0.00)	NA	NA	NA	NA	NA
CD viewing	90		25.38 ± 7.38 25.0 (10.00)	NA	NA	NA	NA	NA
Counseling		6.42 ± 5.11 5.00 (9.00)	6.42 ± 5.11 5.00 (9.00)	NA	NA	NA	NA	NA
Clinic‡	90		40.1 ± 10.44 43.0 (16.00)	40.1 ± 10.44 43.0 (16.00)	96	NA	57.1 ± 30.26 60.0 (45.00)	57.06 ± 30.26 60.00 (45.00)
Session 3 time								
Book review	76	NA	20.37 ± 4.00 20.00 (5.00)		NA	NA	NA	NA
Counseling	76	4.38 ± 3.64 5.00 (7.00)	4.38 ± 3.64 5.00 (7.00)	NA	NA	NA	NA	NA
Clinic‡	76	NA	47.5 ± 42.07 30.0 (45.00)	47.5 ± 42.07 30.0 (45.00)			79.5 ± 46.01 60.0 (63.00)	79.5 ± 46.01 60.00 (63.00)
Total sum of means								
Unweighted	NA	21.61	236.10	138.48	NA	NA	179.85	179.85
Weighted§	NA	19.47	211.39	123.06	NA	NA	170.42	170.42

Data are means ± SD and median (interquartile range) unless otherwise indicated. ‡Clinic time = face-to-face with health care provider, not intervention time. §Means weighted by participation weights (proportion of group that participated) before computing the weighted sum of means.

(available in an online appendix at <http://care.diabetesjournals.org/cgi/content/full/dc09-1821/DC1>), we estimate that the READY-Girls intervention cost \$18 per participant. Thus, it would cost approximately \$1,800 to deliver the program to 100 teens. We have estimated that one unplanned pregnancy for a teen in the U.S. would cost approximately \$2,800 (supplemental Appendix 1). Thus, if pregnancy were prevented in 1 year for 100 teens, the program costs would be offset. If >0.6 pregnancies were prevented in 1 year, the program would be cost-saving.

**CONCLUSIONS**— The READY-Girls intervention had beneficial effects and was economic. Teens who received the READY-Girls intervention had greater knowledge and perceived benefits about reproductive health and preconception counseling and fewer barriers to receiving

preconception counseling. Although the IG subjects were calculated to spend less time in the clinic, READY-Girls appeared to have enhanced patient-provider interaction. This was demonstrated by IG teens having initiated more discussion with their diabetes health care team about reproductive health and preconception counseling and being more likely to seek additional preconception counseling information than teens who did not receive the program. We have previously demonstrated that discussion of preconception counseling with a health care provider is the most important predictor of seeking preconception counseling care; and preconception counseling has been shown to reduce the incidence of unintended pregnancy (9). Discussion with a health care provider is considered a Motivational Cue according to the Expanded Health Belief Model (8). IG teens were also more consistent in their use of effective birth con-

trol. These results were sustained over 9 months. Several of the outcomes (e.g., self-efficacy, perceived susceptibility, or severity) did not have significant group-by-time effects, or their effects were not sustained over 9 months. This could have been due to a Hawthorn effect in the SC group.

READY-Girls is predominantly an education/counseling reproductive health program specifically tailored for teens with diabetes with a focus on preconception counseling in prevention of diabetes-related complications. In teens with diabetes, knowledge about preconception counseling, pregnancy risks, and A1C were associated with better metabolic control and intention to seek preconception counseling (10). Studies that examined the effects of non-diabetes-specific comprehensive sexual education programs for general teen groups had fa-

avorable results in reducing sexual risk and preventing teen pregnancy (11,12).

With regard to program costs, we found the direct medical costs of the program to be low, the costs of adverse reproductive outcomes to be high, and the likelihood that the READY-Girls intervention will improve outcomes and reduce costs to be high. The cost of unplanned pregnancies and adverse reproductive outcomes are high due to the rates of pregnancies among teens. The U.S. Census Bureau has reported that ~850,000 pregnancies occur among the >10 million girls 15–19 years of age in the U.S. each year (8.2% pregnancy rate) (13). Fully 700,000 (82%) of these pregnancies are unplanned. Thus, ~6.7% of girls 15–20 years of age in the U.S. have an unplanned pregnancy each year (13). If the READY-Girls program reduced the absolute risk of an unplanned pregnancy by 0.6% or the relative risk of an unplanned pregnancy by ~10%, the program would be cost-neutral. If the program reduced the risk of unplanned pregnancy by more than this threshold, it would be cost-saving. In a previous study comparing pregnancy outcomes among women with diabetes who received and did not receive preconception counseling, Herman et al. (14) reported that the net cost savings associated with preconception counseling was approximately \$34,000 per patient.

Our results should be interpreted in light of the following limitations. The sample size was smaller than planned. The power for a sample size of 88, with a medium effect (0.40) and two-tailed significance of 0.05, is 0.63. The behavioral outcomes were only measured for 9 months and the sample was predominantly Caucasian.

This early self-instructional computer-based program appears to be a low-cost method of delivering easily disseminated preconception counseling to young women. Furthermore, this study had a clinic-based intervention, but READY-Girls can be easily placed on the web for teens to have direct home access, thus eliminating the health care delivery cost, thereby making it potentially more cost-effective. Preconception counseling can reduce the risks of unplanned preg-

nancies and adverse infant outcomes. Therefore, READY-Girls can potentially empower young women with diabetes to make well-informed reproductive health choices for themselves and possibly improve the future health of their children with little burden and cost added to their diabetes management program.

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