EXAMINING SHORT- AND LONG-TERM EFFECTS OF PRECONCEPTION COUNSELING DELIVERED DURING ADOLESCENCE ON RISK-TAKING BEHAVIORS, CONDOM USE, AND SEXUALLY TRANSMITTED INFECTIONS AMONG FEMALES WITH TYPE 1 DIABETES

by

Jennifer L. Thurheimer, PhD, RN

Bachelor in Science in Nursing, Indiana University of Pennsylvania, 1997

Master of Education, Saint Francis University, 2003

Master of Science in Nursing, Indiana University of Pennsylvania, 2006

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This dissertation was presented

by

Jennifer L. Thurheimer, PhD, RN

It was defended on

April 10, 2015

and approved by

Sandra Founds, PhD, CNM, FNP, Associate Professor, School of Nursing

Julie Downs, PhD, Associate Professor, Carnegie Mellon University

Dissertation Co-Chair: Susan M. Sereika, PhD, Professor, School of Nursing

Dissertation Chair: Denise Charron-Prochownik, PhD, RN, CPNP, FAAN, Professor, School of Nursing

EXAMINING SHORT- AND LONG-TERM EFFECTS OF PRECONCEPTION COUNSELING DELIVERED DURING ADOLESCENCE ON RISK-TAKING BEHAVIORS, CONDOM USE, AND STIs AMONG FEMALES WITH T1D

Jennifer Thurheimer, PhD, RN

University of Pittsburgh, 2015

Aims: To examine the short-term efficacy (3-months post-intervention during adolescence) and long-term efficacy (15-years post-intervention) of receiving preconception counseling (*READY-Girls*) as an adolescent on risk-taking behaviors, condom use, and STI acquisition among females with type 1 diabetes (T1D).

Methods: Secondary analysis was conducted on data from randomized-control-trials of *READY-Girls* using a cohort of women with T1D during adolescence (N=136) and an expanded follow-up study of these and other adult women with T1D (N=75) using online surveys to measure risk-taking behaviors (e.g., substance use and unsafe sex), birth control (BC) use and STIs.

Results: Overall, there were no significant changes in risk-taking behaviors in this cohort over time. Only 25% of the adolescent sample reported having ever been sexually active. As adolescents, 60% reported having unprotected sex compared to 58% as adults. The three BC methods most frequently used by this cohort over time: oral contraceptives, condoms and withdrawal. Sixteen-percent had reported ever being diagnosed with an STI. No significant differences between groups were noted at 3-month post-*READY-Girls* in adolescence. However, adult women who received *READY-Girls* as adolescents were more likely to report later sexual

debut and used condoms. *READY-Girls* appeared to increase adolescent perception of susceptibility, which was significantly associated with less unprotected sex during adulthood.

Conclusion: *READY-Girls* did not directly impact short or long-term risk-taking behaviors or STIs. However, *READY-Girls* focused on the effects of diabetes on reproductive health and the prevention of unplanned pregnancies to avoid complications. Consistent with our previous findings, it impacted age of sexual debut. Only a few adolescent health beliefs were associated with some sexual risk-taking behaviors as adults. The three most frequently used BC methods: oral contraceptives, condoms, and withdrawal remained consistent over time. Episodes of unprotected sex and use of withdrawal which started during adolescence and continued into adulthood was concerning. Our findings suggest, starting in adolescence, that some women with T1D appeared to engage in some risk-taking behavior and ineffective BC use, thereby, increasing their risks for STIs. Adding information to PC, including READY-Girls, on avoiding risk-taking behaviors, engaging in safer sexual practice and using condoms to prevent STIs is warranted.

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PREFACE

This study was supported through the American Diabetes Association funding via the following grants: CR-2684232, 7-02-CR-06, 11-CT-1; and the National Institutes of Health/Eunice Kennedy Shriver National Institute of Health & Human Development NIH R01-HD044097; and the Greater Pittsburgh Nursing Research Conference. The principal investigator would like to acknowledge the individual contributions of her dissertation chair, co-chair, and committee; Denise Charron-Prochownik, PhD, RN, CPNP, FAAN, Susan M. Sereika, PhD, Sandra Founds, PhD, CNM, FNP and Julie Downs, PhD. She would also like to thank her family, fiancée, and friends for their patience and support.

1.0 INTRODUCTION

Sexually transmitted infections (STIs) are a burden to the individual and to society. Diagnosis and treatment of STIs is costly; direct medical expenses are estimated at $16 billion a year [Egendorf, 2007; Centers for Disease Control (CDC), 2013]. Despite advances in medicine, the prevalence of STIs continues to rise since 2008 with approximately 110 million diagnosed across the nation among adolescents and young adults (CDC, 2013). The highest incidence is between ages 15 to 24 years (Staras, Cook, & Clark, 2009). Every day in the U.S., 12,000 adolescents contract a STI (CDC, 2010). This coincides with the mean age of sexual debut for females at 17 years old (Guttmacher Institute, 2014; CDC, 2013). Among sexually active 14 to 19 year old female adolescents, 38% have been diagnosed with at least one STI (National Health And Nutrition Examination Survey, 2006). One in two sexually active individuals will contract an STI before the age of 24 years and females are four times more likely to be diagnosed with an STI than to have an unplanned pregnancy (CDC, 2009) with unplanned pregnancies occurring in 40% of females under the age of 20 years (Henshaw, 1996). Undiagnosed STIs can lead to reproductive health complications such as pelvic inflammatory disease (PID), ectopic pregnancy, infertility, and cervical cancer in young females of child-bearing age (CDC, 2011).

These complications could be compounded in adolescent females with chronic diseases, especially diabetes. Diabetes increases the risks of reproductive health complications. Diabetes could cause women to experience sexual dysfunction and medical problems during pregnancy, compromising fetal health [American Diabetes Association (ADA), 2013]. Chances of complications are higher in women with diabetes who have uncontrolled blood sugars and unplanned pregnancies.

Preconception care is an integral part of primary care for all women of reproductive age. It specifically addresses family planning, maintaining a healthy weight, screening and treating STIs, updating immunizations, and assessing current medications for teratogenic effects (Farahi & Zolotor, 2013). Preconception counseling (PC) is discussion with a health provider prior to pregnancy to assess possible pregnancy complications and modification of risk factors (Williams et al., 2012). PC also provides information about family planning and effective use of birth control. However, for a chronic illness such as diabetes, pregnancy planning requires additional education. The ADA has established recommendations for those women of reproductive age who have diabetes. According to the ADA (2013), diabetes specific-PC requires additional advice and care for women with diabetes prior to pregnancy to plan their pregnancy, control blood sugars, and thus, decrease sexual risks for reproductive health complications.

A developmentally-appropriate PC program was developed specifically for female adolescents with diabetes mellitus (DM) called *R*eproductive-health *E*ducation and *A*wareness of *D*iabetes in *Y*outh for *G*irls (*READY-Girls*). *READY-Girls* (RG) targets female adolescents starting at puberty and focused on the importance of preventing unplanned pregnancies, benefits of tight metabolic control before conception, how to plan a pregnancy that is safe and wanted, effective

use of birth control and to decrease risky behaviors (Charron-Prochownik et al., 2006). These latter topics are also relevant for STI education for adolescents as well.

Conventional STI programs usually include the discussion on prevention of STI, contraception, risky behavior, and complications of STIs (Schlat et al., 2014). Although *READY-Girls PC* (*RGPC*), addresses some of these topics, we questioned whether this information in *RGPC* is sufficient to also have an effect on preventing general risky behaviors and STIs? To address this research question, data were pooled from three previous randomized controlled trials (RCTs) studies to examine the short-term effect of RG in female adolescents with T1D on risk-taking behaviors, condom use, and STI acquisition. In all three studies, subjects were randomized into an intervention group (hereafter termed RG-I) that received the *RGPC* or a standard care control group. The *RGPC* was delivered as a book and/or a CD-ROM or DVD. All three formats contained the same information. In all 3 RCTs, the subjects in the control group were given access to the *RGPC* program upon completion of the studies. The control groups were given the opportunity to watch the CD-ROM or DVD in the clinic; most chose not watch it. All the subjects in the control groups received the RG book to take home. However, no immediate follow-up studies were conducted on the standard care control groups' response to the *RGPC*. For this dissertation, the standard control groups will be referred to as the RG control group (RG-C). Additionally, the three-month post-intervention time period during the adolescent RG studies will be referred to as "3-month". Furthermore, all subjects in all 3 RCTs were given March of Dimes (March of Dimes, 2015) pamphlets as standard general PC information. This information included engaging in behaviors before and during a pregnancy, such as, taking folic acid, decreasing substance use, and getting tested for STIs.

Additionally, the “short-term effect” period will reflect the three-month post-intervention time period during the adolescent RG studies and will be referred to as “3-month”. The “long-term effect” period refers to the adult follow-up survey up to 15 years of this pooled adolescent cohort and was conducted to further examine the reproductive health outcomes as adults. An expanded follow-up study was conducted using an on-line survey to collect additional data from this cohort on risk-taking behaviors and STIs. A comparison group of women with T1D matched on age, race, and age of diagnosis was added to the adult follow-up and expanded follow-up studies.

1.0.1 Glossary of Terms

Adult Follow-up Study: *READY-Girls* RCTs cohorts as adults and matched comparison groups from 2010 to 2013 (N=102)

Diabetes-specific PC: Includes information about general preconception counseling, such as family planning, in addition to tight metabolic control and the importance of planning a pregnancy to decrease maternal and fetal complications

Expanded Follow-up Study: Ancillary survey of Adult Follow-up on risk-taking and STIs. Subset of adult subjects (N=75) including FRG and FCG (see below)

FCG: Follow-up Comparison Group in adult follow-up study (n=43)

FRG: Follow-up *READY-Girls* cohort in adult follow-up study (n=32)

FRG-C: Follow-up *READY-Girls* cohort, the adolescent Control group in adult follow-up study (n=13)

FRG-I: Follow-up *READY-Girls* cohort, the adolescent Intervention group in adult follow-up study (n=19)

PC: Preconception Counseling about family planning for all women of reproductive age

RCT: Randomized Control Trial

RHAB: Reproductive Health Attitudes and Behavior questionnaire

RG: READY-Girls

RGPC: *READY-Girls* Preconception Counseling that targets adolescent females with diabetes

RG-RCT1: *READY-Girls* 1999 RCT adolescent study (N=53)

RG-RCT2: *READY-Girls* 2002 RCT adolescent study (N=88)

RG-RCT3: *READY-Girls* 2006 RCT adolescent study (N=109)

RG-C: *READY-Girls* Control group from adolescent RCT studies (n=60)

RG-I: *READY-Girls* Intervention group from adolescent RCT studies (n=76)

Risk-taking behaviors: substance use and unsafe sexual practices

RTB: Risk-Taking Behaviors

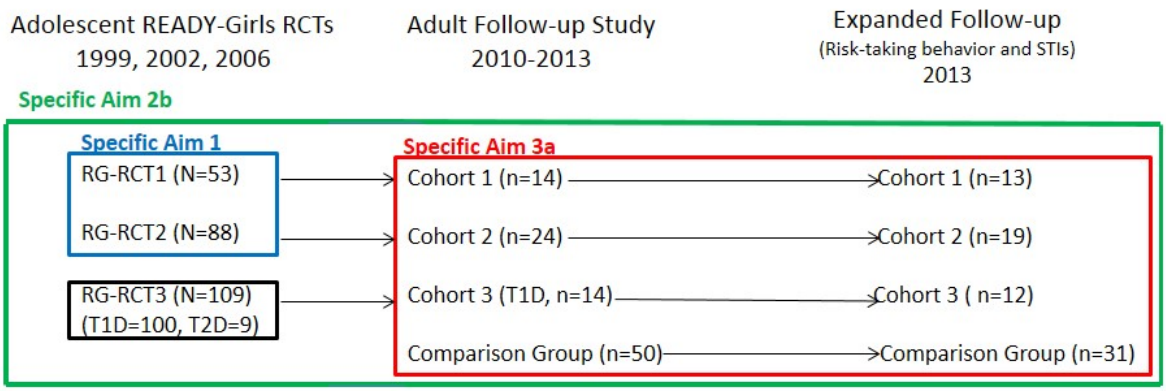
Standard Care: March of Dimes pamphlet provided to the subjects in the RG-RCTs. Included general PC before and during a pregnancy about taking folic acid, decreasing substance use, and also getting tested for STIs

STIs: Sexually transmitted infections

Substance Use: tobacco, alcohol, and illicit drug use

TID: Type 1 Diabetes

Unsafe sexual practices: unprotected sex and multiple sexual partners



Legend:

RG-RCT	Adolescent READY-Girls Randomized Controlled Trial
RG-RCT1	1999 READY-Girls RCT #1
RG-RCT2	2002 READY-Girls RCT #2
RG-RCT3	2006 READY-Girls RCT #3
Cohort 1	RG-RCT1 as adults
Cohort 2	RG-RCT2 as adults
Cohort 3	RG-RCT3 as adults
Comparison Group	Matched comparison group of adult women with T1D
Adult Follow-up	Repeated measures online survey of adult cohort from READY-Girls RCTs and comparison group (N=102)
Expanded Follow-up	Cross-sectional online ancillary survey of risk-taking behaviors and STIs in participants from the Adult Follow-up (N=75)
Manuscript #1	Specific Aim 1
Manuscript #2	Specific Aim 2b
Manuscript #3	Specific Aim 3a

Figure 1. Description of READY-Girls Studies and Specific Aims

1.1 PURPOSE

The purpose of this study was to examine the short-term efficacy (3 months post-intervention during adolescence) and long-term efficacy (up to 15 years post-intervention) of receiving *RGPC* as an adolescent on risk-taking behaviors, condom use, and STI acquisition among females with TID.

1.2 SPECIFIC AIMS

The specific aims are to:

1. To compare the short-term efficacy of receiving *RGPC* early in adolescence at 13-20 years on risk-taking behavior, condom use, and STI acquisition among adolescent females with T1D to adolescent females who received standard care.

Research Question: In the adolescent RG studies, is there a difference between those adolescent females who received RG (RG-I) compared to adolescents who received standard care (RG-C) on risk-taking behaviors, condom use, and STIs

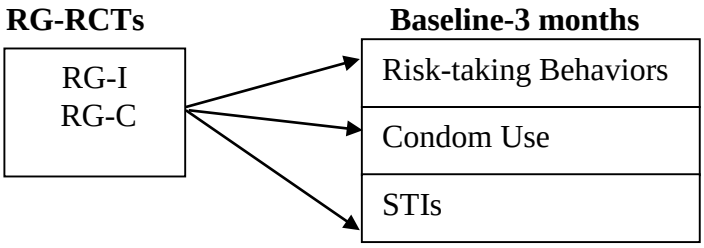


Figure 2. Specific Aim #1 Diagram

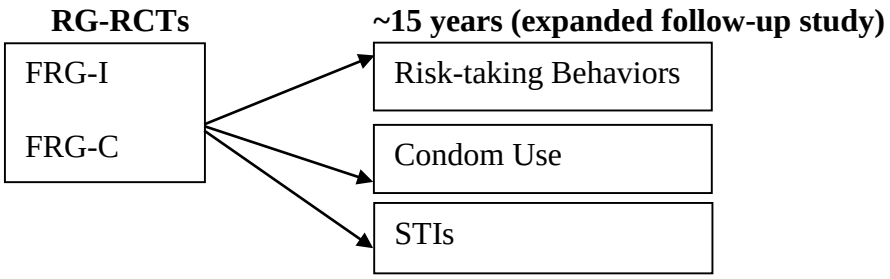
2. Through a 15 year follow-up survey (expanded follow-up study) of the adolescent cohort, to examine the long-term efficacy of *RGPC* received early in adolescence on risk-taking behavior, condom use, and STIs as adult females with T1D.

Research Questions:

2a) Is there a difference as adults (in the adolescent cohorts of RG subjects) between the intervention group [FRG-I] (n =19) and the control group [FRG-C] (n =13) on adult risk-taking behaviors, condom use, and STIs?

2b) Do adolescent health beliefs (e.g., susceptibility, severity, barriers, and self-efficacy) from 3 month post-intervention RG data predict long-term outcomes (up to 15 years) of adult risk-taking behaviors, condom use, and STIs?

2a)



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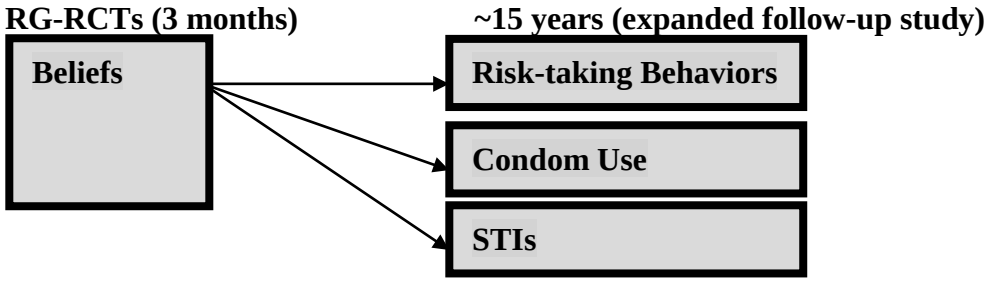


Figure 3. Specific Aim #2 Diagram

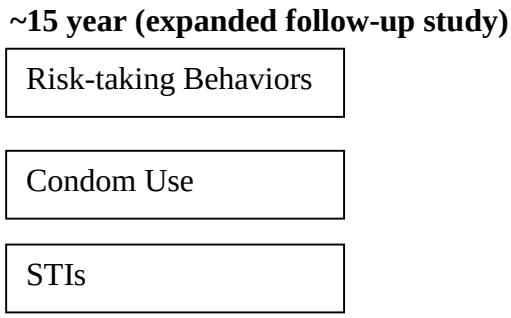
3. To describe risk-taking behaviors, condom use, and STIs in adult women with T1D.

Research Question:

3a) What are the self-reported risk-behaviors, frequency of condom use, and STIs in adult women with T1D?

3b) What is the consistency of self-report regarding risk-taking behaviors items from adolescence to adulthood?

3a)



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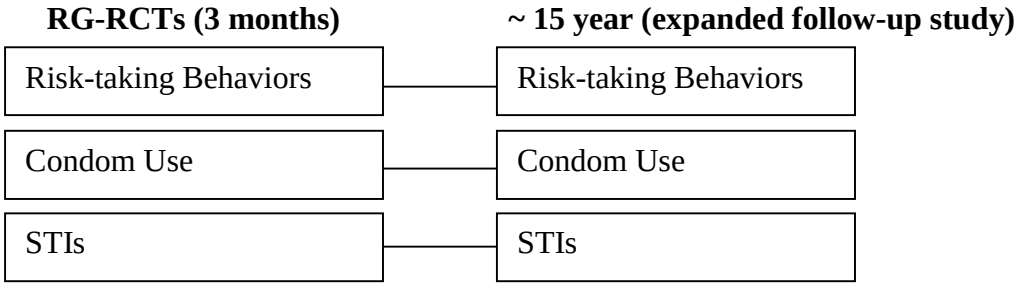

Figure 4. Specific Aim #3 Diagram

1.2.1 Significance

Adolescent females with diabetes have a higher risk of developing complications from unplanned pregnancies and STIs. Moreover, STIs cause many of the same complications of uncontrolled diabetes (e.g., birth defects, pre-term labor), thus can compound problems for females with diabetes (CDC, 2011). There are several birth defects caused by uncontrolled diabetes which are similar to those caused by STIs as well, including brain damage and bone/joint deformities in the

fetus from herpes simplex virus, syphilis, and gonorrhea respectively (National Institute of Child Health and Development, 2013).

Diabetes impacts reproductive health. Approximately 1.85 million women of reproductive age have diabetes and are at greater risk for reproductive complications (CDC, 2011). Diabetes increases the risk of sexual dysfunction and pregnancy-related complications in about 9% of diabetic women (ADA, 2004). Pregnancy–related complications can be decreased by PC from 9% to 2% (ADA, 2014). However, two-thirds of women with diabetes have unplanned pregnancies (Kitzmiller, Buchanan, & Kjos et al., 1996); and very few have received PC (Kitzmiller et al., 1996). Despite the ADA's recommendation (ADA, 2014) to begin PC at puberty, prior to sexual debut, PC is not routinely provided in diabetes standard care for female adolescents. When PC is given, it is often too late. Studies have shown that the cost effectiveness of PC was approximately $34,000 per patient (Herman, Janz, Becker & Charron-Prochownik, 1999). Awareness of PC should be initiated early, focusing on the importance of tight glycemic control and safe sex practices among women of reproductive age with diabetes (ADA, 2013). Moreover, timing of receiving PC is critical since 43% of sexually active high school females reported an onset of sexual debut by the tenth grade (Abma et al., 2002). Adolescent females with diabetes who are unaware of PC or risks of reproductive health problems, have early sexual debut using unsafe sexual practices, and therefore, are at high risk for future unplanned pregnancies, complications (Charron-Prochownik et al., 2006), including STIs (Scaramuzza et al., 2010). Adolescent females with diabetes do not realize their risk of complications or understand that these complications can be prevented by tight glycemic control. (Charron-Prochownik, Dean-McElhinny, Hagerty et al., 1998). Prior to receiving the RG intervention, the adolescent females with diabetes were unaware

that complications could be reduced by receiving PC and preventing an unplanned pregnancy (Charron-Prochownik et al., 1998). However, prevention of STIs is also paramount in this population. Therefore, in addition to information about planning a safe pregnancy, PC for adolescent females with diabetes should also include information to decrease risk-taking behaviors and prevention of STIs. PC during early adolescence for females with diabetes is critical for preventing risky behaviors which can result in unplanned pregnancies, STIs, and reproductive health complications.

2.0 LITERATURE REVIEW

2.1 DIABETES AND ADOLESCENCE

Type 1 diabetes (T1D) is the most common chronic disorder in childhood and has a peak age of onset during adolescence (Jaser, Yates, Dumser & Whittemore, 2011). The number of diabetes cases continues to rise in youth with the estimated U.S. incidence of new cases of T1D in children less than 19 years of age being 18.2/100,000 or 13,171 per year (Libman, Songer, & LaPorte, 1993). Approximately 11.5 million females in the United States have diabetes with the highest rate of new diagnoses of T1D being among Caucasian youth (CDC, 2010).

Several factors impair metabolic control during adolescence. Growth spurts, during this period, pose a significant and metabolic burden in the healthy adolescent (Suris, Michaud, & Viner, 2004). A two to threefold increase in daily growth hormone secretion occurs during puberty. This change in growth hormones counteracts with achieving optimal glycemic control, causing insulin resistance (Dunger & Acerini, 1998). Adolescents need to monitor their glucose levels more frequently, increase the insulin dosage due to insulin resistance and may also experience weight gain. Adolescence is a time where many aberrant dietary behaviors occur, such as skipping meals, eating high calorie/high fat foods, or trying fad diets, which can be very problematic to an adolescent managing diabetes (Jaser et al., 2011). During this period, the adolescent becomes more responsible for their own self-management. Furthermore, peer pressure and risky behaviors becomes a dominant force during these formative years. For adolescent

females with diabetes, this may lead to unprotected sex and its consequences. Diabetes increases the risks of reproductive health related complications.

2.2 EFFECTS OF DIABETES ON REPRODUCTIVE HEALTH IN ADOLESCENT FEMALES

Adolescent Reproductive Health

Adolescent sexual and reproductive health is the physical, mental, and emotional well-being of adolescents. Puberty occurs between the ages of 10 to 19 years and offer an opportunistic time to develop skills to become healthy adults (Tharp et al., 2013). Adolescents struggle between the need for protection and guidance from caregivers and the right of autonomy for themselves (Schalet et al., 2014). Both physical and emotional changes are continuous throughout the adolescent years and education is focused on prevention of pregnancies, STIs and sexual violence (Forcier & Garofalo, 2014).

Females are reaching puberty (e.g., breast development and menarche) and sexual maturity at younger ages than ever (Euling et al., 2008). Puberty is trending earlier with menarche occurring around 12 years of age in all ethnic groups for girls and spermarche around 10 years of age for boys (Chumlea et al., 2003; Zehetner, 2014). With the initiation of menarche and spermarche, adolescents are able to produce offspring physically, yet there is no evidence to suggest that cognitive development and maturation are occurring at similar times. Adolescents can begin to imagine, but cannot fully comprehend consequences of their actions, which leads to risk-taking

behaviors, such as, drug and alcohol use and unprotected sexual contact (Forcier & Garofalo, 2014).

Reproductive Health and Diabetes

Diabetes affects all aspects of human sexuality (Lamone, 1993). For women, diabetes poses challenges throughout their life particularly in relation to both reproductive and sexual health (Stenhouse, 2012). Reproductive abnormalities can occur at any time increasing the risks for sexual health dysfunction, especially for women of child-bearing age. Tight glycemic control can decrease these complications (Kitzmiller et al., 1996; Nankervis, 1998; Schroeder et al., 2000).

Women with diabetes may experience menstrual irregularities during their fertile years, such as amenorrhea, polymenorrhea, or oligomenorrhea, associated with abnormal metabolism rates (Schweiger et al., 2011). Diabetes causes hormonal imbalance which produces a domino-like effect on other hormone levels (estrogen, testosterone, progesterone). These fluctuations in levels and insulin resistance are key factors in causing Polycystic Ovarian Syndrome (PCOS) and infertility (Falcone & Falcone, 2009). Also, women with diabetes are also more susceptible to both yeast and urinary tract infections. Higher levels of glucose in the blood cause vaginal secretions to contain more glucose, allowing yeast to multiply. Hyperglycemia interferes with the immune function to prevent yeast infections (Joslin Diabetes Center, 2014).

Adolescent females with a lower body mass index, poor metabolic control, and a longer duration of diabetes may have a delay in the age of menarche (Rohrer, Stierkorb, Heger et al., 2007; Danielson, Palta, Allen et al., 2005). However, due to the recent increase in childhood obesity, females with diabetes are associated with an earlier onset of puberty which poses a

problem. Their menstrual cycles are lengthy and irregular which highlights the importance of discussing safe sex practices to avoid unplanned pregnancies and STIs (Codner, Soto & Merino, 2012). Hormonal fluctuations that occur naturally in adolescence make it more difficult for females to maintain tight metabolic control (Falsetti et al., 2003). Females with diabetes will experience worsening menstruation disturbances, make poor choices for weight control methods, and experience increased mood swings compared with those without a chronic illness (Brindley & Javanovic, 2004).

With a high incidence of adolescent sexual activity and risk for unplanned pregnancy, uncontrolled blood sugars can cause pregnancy-related complications, such as, preeclampsia and increase the incidence of major congenital malformations and mortality of the infant (Kitzmiller et al., 1996; Pettitt & Jovanovic, 2007). Both maternal and fetal complications can require lengthy, complex, and costly hospitalizations (Herman et al., 1999). Approximately 70% of diabetic pregnancies are unplanned (Kjaer, 1992; St. James, 1993). Unfortunately, 40% of adolescent females become pregnant before the age of 20 and are a greater risk of having health complications whether they have diabetes or not (Herman, Engelgou, & Janz, 1995). Since congenital malformations can happen two to four times more often for those mothers with TID and the incidence of preeclampsia is higher in young women, an unplanned pregnancy in adolescent females with diabetes should be prevented (Charron-Prochownik et al., 2006).

Normal adolescence development is challenging, diabetes makes it even harder. Adolescent females may choose harmful coping strategies to “fit in” among their friends. Peer acceptance is highly important, especially among adolescents with chronic disorders (Falsetti et

al., 2003). Trying to “fit in” may lead to poor choices such as dietary selections, medication usage, and questionable social behaviors may occur (Brindley et al., 2004).

2.3 RISKY BEHAVIORS IN ADOLESCENT FEMALES WITH DIABETES

Risk-Taking Behaviors and Adolescence

Adolescence is a period of physical, cognitive, emotional, and sexual growth. Teenagers are searching for their own identity, influenced by both their parent’s beliefs and peer relationships. During this identity exploration, adolescents may experiment with risky behaviors, such as smoking, alcohol consumption, illicit drug use, and unprotected sexual contact. These behaviors can be detrimental to their health (Jaser et al., 2011). Among American high school students, 73% have consumed alcohol, 46% have smoked cigarettes, 48% have tried illicit drugs, and 46% are sexually active (CDC, 2009; Eaton et al., 2009). In the U.S. 80% of young adults become sexually experienced during their teen years (Gilmore et al., 2002). Adolescent females have an increasing level of sexual activity with the mean age of sexual debut being 17 years of age (Guttmacher Institute, 2014; CDC, 2013). From 2006 to 2010, 43% (4.4 million) of females who have never been married admitted to having sexual intercourse at least once and this number has been constant since 2002 (Martinez, Copen & Abma, 2011).

Risk-Taking Behaviors and Diabetes

Risky behaviors (e.g., substance use, and unsafe sexual practices) interfere with illness management of diabetes. Adolescents with T1D are as likely as their healthy peers to engage in these risky behaviors (Martinez et al., 2007). The prevalence of tobacco, alcohol, and illicit drug use among adolescents with diabetes are equal to or higher than the national average (Jaser et al., 2011). Adolescents with diabetes who smoke tobacco regularly are at a 50-75% greater risk for morbidity and mortality in adulthood than those adolescents with diabetes who do not smoke (Schwab, Doerfer, Hallermann et al., 2008). Alcohol use causes hypoglycaemia in T1D and illicit drugs can cause hyperglycaemia or ketoacidosis (Ng, Darko,& Hillson, 2004). These behaviors pose a greater threat to an adolescent's health status than the illness does in the adolescent population. The consequences of these behaviors are not consistent with diabetes adherence and are likely to divert financial resources away from healthy food, health care, and necessary medical supplies (Frey, Guthrie & Loveland-Cherry, 1997). Few adolescents believe that tobacco, alcohol, or drug consumption would influence their ability to maintain glycemic control or adhere to their diabetes regimen (Gold & Gladstein, 1993). Yet, adolescents who engage in one or more risky behavior have significantly higher HbA1c than those who do not (Scaramuzza et al., 2010).

Nearly half of high school students in the U.S. are sexually active (Gaydos et al., 2008). Adolescents with chronic illness report a higher rate of sexual intercourse and other risky behaviors than adolescents without chronic illness (Suris et al., 2004). Most adolescents are waiting longer to have sex than in the past (Finer & Philbin, 2013), with the exception of those with a chronic illness. Sexual debut occurs earlier in females with a chronic illness (13.8 years) compared to their healthy peers (16.9 years) (Alderman, Lauby, & Coupy, 1995, CDC, 2014). And females with

diabetes have lower rates of contraception use and are more involved in risk-taking behaviors (Scaramuzza et al., 2010; Chuang, Velott & Weisman, 2010; Fennoy, 1989). One study reported 29% of females with T1D, engaged in unprotected sex (Frey et al., 1997).

In the U.S., adolescents account for about one-fifth of all unplanned pregnancies annually (Guttmacher Institute, 2014) and more than half of new STI cases (18 million/year) are among individuals 15-24 years old (CDC, 2010). STIs are common among adolescents and often asymptomatic (Gaydos et al., 2008). Over 100,000 pregnancies are complicated with diabetes each year (York et al., 1995). But little is known about STI rates in females with diabetes and how it may impact metabolic control (Falsetti et al., 2003). Thus, it is critical that unplanned pregnancies and STIs can be avoided through effective birth control methods.

2.4 BIRTH CONTROL USE IN ADOLESCENT FEMALES WITH DIABETES

Birth Control Use and Adolescence

Although condoms are readily available, adolescents are not compliant users of contraception (Kaiser Family Foundation, 2006). Most teens report their sexual activity to be unexpected, therefore unprepared (Suris et al., 1996). Eighty-two percent of teen pregnancies are unplanned (Guttmacher Institute, 2014). When compared to other industrialized countries, the U.S. has the highest incidence of unplanned pregnancies (Braverman & Strasburger, 1993) and STI rate of any sexually active age group (Braverman & Strasburger, 1994).

There are several types of birth control methods to prevent unplanned pregnancies. These include hormonal methods that interfere with ovulation, such as oral contraceptive ('the pill"), the patch which releases hormones through the blood stream, vaginal ring that releases hormones vaginally, or injectable birth control ("Depo-Provera") that is received every three months (CDC, 2014). Barrier birth control methods prevent the sperm from entering the uterus (CDC, 2014). These methods are the male condom, female condom, diaphragm, cervical cap, contraceptive sponge, and spermicide. However, condoms are the only birth control method, other than abstinence, that can prevent both STIs and unplanned pregnancies.

Condoms are highly effective in preventing transmission of STIs and pregnancy, yet more than half of adolescent pregnancies admitted to not using birth control (Kaiser Family Foundation, 2006). Some adolescents believe that using oral contraceptives or long-acting hormonal methods is effective enough and are less likely to use another barrier method, such as, condoms. Adolescents who had been previously diagnosed with an STI, however, were more likely to use condoms only (Roye, 1998). According to the American College of Obstetrics and Gynecology (2012), "sexually active adolescents should be encouraged to use condoms in conjunction with a more effective method of contraception to provide both effective pregnancy prevention and protection against STIs".

Birth Control and Diabetes

Contraceptives used by adolescents with chronic illness are more likely to be nonprescription contraceptives, such as, withdrawal, condoms, spermicide, and douches (Suris et al., 1996).

However, these methods are the least effective, providing very little protection pregnancy and none against STIs. Condoms are the only method that protects against both. A study of adolescents with T1D found that only half who were sexually active used condoms or other forms of birth control compared to 61% in the general population (Schwartz et al., 2010). Oral contraceptives (e.g., birth control pills) are one of the most efficient methods but is used less frequently in females with T1D (Falsetti et al., 2003; Shawe, Mulnier et al., 2008). Adherence to the daily dose is essential for the birth control pill to be effective. However, some adolescent females with diabetes have shown to be noncompliant with their diabetes regimen and may do so with oral contraceptives as well (Cramer, 2004).

Adolescent females with diabetes perceive their risk to be low for unplanned pregnancies and pregnancy related complications (Charron-Prochownik et al., 2006). And females are less likely to use contraception based upon the belief that having a chronic illness will make conceiving more difficult (Chuang et al., 2009; St. James et al., 1993). Yet, nearly one million adolescents between the ages of 15-19 years get pregnant each year (CDC, 2010). Adolescent females with a chronic illness have an earlier engagement in sexual activity, which could result in a greater number of lifetime partners (Alderman et al., 1995). Those who have an early sexual debut are also less likely to use contraception increasing, the risk for unplanned pregnancy and STIs (Feldmann & Middleman, 2002; Bearinger et al., 2007). There is a lack of sexual knowledge in adolescents with chronic illness which can result in unprotected sexual contact (Cromer et al., 1990). Not surprisingly, this unawareness has resulted in more cases of STIs among chronically ill adolescents than in their healthy peers (Sawyer et al., 2007).

STIs and unplanned pregnancy are especially problematic for adolescent females with diabetes by further complicating glycemic control (Falsetti et al., 2003). Adolescents already have difficulty maintaining their blood sugars during puberty. Poor glycemic control before conception and during early pregnancy increases the risk for maternal and fetal complications, such as, miscarriage, preterm delivery, intrauterine growth restriction, congenital malformations, and renal/ocular/microvascular issues (Jaser et al., 2011; Falsetti et al., 2003). STIs, most commonly chlamydia, gonorrhea, and herpes simplex virus, can result in infertility, pregnancy loss, premature birth, vision and hearing deficiencies, respiratory complications, and encephalitis in the newborn (CDC, 2010). Females with diabetes need to have good metabolic control before planning a pregnancy. For sexually active females who do not want a pregnancy, consistent birth control use is essential to protect against unplanned pregnancies and STIs. Condoms are easily accessible and protect against both (CDC, 2014).

2.5 SEXUALLY TRANSMITTED INFECTIONS

STIs and Adolescence

Young adults ages 15–24 years account for nearly half (9.1 million) of the 18.9 million new cases of STIs each year in the U.S. (Weinstock et al., 2004). It is assumed that many cases diagnosed in adulthood where actually contracted during the adolescent years (Office of Adolescent Health, 2012). Several STIs [Acquired immune deficiency syndrome (AIDS), human immunodeficiency virus (HIV), chlamydia, gonorrhea, human papillomavirus (HPV), herpes simplex virus (HSV),

and trichomonas] can be asymptomatic and only be diagnosed through testing (Guttmacher Institute, 2014). STIs are more likely to remain undetected in females than in their male counterparts. This results in delaying diagnosis and obtaining treatment. Untreated STIs can cause severe health issues in females (CDC, 2008; Eng & Butler, 1997). The incidence of STIs is higher in young females, sometimes causing irreversible reproductive health complications.

For females, the prevalence of STIs has increased, along with vaginal infections, inflammation and cervical cancer (Naz, 2009). The reported rate of chlamydia infection among females is three times the rate of males (CDC, 2008). Adolescent females continue to have increasing rates of chlamydia infections compared to older females; and 15 to 19 year olds females have the highest rates of gonorrhea (CDC, 2010). Untreated chlamydia and gonorrhea infections in females can result in PID causing ectopic pregnancy, infertility and chronic pain. Approximately 10–40% of untreated chlamydia cases leads to PID; and 20% of females PID will develop infertility (CDC, 2009).

Young females, ages 15 to 24 years, continue to have a higher incidence of HPV, HSV, trichomonas vaginalis, and HIV infections compared to their young male counterparts (CDC, 2010). HPV is the most common STI among sexually active adolescents. It is estimated in the U.S. that 7.5 million females, ages 14-24 years, have HPV (Dunne et al., 2007). HPV can lead to cervical cancer in women if undetected (CDC, 2004). Approximately, 11,000 cases of HPV related cervical cancer will occur among American women, resulting in 4,000 deaths (American Cancer Society, 2008). HIV/AIDS continue to be a fatal disease regardless of age. Despite stable rates of HIV diagnosis in older population, the HIV rate has increased in adolescents 15-19 years (Office of Adolescent Health, 2012). It is estimated that more than half of all undiagnosed HIV

occur in youth ages 13-24 years. Those females who have HIV/AIDs, 80% contracted the disease from unprotected heterosexual contact (CDC, 2006). STIs, especially HSV and trichomonas, increases the susceptibility of HIV infection and can have negative health outcomes during pregnancy and childbirth (Guttmacher Institute, 2014).

STIs and Diabetes

Adolescents with chronic illness have a higher risk of acquiring an STI than their healthy peers (Valencia & Cromer, 2000). It is well documented that adolescents with chronic illness have earlier sexual debut and are also less likely to use birth control, increasing this group risks for pregnancy and STIs (Fennoy, 1989; Scaramuzza et al., 2010). These sexual behaviors may be motivated by a need to demonstrate their normality but may result in more negative consequences (Neinstein & Zeltzer, 1996; Suris et al., 1996). Specifically, studies have shown that adolescents with chronic illness are more likely to report ever having an STI when compared to adolescents without chronic illness (Suris et al., 1996; Valencia & Cromer, 2000; Sawyer et al., 2007). The incidence of STI cases in females with diabetes is unknown.

Adolescent females are more susceptible to STIs than males because of their anatomy. During younger years, the epithelia cells are unprotected by the cervical mucus and can be invaded by an STI (CDC, 2008; Eng & Butler, 1997). Protection improves with age. STIs contain infectious organisms that invade the host and release toxins to process the infection. These infections will occur when the host defense mechanisms has been compromised by age, burns, corticosteroid use, or metabolic disease such as diabetes (Beers & Berkow, 1999). The alteration predisposes females with diabetes to infections caused by bacteria, fungi, viruses, or parasites

(Falsetti et al.., 2003). It is assumed that the STI risk for diabetics is increased because of deceased cellular immunity and circulatory deficits caused by acute and chronic hyperglycemia respectively (Beers & Berkow, 1999). The incidence or prevalence of STIs or the effect it has on metabolic control in the diabetic female is unknown (Falsetti et al., 2003). Both uncontrolled diabetes and STIs cause reproductive health complications. As previously mentioned, STIs cause many of the same complications as uncontrolled DM (e.g., birth defects such as brain damage, bone/joint deformities, or pre-term labor), thus can compound problems for females with diabetes (CDC, 2008).

Although STIs can be prevented with using condoms during sexual contact, adolescents with chronic illness, particularly females, are engaging in unprotected sexual intercourse increasing their risk for STIs (Scaramuzza et al., 2010). It is crucial that prevention focus is directed towards reduction in prevalence of unplanned pregnancy and STIs which serves as the greatest risk among all young females (O'Leary, 2011). Education on family planning to prevent STIs is essential for all adolescents prior to sexual activity. Family planning should be included in routine PC for all adolescent females with diabetes.

2.6 PRECONCEPTION COUNSELING

Sexual Education and Adolescence

Adolescents continue to engage in early and unprotected sexual contact with approximately 33% of adolescents becoming sexually active by middle school and increasing to 63% by 12th grade (Mosher et al., 2011; Eaton et al., 2012). It is well documented that comprehensive sex education can decrease risk-taking behaviors and promote safe sexual activity (Schalet et al., 2014). Yet, 40% of adolescents have sexual intercourse before ever receiving health information about birth control, STIs, and abstinence (Beckett, Elliott, Martino et al., 2010). The term "sex education" is a broader term and more commonly used in the literature for adolescents, whereas, the term "preconception counseling" is used specifically for females of reproductive age to discuss pregnancy planning (Williams et al., 2012). Adolescents usually receive some formal education about sexual and reproductive health from schools and/or pediatric offices. However, schools are limited in their discussion about sexual orientation and gender identity, which can alienate teens who are exploring their gender and sexual identities (Pingel, Thomas, Harmell, & Baurermeister, 2013). Healthcare providers (HCP) may not routinely target early adolescence with safe sex education (National Campaign to Prevent Teen Pregnancy, 1997). And clinicians in pediatric offices are spending less than a full minute per visit discussing sexual health with adolescents; in fact, over 35% of HCPs do not take advantage of the opportunities to provide sexual health counseling to their adolescent patients at all (Alexander, Fortenberry, Pollak et al., 2014). Parents should be included in sexual education discussions as well. In fact, parental communication with their adolescent about sex is associated with delayed sexual debut, and can increase birth control

and condom use in sexually active adolescents (Martinez, Abma, & Copen, 2013). It is critical that sexual and reproductive health information be discussed with all adolescents prior to sexual debut, especially those females of child-bearing age to prevent STIs and unplanned pregnancies.

Preconception Counseling and Diabetes

Females with diabetes require a special kind of sex education that is diabetes-specific preconception counseling (PC). PC is standard care for all women, especially those with diabetes, at child-bearing age to prevent unplanned pregnancies and plan future pregnancies (Charron-Prochownik et al., 2008). However, diabetes-specific PC also includes information about tight metabolic control and the importance of planning a safe and wanted pregnancy because of the higher risk of reproductive health complications. Diabetes-specific PC program typically includes four components: 1) counseling and education about the interaction of diabetes, pregnancy, and effective family planning; 2) education in diabetes self-management skills; 3) HCP-directed medical care and laboratory testing, and 4) counseling by a mental health professional when indicated to reduce stress and improve adherence to a treatment plan (Jones & Schmeltz, 1995).

PC has three phases: *awareness*-for women preventing an unplanned pregnancy, *overview*-for women contemplating a pregnancy, and *in-depth-for women actively planning a pregnancy* (Jones & Schmeltz, 1995). PC should be targeted to women during the *overview* and *in-depth*, yet two-thirds of diabetic women have unplanned pregnancies and very few have received PC (Janz et al., 1996; Charron-Prochownik et al., 2013; ADA, 2014). Women are unaware of PC and even when they are aware of the need, PC is begun too late (Charron-Prochownik et al., 2006). Due to unplanned pregnancies and elevated maternal blood glucose levels, females with diabetes have

higher risks (approximately 10%) of pregnancy-related and fetal complications (Kitzmiller, Wallestein, Correa, & Kwan, 2010). Normal blood glucose prior to conception reduces these risks of maternal and fetal complications from 9% to 2% (Rodgers et al., 2010). To prevent any complications, PC should be given during the *awareness* phase, especially for adolescent females with diabetes (Charron-Prochownik et al., 2008).

The ADA (2014) recommends that, starting at puberty, PC should be given to all women with diabetes of child-bearing potential at their routine clinic visits. Despite these recommendations, adolescents with T1D are unaware of their risks of unplanned pregnancies and do not prevent this risk when engaging in risky behavior (Charron-Prochownik et al., 2006; Martinez-Aguayo et al., 2007). Several studies have shown that PC is effective in preventing complications among females with diabetes (Kitzmiller, Gavin, Gin et al., 1991). It recommends tighter glycemic control before planning a pregnancy to have better sexual functioning, improved reproductive health and pregnancy outcomes. The goal of PC is to prevent unplanned pregnancies, but offers an opportunity to educate about STI prevention as well. It is critical that PC is discussed early, prior to sexual debut, and often with diabetic females.

A PC program called *R*eproductive-health *E*ducation and *A*wareness of *D*iabetes in *Y*outh for *G*irls *(READY-Girls)* is specifically tailored for adolescent females with diabetes. *READY-Girls* is a fundamental PC program (hereafter termed *RGPC*), that provides the information and builds self-management skills necessary to promote effective family planning decisions and seek PC when initiating future pregnancy planning behaviors (Charron-Prochownik, 2003). It presents information on the effects of diabetes on puberty, sexuality, and pregnancy; the benefits of PC; and prevention of unplanned pregnancies. The incorporation of PC into health visits, diabetes

education and reproductive health education can decrease risks for health complications among female adolescents with diabetes. Routine PC should provide adequate information to prevent STIs as well. *RGPC* addresses risk behaviors, contraception, and STIs; however, it is unknown if the message is sufficient to change risky behavior to prevent STIs.

Preconception Counseling for Chronic Illness and STIs

The National Campaign to Prevent Teen Pregnancy (1997) states an underlying cause for high rates of unplanned pregnancies and STIs is insufficient information provided to children and teenagers about human sexuality, contraception, how to avoid pregnancy and STIs and related topics in reproductive health. In a controlled field study involving 1,444 adolescent males and females comparing sex education programs, researchers found that greater sex knowledge helped sexual decision making and led to improved contraceptive use or continued abstinence at a later time (Eisen, Zellman & McAlister, 1990). Adolescents improved their adherence to contraceptive regimens after receiving comprehensive, developmentally appropriate, reproductive counseling (Hedberg, Klein & Andresen, 1998). However, chronically ill adolescents are less likely to receive sexual and contraceptive education than their healthy counterparts (Jones & Wild, 1994; Manolopoulos, Kiess et al., 2001). Despite increased interaction with the HCPs, information about contraceptive counseling and sexually related health needs with females with diabetes are not adequately addressed (Wager et al., 1986; Schwarz et al., 2006). Medical visits focus on their diabetes, compliance with disease management, and lab values, not discussing birth control or sexual activity (Brindley & Jovanovic, 2004).

Adolescents with chronic illness lack the knowledge about contraception, therefore are less likely to use birth control with sexual activity. Unsurprisingly, more STIs are reported within this population (Sawyer et al., 2007). Many females are unaware of preconception counseling, have unplanned pregnancies and are at high risk for contracting STIs (Janz et al., 1995). Risky behaviors, especially unprotected sex, in females with diabetes can be detrimental to their health (Charron-Prochownik et al., 2006). PC can decrease these risks. It is essential that adolescent females of child-bearing age receive PC early before becoming sexually active.

2.7 SUMMARY

Based on the review of the literature, adolescent females are at high risk for STIs. Both uncontrolled diabetes and STIs can cause reproductive health complications. Adolescent females with diabetes could have an even higher risk for compounded reproductive complications due to poor metabolic control, unplanned pregnancies and STIs. Therefore, preventing these problems is imperative. Prevention starts with education and counseling. The goal for this project was to evaluate an existing PC program, *RGPC,* that targeted adolescents with diabetes, which focused on preventing poor metabolic control and unplanned pregnancies. PC for females with diabetes provides information on the importance of glycemic control and pregnancy planning. Receiving PC prior to sexual debut is essential for adolescent females with diabetes. The need for PC for adolescent females with diabetes is well documented on pregnancy prevention but lacks information about risk-taking behaviors and STIs. Although routine PC for women with diabetes

does not specifically address STIs, *RGPC* did provide some information. HCPs cannot assume that because PC provides information on contraception, it could have an effect on STI prevention as well. Furthermore, it is unknown if starting PC during early adolescence effects risk-taking behaviors, condom use and STIs throughout their child-bearing years. Therefore, this dissertation compared women who received *RGPC* as adolescents to those who received standard care only on these outcomes. The first aim was a secondary analysis of the adolescent data from RCTs of adolescent females with T1D to compare the short term efficacy of receiving *RGPC* during adolescence on risk-taking behavior, condom use, and STI. The second aim was a 15 year follow-up survey (expanded follow-up study) of the adolescent *RGPC* cohort, to examine the influence of early health beliefs and the long-term efficacy of PC received in early adolescence on risk-taking behaviors, condom use, and STIs as adults. The third aim described current risk-taking behaviors, condom use, and STIs in adult women with T1D (expanded follow-up study).

3.0 THEORETICAL FRAMEWORK

Because the outcomes of the adolescent RG-RCTs studies were behavioral, a cognitive-behavioral model, namely, the Expanded Health Belief Model (EHBM) was used to explain behavior change and guide the intervention. The EHBM describes six main beliefs (constructs) that influences behavior change: Perceived Susceptibility, Perceived Severity, Perceived Benefits, Perceived Barriers, Cues to Action, and Self-Efficacy. (Burns, 1992; Charron-Prochownik et al., 2001). Perceived susceptibility is a person's perception of acquiring a risk while perceived severity is the belief of the seriousness of that risk. When perceived susceptibility and severity are combined, it results in perceived threat or risk perception, leading to changes in behaviors (Stretcher & Rosenstock, 1997). Perceived benefits is one's opinion that a behavior change will decrease their risk, and perceived barriers is the assessment of obstacles that may deter a behavior change (Janz & Becker, 1984). Cues to action are events, people, or things that trigger a change in behavior (Stretcher & Rosenstock, 1997). Self-efficacy is the belief or confidence in a person's own ability to do something (Bandura, 1977). In previous PC studies, only some of the EHBM constructs have been predictive of reproductive health behaviors. In a study by Janz et al. (1995), the main construct of perceived benefits was found to be most influential. Patients who received PC were more knowledgeable about diabetes, perceived greater benefits of PC care, and received more instrumental support. For studies involving *RGPC*, similar findings were noted. Compared to the standard care group, the intervention group had greater perceived benefits concerning reproductive

health and PC information (Charron-Prochownik et al., 2008), along with fewer barriers to receiving PC (Rodgers et al., 2010).

The effects of *RGPC* have not been used to assess specific risk-taking behaviors in adolescents with diabetes. *RGPC* is based on the EHBM to raise awareness of the risks of uncontrolled blood sugars on unplanned pregnancies. However, it is not known if awareness of risk carries over to other risks from adolescence to adult women. *RGPC* does not target STIs specifically, but includes a brief section of STI information (unprotected sex can lead to STIs in teenage women, choosing abstinence protects from STIs and condoms protect against STIs) in the program. Yet, it is unclear if *RGPC* provides enough education during adolescence about STI acquisition into adulthood. Furthermore, *RGPC* has demonstrated that it has an impact on perception of benefits and barriers and self-efficacy to using birth control for preventing an unplanned pregnancy and seeking PC. Yet, it is not known if there is any carry-over effect of changes in these beliefs impacting long-term risk-taking behaviors, condom use, or STIs. The variables of risk-taking behaviors, condom use, and STI prevention were not outcomes in the adolescent RG-RCTs studies. Since this is a secondary analysis, the variables of unplanned pregnancy items were chosen as to be most relevant to this study's outcomes: susceptibility and severity to unplanned pregnancy, barriers to BC, self-efficacy to waiting to have sex (Figure 4). For Specific Aim #2, data from the adolescent RG-RCTs studies of the EHBM constructs, namely, perceived severity and susceptibility to unplanned pregnancy, barriers to birth control, and self-efficacy on avoiding sex were used in the analysis. However, perceived benefits of birth control were not used because these items were not measured consistently across the RG-RCTs studies.

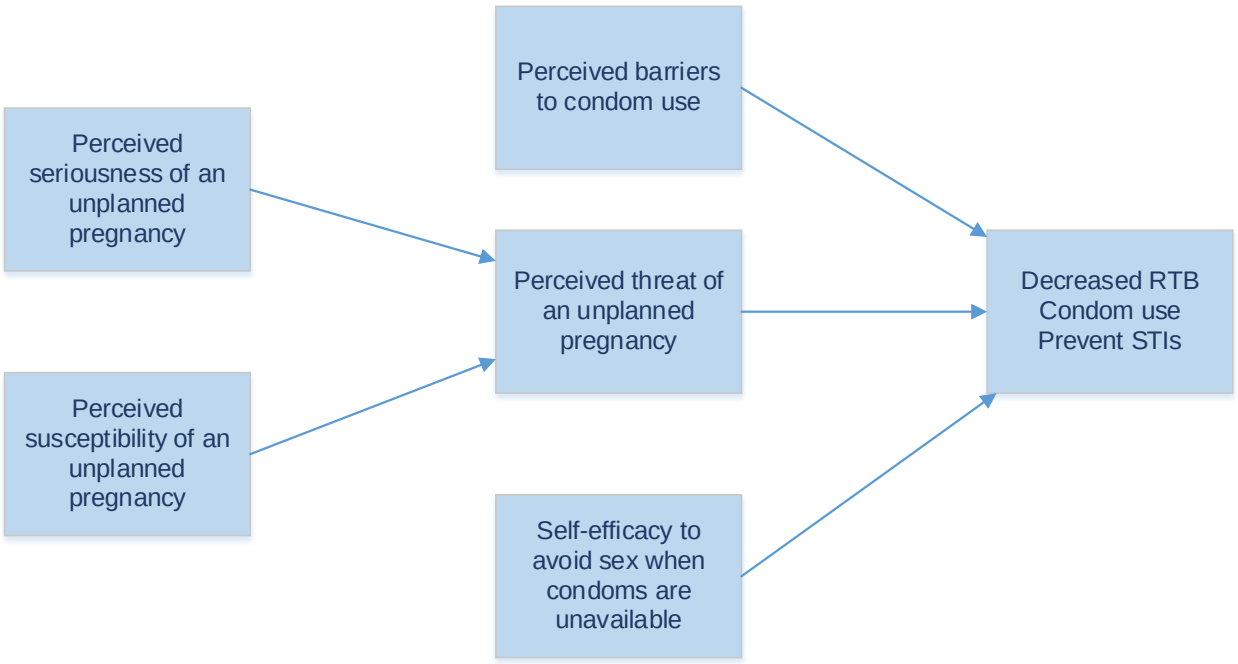

Figure 5. Application of the Expanded Health Belief Model (Rosenstock, Strecher, & Becker, 1998)

4.0 PRELIMINARY WORK

Type 1 Diabetes (T1D) is the most chronic disorder in childhood and has a peak age of onset during adolescence. Adolescents are less likely to comply with treatment regimens as an attempt to be a normal teenager. They may engage more often in risky behaviors, including earlier sexual activity, than their healthy peers. Adolescent females with T1D are unaware of reproductive health complications and are using unsafe sexual practices. These females report lower rates of birth control use and self-esteem. Low self-esteem is associated with risky behaviors which may lead to sexually transmitted diseases (STIs) and unplanned pregnancies (Ethier, Kershaw, Lewis et al., 2004). Therefore, the purpose of this study is to examine the role of self-esteem as a mediator of the association between personal characteristics and risky behaviors in adolescent females with T1D. A secondary analysis was performed on baseline data from two consecutive independent RCTs evaluated efficacy of *RGPC*. *RGPC* is a PC program developed for adolescent females with diabetes. Two RG-RCTs were conducted with adolescent females with T1D ranging in age from 13 to 20 years. The 141 participants from both studies completed a battery of paper-pencil questionnaires measuring cognitive, psychosocial, and behavioral outcomes. Items and measures were taken from the "Reproductive Health Program for Teen Girls with Diabetes Questionnaire" (Card, 1993) and Rosenberg's Self-Esteem Scale (Rosenberg, 1965). The subjects age ranged 13-19 years, (mean =17years); 4.0% (n=7) were African American, 26% (n=36) were sexually active, with 17.0% (n=23) had unprotected sex, mean age for sexual debut was 15.6 years. Descriptive, bivariate, and multivariate analysis was performed. Self-esteem was associated among stage of

adolescence, and age of puberty (r =.068, p=.351; r=.325, p=.029 respectively) with risky behaviors in adolescents with T1D. Self-esteem was not associated with personal characteristics. Regression analysis showed personal characteristics (r^2=.011, p=.448) predicted self-esteem level and self-esteem predicted risky behaviors (r^2=.021, p=.455). Self-esteem was associated with drug use. Adolescents with higher levels of self-esteem were less likely to experiment with drugs. Both self-esteem (r^2=.071, p<.05 and personal characteristics (r^2=.065, p=.029) were significant predictors of risky behavior. Those adolescents who were younger at T1D diagnosis and younger at puberty were more likely to engage in risky behaviors. In conclusion, risky behaviors and lower self-esteem were associated with older adolescents (late adolescence). This suggests earlier intervention for younger adolescents (early and middle adolescence) to boost self-esteem and the need for education on the implications of risky behaviors. HCPs could also be available to provide proper counseling for those patients suffering from lower self-esteem (Thurheimer et al., 2013).

5.0 RESEARCH DESIGN AND METHODS

5.1 DESIGN

The short and long-term efficacy of receiving *RGPC* during early adolescence on risk-taking behavior, condom use, and STI acquisition among a cohort of adult women with T1D up to 15 years were examined by using data from adolescent RG-RCT studies, an adult follow-up study of the cohort, and a recent follow-up survey (expanded follow-up study). These data were obtained from the combination of two methods, extracting data from an existing database of the RG cohort as adolescents for a secondary analysis and re-contacting these RG cohorts who are now adults to complete an expanded follow-up study survey. Limitations of these survey designs are described in Section 5.7.4.

5.1.1 SPECIFIC AIM #1

The secondary analysis of data from two RCTs evaluating the RG program in adolescent females with T1D funded by ADA, (1999: CR-2684232, 2002: 7-02-CR-06), were used to compare between the RG intervention group (RG-I) and the standard care group (RG-C) on the short-term efficacy of receiving early preconception counseling during adolescence on risk-taking behavior, condom use, and STI acquisition. For Specific aim #1 we used data from these two earlier RG-RCT studies. These adolescents were later recruited to participate in the adult follow-up study.

5.1.1.1 ADA Original *READY-Girl* Studies

An adolescent diabetes-specific PC intervention called *READY-Girls* (*RGPC*) is evidence-based and theory-driven, available in both DVD and book format, guided by the Expanded Health Belief Model that raises awareness and provides information on the effects of diabetes on reproductive health, puberty, sexuality and pregnancy. Two RCTs have been previously conducted that examined cognitive, psychosocial and reproductive behavioral health outcomes of *RGPC*. Inclusion criteria for both studies were females with T1D and able to speak and read English. Eligible females were excluded if they were currently pregnant or were diagnosed with T1D and another chronic disorder or mental retardation. The 1999 *READY-Girls* ADA funded study (CR-2684232), hereafter named **RG-RCT1**, was to develop and assess the feasibility of an early PC program (*READY-Girls*) tailored for adolescents with diabetes. The study involved 53 adolescent females ages 16 to 20 years with T1D who were randomized into one of three protocols: Two PC intervention groups, hereafter termed **RG-I**, with 1) *READY-Girls* CD-ROM (n=17), or 2) *READY-Girls* book (n=16), or standard care group, hereafter termed **RG-C**, (n=20). The participants completed a questionnaire before the intervention, immediately after the intervention, and 3-months post-intervention to assess the impact of the *RGPC* on intentions, behaviors and birth control towards PC. Compared to those who received standard care, adolescents who received the *RGPC* program showed greater improvement in diabetes knowledge; perceived more benefits of receiving PC; used effective family planning; and perceived more support concerning reproductive health complications, preventing an unplanned pregnancy, and seeking PC (Charron-Prochownik et al., 2008).

In the 2002 *READY-Girls* ADA funded study (7-02-CR-06), hereafter named **RG-RCT2**, the second efficacy trial was conducted combined two CDs with book boosters and included younger girls with diabetes (13-20 years) compared to a standard care control group. The primary objective of the trial was to evaluate the impact of the combined PC intervention on cognitive, psychosocial, and behavioral outcomes and assess its cost-effectiveness. Adolescent females ages 13 to 20 years with T1D were randomized into a PC intervention group, **RG-I**, (n=43) or a standard care group, **RG-C**, (n=45). During three consecutive diabetes visits over a nine-month period, the intervention group received two CDs, read a book version and received counseling from a nurse researcher. At sessions two and three, the RG-I had a one-on-one interview with the research nurse to answer questions about PC and reproductive health. Both the RG-I and RG-C received pamphlet information about general PC provided by the March of Dimes (e.g., taking folic acid, decreasing substance use during pregnancy, and getting tested for STIs) at the first session (March of Dimes, 2015). Compared to the standard care group, the intervention group had greater knowledge and perceived benefits concerning reproductive health, and PC information, along with fewer barriers to receiving PC (Rodgers et al, 2010); for cost-effectiveness, it was determined that *RGPC* could improve and reduce costs of adverse reproductive health outcomes.

The control groups were given the opportunity to watch the CD-ROM or DVD in the clinic; most chose not watch it. All the subjects in the control groups received the *RGPC* book to take home (Charron-Prochownik et al.; Rodgers et al., 2010). However, no immediate follow-up studies were conducted on the standard care control groups' to determine whether they read the book or their response to the *RGPC* program.

RGPC has shown to be effective for the topics it was intended, however it is unclear whether the program had an influence on more general PC, such as, risk taking behaviors, condom use, and STI acquisition.

5.1.2 SPECIFIC AIM #2

For **Specific aim #2,** we combined data from the two earlier READY-Girls studies [RG-RCT1 and RG-RCT2 (ADA studies described in **Specific Aim #1)**] and survey data from the adult follow-up study and the expanded follow-up study.

For research question 2a, we used a comparative design to examine differences in the adult cohort between the two READY-Girls groups (see section 5.1.2.1 for definitions of FRG-I and FRG-C) on risk-taking behavior, condom use, and STIs. For research question 2b, a prospective, longitudinal cohort repeated measures design was used to examine the long-term efficacy of PC (*RGPC*) received early in adolescence on the above outcome variables among adult females with T1D.

5.1.2.1 Adult Follow-up Study (*RGPC* Cohort Follow-up Study)

The adult follow-up study is an online, longitudinal cohort follow-up study with repeated measures titled "Long-term Effects of Receiving Preconception Counseling in Early Adolescence" funded by the ADA (1-11-CT-10), hereafter termed the **adult follow-up study**. The purpose of the adult follow-up study was to examine distal outcomes of pregnancy planning behaviors, pregnancy

outcomes and metabolic control in women with diabetes who received PC during adolescents [subjects who participated in either a single or intensive *RGPC* study, hereafter termed **FRG** (**FRG-I** was the intervention group and **FRG-C** was the control group in *RGPC* studies). These studies are described in the above Section 5.1.1.1)] compared to an historical comparison group, hereafter termed **FCG**, from a diabetes research registry who did not receive *READY-Girls*. The FCG was matched with the *READY-Girls* subjects on current age, age of diagnosis, and race. The 18 month adult follow-up study consisted of an online tracking system to collect data every 6 months with web-based questionnaires completed by subjects. In addition, subjects (N=113) from a third *READY-Girls* RCT study entitled "Reproductive Health Intervention for Teen Girls with DM" (funded NIH R01-HD044097), hereafter termed **RG-RCT3**, were recruited for this adult follow-up study. All three studies were similar in subject recruitment criteria. The RG-RCT1 and RG-RCT2 studies were similar in design and measures; therefore, making it possible to merge the data files. Of the 102 subjects enrolled, 99 (97%) were white, had a mean age of 23.7 (SD = 4.48; range = 18 to 38 years), 73 (82%) had some college, 69 (70%) had a husband/boyfriend, 25 (26%) were married, 42 (58%) were Catholic, 24 (30%) had an income < $40,000, and 75 (86%) had private health insurance. Regarding sexual activity, 79 (78%) had ever had sexual intercourse with a mean age of sexual debut at 18.8 years (SD = 2.43; range = 14 to 28 years) and of these 79 subjects, 71 (93%) were currently sexually active. The primary aims of the adult follow-up study did not focus on the examination of risk-taking behaviors or STIs. These items were missing from the questionnaires used in the adult follow-up study. Therefore, an expanded follow-up survey was conducted to collect these missing variables using the same items from the adolescent *READY-Girls* RCT studies, thus making it possible to link the data across all studies. The availability of

the adult follow-up study data provides a unique opportunity to more fully inform the quantitative inquiry through comparisons of survey responses and objective measure obtained as part of the expanded follow-up study.

5.1.3 EXPANDED FOLLOW-UP

This expanded follow-up study (funded by Greater Pittsburgh Nursing Research Conference) utilizes a survey design which is cross-sectional, self-reported online survey using REDCap software (Harris, Taylor, Thielke et al., 2009). The variables, risk-taking behaviors and STIs that were missing from the adult follow-up study were added to this survey. This expanded follow-up study consisted of subjects from the adolescent *READY-Girls* RCTs cohort and the comparison group from the adult follow-up study. To allow for comparison, the same items from the adolescent *READY-Girls* RCT studies (RG-RCT1 & RG-RCT2) were used to measure these variables in our survey. Descriptions of the variables for this expanded follow-up study are in Measures section 5.5.1. The recruitment letter and instrument is in Appendix A.

5.1.4 SPECIFIC AIM #3

Specific Aim #3 was a descriptive analysis of the expanded follow-up study sample combining data from a survey of a cohort of adult women with T1D who participated in a *READY-Girls* study as an adolescent (FRG) and comparison group (FCG) to describe risk-taking behaviors, condom use, and STIs as adult women with diabetes. It also examined consistency of self-report on time

related outcomes (e.g., age of sexual debut, use of BC during first sexual experience) and non-time related outcomes (e.g., "ever been diagnosed with an STI?", "have you ever smoked?"). Limitations of these survey designs are described in Section 5.7.4

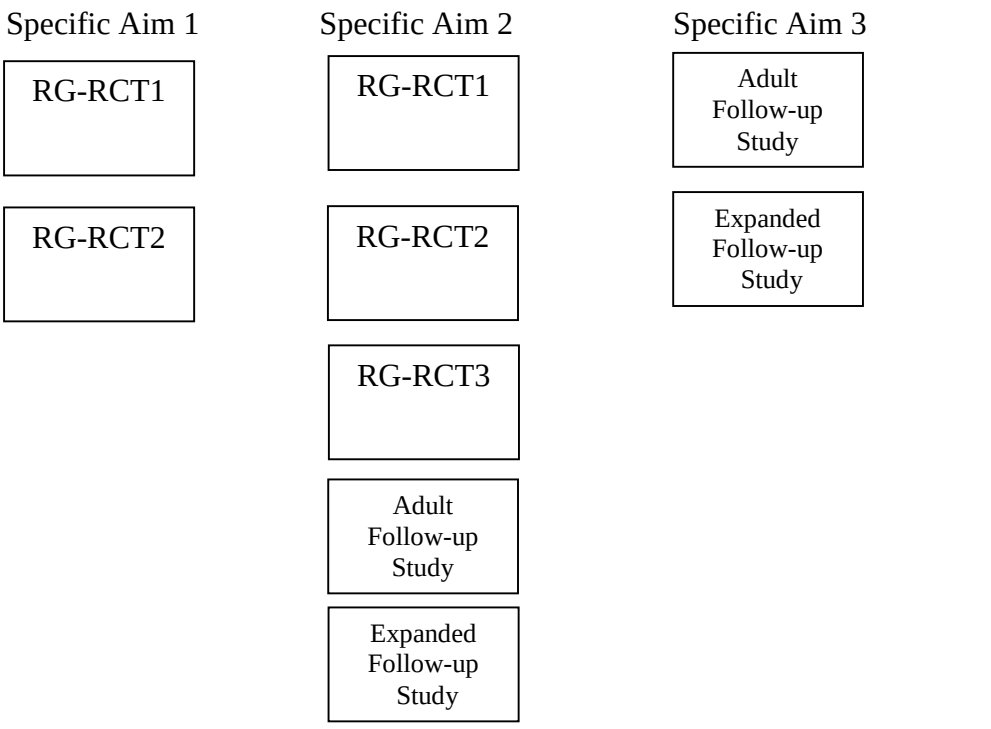

Figure 6. Diagram of Specific Aims

5.2 SETTING

Participants were subjects with T1D re-contacted from the three previous *READY-Girls* studies (RG-RCT1, RG-RCT2, and RG-RCT3) and the Children's Hospital of Pittsburgh (CHP) Diabetes Research Registry in the Greater Pittsburgh Metropolitan Area.

5.3 SAMPLE

All subjects from the adult cohort of *READY-Girls* RCTs (FRG) and the comparison group (FCG) were eligible to participate (see Section 5.1.1.1 for inclusion criteria for RG-RCTs). The inclusion criteria for the comparison group in the adult follow-up study were: 1) ≤ 45 years, 2) newly diagnosed and new patient with T1D at CHP who were seeking treatment or were being treated at the Diabetes Research Center at CHP, and 3) using insulin. Exclusion criteria were: 1) non-English speaking, and 2) history of another chronic illness or mental retardation. The FCG were members of the CHP Diabetes Registry. All of the subjects in the adult follow-up study had received the same standard care for patients with diabetes at CHP.

Description of Sample Characteristics for SPECIFIC AIM #1

Demographics were analyzed. The pooled sample for Specific Aim #1 consisted of 136 subjects, 76 in the intervention group (RG-I) and 60 in the control group (RG-C). The subjects had a mean

age of 17 years (range=13-20yrs), 7 (5%) were African American, 56 (41%) listed Roman Catholic as their religion, 128 (94%) were full time students with 86 (63%) in high school. The majority of the subjects (n=128) lived with their parents with 53 (39%) having an income > $20,000/yr. As for sexual behavior, 36 (26%) were sexually active with a mean age of sexual debut at 15.4 years (range=13-20 years), 23 (64%) had unprotected sex, 33 (92%) used condoms and 3 (9%) had an STI.

Description of Sample Characteristics for SPECIFIC AIM #2 & #3

Demographics from adult follow-up study were analyzed for the present expanded follow-up study. A total of 102 subjects (n=52 FRG subjects; n=50 FCG subjects) were enrolled in the adult follow-up study from 2010-2013. A subsample of 75 subjects from the adult follow-up study was recruited for this expanded follow-up study to complete an additional on-line survey. This subsample had a mean age of 24 years (SD = 4.5; range = 18 to 33 years). Respondents were primarily white (98%) and 23 (34%) had some college education. The mean age of T1D diagnosis was 10 years (SD = 4.9; range = 1 to 28 years) with the duration of T1D being 15 years (SD = 6.4; range = 0 to 30 years). Forty-seven (70%) of respondents were married or had a boyfriend, 31 (51%) were Catholic, 19 (27%), and reported their income ≤ $40,000/year. As for sexual activity, 54 (79%) had ever had sexual intercourse with a mean age of sexual debut of 18 years (SD = 2.33; range = 15 to 25 years).

5.4 RECRUITMENT

Secondary Analysis Study (Aim #1)

Recruitment guidelines for the two adolescent *READY-Girls* ADA studies is included above in the *READY-Girls* section 5.1.1.

Adult Follow-up Study

The consent forms from the previous adolescent RG-RCTs studies included statements allowing for re-contacting subjects. The project nurse called subjects who participated in the earlier *READY-Girls* studies and briefly explained the adult follow-up study and invited them to participate. The project nurse explained the study in detail, consent the subject, and provided web access instructions. A protocol manual was developed for the project nurse with scripted instructions for each task to keep consistency in instructions and procedures. Participants were able to complete each data point collection on their home computer for the adult follow-up study.

Expanded Follow-up Study

For the expanded follow-up study, participants of the adult follow-up study were contacted by either email or a mailed letter requesting completion of an additional survey. The additional survey were emailed or mailed (in paper form) to participants for completion.

5.5 MEASURES

Specific Aim #1

Specific aim #1 was a secondary analysis to compare the short-term efficacy (3 months) of receiving early preconception counseling during adolescence on variables of risk-taking behaviors, condom use, and STI acquisition. Measures for all the variables in all three previous RG-RCT studies were condensed into a single questionnaire called the "Questionnaire for the Reproductive Health Program for Teen Girls with Diabetes" (Card, 1993).

Specific Aim #2

Specific aim #2a is a 15 year follow-up survey of the original cohort, to examine the long-term efficacy of PC (*READY-Girls*) received early in adolescence on risk-taking behavior, condom use, and STIs among adult females with T1D. Data were collected using an online survey in the adult follow-up study that had selected components of the original "Questionnaire for the Reproductive Health Program for Teen Girls with Diabetes" (see above) on sexual activity and birth control. (Card, 1993). Data regarding demographic data (age, race, education, income, health insurance, relationship status, and religion), and personal health (age of menses, duration of T1D and age of onset) were also included. These variables are described in detail in sections 5.5.1.1. to 5.5.1.5. However, the questionnaire in the adult follow-up study did not utilize items on risk-taking behaviors or STIs that were included in all three of the adolescents *READY-Girls* questionnaires completed by the subjects.

An expanded follow-up study survey questionnaire (Appendix A) was created to obtain data on risk-taking behaviors and STIs, using the exact questions from the original "Questionnaire for the Reproductive Health Program for Teen Girls with Diabetes" (Card, 1993).

The Risk Profile section consists of 12 items to measure risk-taking behaviors (e.g., "Have you ever had more than 1 sex partner?"; "Have you ever passed out from alcohol?"; "Have you ever taken recreational drugs/street drugs?'). The STI items included "Have you ever been told you had an STI?"; "Which disease?"; "Have you ever been diagnosed with more than one STI?").

Specific aim #2b, was to determine whether earlier adolescent health beliefs (e.g., risk perception, barriers, and self-efficacy) predicted long-term (~15 years) outcomes of risk-taking behaviors, condom use, and STIs as adult women. Data regarding health beliefs were taken from the "Reproductive Health Attitudes and Behavior Questionnaire" (RHAB) used in all three RG-RCTs. Validity, reliability, [internal consistency (Cronbach's alpha > 0.70)], other psychometric properties and scales scores have been established and published (Charron-Prochownik, Wang et al., 2006). These health belief variables are described in detail in the section 3.0. The outcome variables of risk-taking behaviors and STIs were taken from the expanded follow-up survey. These variables are described in 5.5.1.1.

Specific Aim #3

Specific aim #3 was to describe risk-taking behaviors, condom use, and STIs in adult women with diabetes. Data were collected using an online questionnaire used in the adult follow-up study and the expanded follow-up study survey questionnaire as discussed above in Specific aim #2. To examine the consistency on self-reported risk taking behaviors over time, secondary data on these variables were used as described above in Specific aim #1.

5.5.1.1 Risk-taking behaviors

Risk-taking behaviors are behaviors that may compromise the physical and mental health initiated by exploration or the influence of others, such as peers. For this study, risk-taking behaviors include *cigarette smoking, alcohol consumption*, and *illicit drug use*. These variables will be assessed using the Risk Profile section in the questionnaire described in Specific aim #2. The items *cigarette smoking, alcohol consumption*, and *illicit drug use* are dichotomous items (yes=1; no=0); yes responses lead to continuous data (amount, frequency). The following questions are: *cigarette smoking*: "Have you ever smoked cigarettes?"; "How many cigarettes per week?"; *alcohol use*: "Have you ever drank alcohol?"; "How many per week?"; "Have you ever passed out from alcohol?"; "Do you drive while drinking?"; *illicit drug use*: "Have you ever taken recreational/street drugs (including marijuana)?" Dichotomous items were added together for a summation score.

5.5.1.2 Sexual Behavior

Sexual behavior is defined as engaging in vaginal intercourse or other sexual contact (e.g., oral sex). Items were taken from adult follow-up. Items relating to sexual behaviors include *age of sexual debut, having >1 sexual partners, history of unprotected sex, current sexual activity*, and *sexual orientation*. *Sexual debut* is the initial occurrence of vaginal intercourse. The item *age of sexual debut* is ratio data with an additional dichotomous item, "Have you ever voluntarily had vaginal sex?" *Sexual partner* is defined as persons who have engaged in sexual contact together. The item *>1 sexual partners* is a dichotomous item (yes=1; no=0); yes responses lead to ratio data (*number of sexual partners*). Unprotected sex is engaging in sexual contact without using

contraception. The item *unprotected sex* is dichotomous (yes=1; no=0) with the questions "The first time you had voluntarily vaginal sex, did you use any method of birth control?"; "Have you ever had sex without using birth control?"; "During the last 6 months, did you ever have sex without using birth control?" The item of *current sexual activity* is dichotomous (yes=1; no=0) to assess the frequency of sexual activity with the question "In the last 6 months, have you had sexual intercourse that was not forced?" The item of *sexual orientation* is a dichotomous item (yes=1; no=0) with questions "Have you voluntarily had vaginal sex with someone of the opposite sex"; "Have you voluntarily had vaginal sex with someone of the same sex?"

5.5.1.3 Birth Control

Birth control (BC) are methods to protect from unplanned pregnancies and/or STIs when engaging in sexual contact. For this study condoms or dual methods including condoms forms of BC were assessed as more protective types of BC from both pregnancy and STIs. Items assessing BC were included in the adult follow-up study. These items are *type of BC, BC use, most frequent BC method(s) used*, and *current type of BC method(s) used*. The item *type of BC* is the method of choice when engaging in sexual activity. This item is dichotomous (yes=1; no=0) and categorical. Questions for *type of BC* were "What method(s) did you use the first time you had sex?"; "Do you usually use a single method or combination of methods of birth control when you have sex?"; "What is the combination?"; "During the last 6 months did you use a single method or a combination of methods of birth control when you had sex?" The item *BC use* is dichotomous (yes=1; no=0) to assess BC use and with sexual activity (past use, present use, and future use) and uses questions "Have you ever used birth control?"; "Are you using birth control now?" The item

most frequent method(s) of BC used is defined as how often BC is used with sexual activity and is a dichotomous item (yes=1; no=0). *Most frequent method(s) of BC used* is asked with questions listing each method individually such as, "Which birth control method(s) are you using most frequently: we used nothing?"; "Which birth control method(s) are you using most frequently: condoms?" *Current BC method(s) used* is the type BC being currently used with sexual activity. The item *current BC methods* is dichotomous (yes=1; no=0) with question "In the last 6 months, which of these did you use to keep from getting pregnant: condoms?"

5.5.1.4 Sexually Transmitted Infections

Sexually transmitted infections (STI) are infections that can be transferred from one sexual partner to another. Items on STIs were taken from the original questionnaire described above in Specific aim #2. These items are diagnosis of an STI, having had more than one STI, and type of STI(s). Items on STIs were taken from the original RG-RCT questionnaire but were not included in the adult follow-up study. Therefore, we developed an additional survey with STI items. *Diagnosis of an STI* is the diagnosis of an STI from a medical provider. This item is dichotomous (yes=1; no=0) with the question "Have you ever been told you have a sexually transmitted infection (STI); "Have you had more than 1 STI diagnosis?" *More than one diagnosis of and STI* item is dichotomous (yes=1; no=0) and asks "Have you had more than 1 STI?" *Type of STI* is a list of seven options of STIs and is dichotomous (yes=1; no=0) with questions "Which STI(s) were you diagnosed with: AIDS; chlamydia, herpes?"

5.5.1.5 Health Beliefs

Although the EHBM describes six main beliefs (constructs) that influences behavior change, only *Perceived Susceptibility; Perceived Severity, Perceived Barriers, and Self-Efficacy* were used for this study as previously discussed under "Theoretical Framework". Except for perceived benefit, each construct had certain items that remained consistent across all of the adolescent *READY-Girls'* studies. These four constructs are operationalized according to these items: perceived severity and susceptibility to unplanned pregnancy, barriers to birth control, and self-efficacy on avoiding sex. The variables of risk-taking behaviors, condom use, and STI acquisition were not outcomes in the adolescent *READY-Girl* studies. Since this is a secondary analysis, the variables of unplanned pregnancy items were chosen as to be most relevant to this study's outcomes (susceptibility and severity to unplanned pregnancy, barriers to BC, self-efficacy to waiting to have sex). To measure *susceptibility and severity*, two items remained consistent across the original *READY-Girls* studies. *Susceptibility* has an ordinal scale (ranging 1 to 10; 1 = not at all to 10 = a lot) with the question, "If you had unsafe sex, would you worry that you might get pregnant?" *Severity* has an ordinal scale (ranging 1 to 10; 1 = not bad at all to 10 = very bad) with the question, "How bad would it be to have these things happen to you: To have an unplanned pregnancy?"

To measure *barriers to BC*, one item remained consistent across all *READY-Girls* studies. *Barriers* also using an ordinal scale (ranging 1 to 10; 1 = not hard at all to 10 = very hard) with the question, "How hard would it be to do these things: To get some type of birth control?' *Self-efficacy* has an ordinal scale (ranging 1 to 10; 1 = not sure at all to 10 = very sure) with the question, "How sure are you that you could do these things: To wait to have sex until you have birth control?"

In addition, a *risk behavior* score was computed from the summation of 7 risk-taking behaviors items. Participants responded yes/no (dichotomous variable) to the following items: not using birth control, not frequently using condoms, not currently using condoms, having unprotected sex, having unplanned pregnancy, having more than one sexual partner, and diagnosed with an STI.

5.5.1.6 Sociodemographic and health characteristics

Sociodemographic and health history variables were included in the adult follow-up study. These sociodemographic data included: age, race, religion, ethnicity, marital status, self-reported income, health insurance, and education. The health characteristics items consisted of: age of menses, and illness characteristics (duration of illness, age of onset, complications).

5.6 DATA COLLECTION PROCEDURE

Specific Aim #1

For **specific aim #1**, secondary data were obtained from the two adolescent *READY-Girls* (RG-RCT) ADA funded studies (1999-CR-2684232 and 2002-7-02-CR-06). Refer to section 5.1.1 for details on these studies. Because both of these RCTs had similar designs and used the same measures, data could be pooled. This data were extracted and cleaned to perform analysis. Data were examined from a pooled sample consisting of 136 subjects, 76 in the *READY-Girls* group

(RG-I) and 60 in the control group (RG-C). The variables of risk-taking behaviors, condom use and STIs were measured in these two adolescent RG-RCT studies. A comparison between the RG-I and RG-C were performed through secondary analysis to determine if receiving *RGPC* had a short-term efficacy (3 months post-intervention) on the variables of interest.

Specific Aim #2 and #3

Although condom use was measured in the adult follow-up study questionnaire, risk-taking behaviors and STI items were not. For **specific aim #2** these items were added to the additional on-line expanded follow-up study survey using REDCap software (with paper/pencil questionnaires available for a back-up) to be completed by the subjects. Subjects from the adult follow-up study were contacted through email or a mailed letter and asked to participate in this expanded follow-up study to complete an additional questionnaire (See Appendix A for recruitment letter and questionnaire). Subjects had their own three digit subject identification number assigned from the adult follow-up study to access the on-line surveys and could use any computer with high-speed internet at home, school, public library, or at the clinic site where there was a laptop for their use. Subjects were asked to complete the on-line survey only once and would take approximately 5-10 minutes to complete. The subjects received $10 as compensation for completing the additional on-line survey. Data was examined to determine the long-term efficacy of *RGPC* received early in adolescence on risk-taking behavior, condom use, and STIs among adult females with T1D. Secondary data from the three adolescent *READY-Girls* studies was combined with the expanded follow-up study survey to determine if adolescent health beliefs (e.g., susceptibility, severity, barriers, and self-efficacy) from 3 month post-intervention *READY-Girls* data predict long-term outcomes of risk-taking behaviors, condom

use, and STIs as adult women. For **specific aim #3**, the online expanded follow-up study survey was used to describe risk-taking behaviors, condom use, and STIs in adult women with T1D. Secondary data of RG-RCT1 and RG-RCT2 as described in **specific aim #1** was combined with the expanded follow-up study survey to determine the agreement between 15 year follow-up self-reported responses as adults for risk taking behaviors and their responses as adolescents from the 3 month post-intervention *READY-Girls* data.

5.7 ANALYSIS

5.7.1 Data Screening

For **Specific Aim #1, #2 and #3**, data was analyzed through SPSS software (version 22, IBM, SPSS, Inc., Chicago, IL). Data screening was set at $p<.05$ for hypothesis testing. Prior to executing the analyses to address research study aims, data quality was assessed. Descriptive analysis provided examination of the data quality through univariate and bivariate distributions, detection of outliers, and evaluation of the amount and pattern of missing data with appropriate data imputation when needed. Screening for univariate and multivariate outliers was conducted via graphical and statistical means. Normality assessment included examination of histograms, normal probability plots, and skewness and kurtosis of individual variable response distributions. Linearity and independence of continuous variable responses was assessed via bivariate

scatterplots. With **specific aim #2**, multicollinearity was assessed using tolerance and VIF. Homoscedasticity was examined using scatterplots. With contingency tables, expected cell counts was scrutinized to assess feasibility of data.

5.7.1 Data Analysis for Aim 1

Specific aim #1 was a secondary analysis to describe and compare the short-term (three months) efficacy of receiving PC during early adolescence on risk-taking behaviors, condom use, and STIs to those subjects who received standard care. To determine the accuracy of data, the analysis included evaluating continuous-type variables, such as age of sexual debut, and age of dating was described using measures of central tendency (means, median) and dispersion (standard deviation, inter-quartile range). Categorical data, such as race, income, religion, education, BC methods was described using frequency counts and percentages. The use of count numbers (number of sex partners, frequency of sexual intercourse, substance use) allowed for Poisson distributions. The secondary analysis was descriptive and comparative between groups using baseline to three month data. Independent *t*-tests were performed on continuous variables (age, age of first date, age of sexual debut) to compare the means, standard deviations, ranges, for each group. Chi-square and Fisher's exact tests were computed to determine differences between the RG-I and RG-C groups on categorical baseline demographic characteristics. Marginal modeling with generalized estimating equations was performed to investigate main effects between groups (group), and over time (time) as well as the interaction between groups by time on risk-taking behaviors, condom

use, and STIs. Overall means and standard errors were computed for each group at baseline and three months. Level of significance was set at $p<.05$.

Preliminary analysis of the secondary analysis revealed very little missingness of demographic data and effect sizes for the variables were medium to allow for group comparisons. The estimation of sample size was 135 subjects to achieve adequate power at .80 with a two-tailed significance level of .05 in the 1999-2002 READY-Girls study. As the study was an extension of the completed *READY-Girls* studies, the sample size for the proposed study was fixed. Therefore, an estimation of effect size was recalculated with G-Power software for this secondary analysis based on the original study criteria. With a sample size of 136, in terms of the standard mean difference (d) between groups using a two-tailed t-test, an effect size as small as d±0.487 at 80% power with an alpha level of .05 was necessary to detect a difference between groups. Systematic biases was addressed and caution was utilized for interpreting results.

5.7.2 Data Analysis for Aim 2

For specific aim #2a, chi-square analysis was performed for categorical variables, along with contingency tables that allowed for cell counts to determine the difference as adults (in the adolescent cohorts of *READY-Girls* subjects) between the FRG-I and the FRG-C on risk-taking behaviors, condom use, and STIs. To determine accuracy of data, continuous-type variables, such as age of menses, age of sexual debut, and age of dating was described using measures of central tendency (means, median) and dispersion (standard deviation, inter-quartile range) was evaluated.

Categorical data such as race, income, religion, education, BC methods and STIs were described using frequency counts and percentages. Level of significance was set at $p<.05$.

For specific aim 2b, the analysis was both logistic and linear regression to determine if adolescent health beliefs (e.g., susceptibility, severity, barriers, and self-efficacy) from 3 months post-intervention data predict long term outcomes (~15 years) of risk-taking behaviors, condom use, and STIs as adult women. Descriptive and exploratory analyses were conducted to describe all participant characteristics. EHBM constructs, and outcomes were examined to identify any data anomalies (e.g., outliers, missing data, multicollinearity, etc.). Adult age served as a covariate to determine the adolescent health beliefs on the outcomes of interest (~15 years). Regression coefficients from logistic regression analyses of binary outcomes (e.g., unprotected sex) were exponentiated to yield odds ratios. Regression coefficients from linear regression analyses were reported as unstandardized coefficients. For both, 95% confidence intervals were obtained. The level of statistical significance was set at $p<.05$.

Preliminary analysis of the adult follow-up study revealed very little missingness of demographic data. The sample size for the study was fixed since the study is an extension of the completed adult follow-up study. An estimation of the smallest detectable effect size necessary for the study was recalculated with G-Power. With a sample size of 75, in terms of the standard mean difference (d), there effect size was computed from the means between groups using a two-tailed t-test to detect a difference of d ±0.328 with 80% at alpha level of .05. Data was analyzed using appropriate techniques for prospective cohort studies.

5.7.3 Data Analysis for Aim 3

Analysis of aim #3a was descriptive (frequencies and percentages) to determine risk-taking behaviors, condom use, and STIs in adult women with T1D. Chi-square analysis was used for the risk-taking variables which are categorical and dichotomous (unprotected sex, substance use, STI diagnosis) along with contingency tables to allow for cell counts. BC methods and consistency of using BC was described using frequency counts and percentages. The use of count numbers (number of sex partners, frequency of sexual intercourse, and substance) allowed for Poisson distributions. For aim #3b, consistency of self-reported risk taking behaviors over time was determined using proportions of the distribution of data. For dichotomous items (e.g., "ever" behaviors), confidence intervals were computed. For continuous type items (e.g., age of sexual debut and age of 1st date/boyfriend), confidence intervals and both means and standard deviations were reported.

5.8 HUMAN SUBJECTS PROTECTION

5.8.1 Human Subjects Involvement

Specific Aim #1

De-identified data from following ADA *READY-Girl* studies: Reproductive Health Awareness in Teens with Diabetes: Program Development (*READY-Girls*), Charron-Prochownik & Becker, 1999-2002, (CR-2684232; ADA Clinical Research Award); Reproductive Health Program for Teen Girls with Diabetes: An Intervention Study (Outcomes and Cost-Effectiveness Evaluation), Charron-Prochownik & Becker, 2002-2005, (7-02-CR-06; ADA Clinical Research Award).

Specific Aim #2 & #3

De-identified data from following ADA *READY-Girl* studies: Reproductive Health Awareness in Teens with Diabetes: Program Development (*READY-Girls*), Charron-Prochownik & Becker, 1999-2002, (CR-2684232; ADA Clinical Research Award); Reproductive Health Program for Teen Girls with Diabetes: An Intervention Study (Outcomes and Cost-Effectiveness Evaluation), Charron-Prochownik & Becker, 2002-2005, (7-02-CR-06; ADA Clinical Research Award); Reproductive Health Intervention for Teen Girls with DM, 2007-2012, Charron-Prochownik & Sereika, (NIH R01-HD044097); and Long-term Effects of Receiving Preconception Counseling in Early Adolescence, 2011-2013, Charron-Prochownik & Sereika, (1-11-CT-10; ADA Clinical Research Award) was provided. Data from all 243 subjects were used in the study. Additional data was obtained on a subset of the data (that of the adult follow-up study) in order to complete Aim #2.

5.8.2 Source of Material

Sociodemographic and health outcomes data was previously collected and obtained from the two adolescent *READY-Girl* ADA studies: (Reproductive Health Awareness in Teens with Diabetes: Program Development (READY-Girls), 1999-2002, Charron-Prochownik & Becker, CR-2684232; ADA Clinical Research Award; Reproductive Health Program for Teen Girls with Diabetes: An Intervention Study (Outcomes and Cost-Effectiveness Evaluation), 2002-2005, Charron-Prochownik & Becker, 7-02-CR-06; ADA Clinical Research Award, IRB Approval #PRO14010121, 1/15/2014) and the adult follow-up study (Long-term Effects of Receiving Preconception Counseling in Early Adolescence, 2011-2013, Charron-Prochownik & Sereika, 1-11-CT-10; ADA Clinical Research Award, IRB Approval # PRO10120019, 8/22/2013). A waiver of informed consent was granted for collection of this data. To answer the aims of the study, IRB approval was obtained for the secondary analysis (Aim #1; Appendix B) and a modification to the existing IRB protocol was sought through the University of Pittsburgh IRB (Aim #2; Appendix C).

5.8.3 Potential Risk, Benefits, and Protection from Risks

This was a minimal risk study. The primary risk of the study was a potential breach of privacy or confidentiality. To minimize the risk, the following practices were exercised: (1) Preliminary data and adult follow-up study data are de-identified and can only be linked to the subject by the unique study identification code (2) All data abstracted from the expanded follow-up study (beyond that

extracted from the adult follow-up study) have been collected by the investigator (3) Abstractors have completed all research privacy training modules as required by IRB regulations (4) All paper study documents are stored in a locked file cabinet in the *READY-Girls* Project Office (5) All computerized data are stored in a password protected computer to ensure data security.

Potential Benefits: There are no direct benefits to the study subjects. However, findings from this study have the potential to provide insight into the benefit of receiving PC during adolescence which could influence risk-taking behaviors, condom use, and STI acquisition.

Data & Safety Monitoring Plan: Data and safety monitoring for this study was developed to maintain the privacy and confidentiality of the subjects. No subject identifiers other than the subject's assigned unique identifier are contained in the paper study documents nor the electronic data files. Hard copies of data with only study, subject, and site identifiers are stored in locked cabinets in the University of Pittsburgh's study office. A data safety monitoring report will be promptly provided to the IRB if any unanticipated adverse events would occur.

6.0 MANUSCRIPT 1: THE EFFICACY OF THE READY-GIRLS PROGRAM ON RISK-TAKING BEHAVIORS, CONDOM USE, AND STI PREVENTIONS AMONG YOUNG FEMALES WITH TYPE 1 DIABETES

TITLE PAGE

The Efficacy of the READY-Girls Program on Risk-Taking Behaviors, Condom Use, and Sexually Transmitted Infections Among Young Adolescent Females with Type 1 Diabetes

Corresponding author: Jennifer Thurheimer PhD, RN
University of Pittsburgh School of Nursing
440 Victoria Building Health Promotion and Development
3500 Victoria St Pittsburgh PA 15261
412-624-9554 (work)
412-624-8521 (fax)
JLT92@pitt.edu

Susan M. Sereika, PhD
University of Pittsburgh School of Nursing
Professor Health and Community Systems
Director for Center for Research and Evaluation

Sandra Founds, PhD, CNM, FNP
University of Pittsburgh School of Nursing
Associate Professor Health Promotion and Development

Julie Downs, PhD
Carnegie Mellon University
Associate Professor Social and Decision Sciences

Denise Charron-Prochownik, PhD, RN, CPNP, FAAN
University of Pittsburgh School of Nursing
Professor and Chair Health Promotion and Development

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Abstract

Purpose: This study examined the short term (3-months) efficacy of early diabetes-specific *READY-Girls* preconception counseling (*RGPC*) on risk-taking behaviors, condom use and sexually transmitted infections (STIs) among adolescent females with type 1 diabetes.

Methods: Secondary analysis was performed with data pooled from two independent randomized control trials (RCTs) to evaluate the short-term impact of *RGPC*. The pooled sample had 136 participants (mean age 16.9, 13-19yrs); and compared those who received the *RGPC* [RG-I; (n=76)] to a standard care control group [RG-C; (n=60)]. Both groups self-reported on demographic characteristics, risk-taking behaviors (e.g., substance use and unsafe sex), birth control (BC), and STIs.

Results: No effect of *RGPC* emerged on risk-taking behaviors, condom use, and STIs. At baseline with 136 participants, descriptively, only 25% (n=36) of the adolescents were sexually active and 29% (n=39) were sexually active at 3-months. An overall mean age of sexual debut was 15.4 years; with more than half having had reported an episode of unprotected sex. Condoms were the most frequent type of BC used by both groups at both time points. By 3 months, only 4 had been diagnosed with an STI. Over time, subjects in both groups became more sexually active, (p=.002) and used more condoms (p=.024).

Conclusion: *RGPC* did not focus on general risk-taking behaviors or STIs and therefore, did not impact these outcomes. Condom use did increase over time in both groups. Because 75% of the subjects were not sexually active, 3-months appears to be insufficient length of time to observe changes in sexual debut. It appears that more information on risk-taking behaviors and STIs could be included in diabetes-specific PC programs, including *RGPC*.

Key words: adolescent females, type 1 diabetes, risk-taking behaviors, condom use, sexually transmitted infection

Every day in the U.S., 12,000 adolescents contract a sexually transmitted infection (STI).[1] The highest prevalence of STIs is between ages 15 to 24 years accounting for more than half of new STI cases annually (18 million/year).[1, 2] This coincides with the mean age of sexual debut for females at 16.9 years.[3] Among sexually active 14 to 19 year old female adolescents, 38% have been diagnosed with at least one STI.[4] One in two sexually active individuals will contract an STI before the age of 24 years; and females are four times more likely to be diagnosed with an STI than to have an unplanned pregnancy, whereby, unplanned pregnancies occur in 40% of females under the age of 20 years.[5-6] Adolescent females in the U.S. have the highest rates of unplanned pregnancy and STIs of any sexually active age group when compared to other industrialized countries.[5] Furthermore, STIs are a burden to the individual and to society. Diagnosis and treatment of STIs is costly; currently direct medical expenses are estimated at $13 billion a year.[7] Some healthcare providers (HCP) may not routinely target early adolescence with safe sex education.[8] Patient education should include the prevention of STIs, use of effective contraception, avoidance of risky behavior, and complications of STIs. Undiagnosed STIs can lead to reproductive health complications such as pelvic inflammatory disease (PID), ectopic pregnancy, infertility, and cervical cancer in women of all ages.[9]

Reproductive health complications may be compounded in females with chronic diseases, especially diabetes.[10] Concomitantly, diabetes can increase the risks of reproductive health complications, such as, medical problems during pregnancy, thus compromising fetal health.[10] Uncontrolled blood sugars, especially due to an unplanned pregnancy, can increase complications up to 9% in women with diabetes.[11] Preconception counseling (PC) is special advice and care for all women of reproductive age given prior to pregnancy about family planning, effective use of

birth control and how to plan a healthy pregnancy when ready.[12] For women with diabetes, PC also focuses on the importance of controlling their blood sugars before and during their pregnancy to decrease their risks for reproductive health complications[10] from 9% to 2% when women with diabetes receive PC.[11] However, two-thirds of women with diabetes have unplanned pregnancies; and very few have received PC.[10] Despite the American Diabetes Association's (ADA) recommendation to begin PC at puberty, prior to sexual debut, PC is not routinely provided in diabetes standard care for female adolescents.[13] When PC is given, it is often too late.[14] Therefore, a PC program was developed specifically for female adolescents with diabetes mellitus called *R*eproductive-health *E*ducation and *A*wareness of *D*iabetes in *Y*outh for *G*irls (*READY-Girls*), hereafter termed *RGPC*. This program targets adolescents starting at puberty. This focused on the importance of preventing unplanned pregnancies, benefits of tight metabolic control before conception, how to plan a pregnancy that is safe and wanted, effective use of birth control and to decrease risky sexual behaviors.[14] Although *RGPC* mentions sexual risk-taking behaviors (e.g., unsafe sex), birth control, and STIs, we questioned whether there is sufficient information to have an effect in changing these behaviors and preventing STIs in adolescents with diabetes; which is different from the depth of information provided by most general sex education for adolescents.[12] Awareness of diabetes-specific *PC* should be initiated early, focusing on the importance of tight glycemic control and safe sex practices among women of reproductive age with diabetes.[13] Moreover, the timing of the receipt of *RGPC* is critical since 43% of sexually active high school females reported an onset of sexual debut by the tenth grade.[15]

Risky behaviors (substance use and unsafe sexual practices) could interfere with illness management of diabetes. Substance use includes tobacco, alcohol and illicit drug use. Unsafe

sexual practices are behaviors, such as, unprotected sex and multiple sexual partners. Adolescents with diabetes are more likely than their healthy peers to engage in these risky behaviors.[16] The prevalence of these risk-taking behaviors of tobacco, alcohol, and illicit drug use among teens with diabetes are equal to or higher than the national average.[16]

With regards to risky sexual behaviors, adolescents with chronic illnesses report a higher rate of sexual intercourse and other risky behaviors than adolescents without chronic illness.[17] Of adolescents with chronic illness, 79% reported initiating sex compared to nearly half of high school students in the U.S.[17, 18] Moreover, while most adolescents are waiting to initiate sex, sexual debut occurs earlier in females with a chronic illness (13.8 years) compared to their healthy peers (15.3 years).[19, 20] Furthermore, females with diabetes have lower rates of contraception use and are more involved in risk-taking behaviors. [21-23]

Sexual risk-taking behaviors include unprotected sex. Studies have reported that 29% of females with T1D, have engaged in unprotected sex.[24] Adverse effects of unprotected sex can result in STIs and unplanned pregnancy; which serves as the greatest risk among all young females.[25] But little is known about STI rates in females with diabetes and how it may impact metabolic control.[26] Thus, it is critical that STIs and unplanned pregnancy can be avoided through effective family planning, including barrier methods of birth control. Although condoms are readily available, young adults are not compliant users of contraception.[27] Condoms can be highly effective in preventing transmission of STIs when used properly.[28]

In early preliminary studies, adolescent females with diabetes were unaware of the risks for reproductive health problems, had early sexual debut using unsafe sexual practices, and therefore, at high risk for future unplanned pregnancies and complications.[14] Furthermore, these

subjects did not realize their risk of complications; or understand that these complications can be prevented by tight glycemic control which is the focus of diabetes-specific PC.[29]

Two independent randomized controlled trials (RCTs) have been previously conducted on adolescent females with T1D that examined knowledge, health beliefs, psychosocial and reproductive behavioral health outcomes of *RGPC*. The first study, hereafter termed RG-RCT1, (1999 ADA) study developed and assessed the feasibility of *RGPC* (3 month follow-up). Females (ages 16-20 years) who received the *RGPC* intervention (hereafter termed RG-I) compared to those who received standard care (hereafter termed RG-C), showed improvement in knowledge, perceived benefits of receiving PC and using effective family planning, and perceived more support concerning reproductive health complications, preventing an unplanned pregnancy, and seeking PC.[30] In the second *RGPC* RCT study (2002 ADA) expanded the RG-RCT1 to include a broader age group of younger girls (ages 13-20 years) with diabetes, involved multiple sites and a longer follow-up period (3, 6, 9 month follow-up), hereafter termed RG-RCT2. Both studies utilized the same battery of measures, including questions regarding risk-taking behaviors, condom use, and STIs. The primary objective of the second trial was to evaluate the efficacy of *RGPC* tailored to adolescent females with T1D on knowledge, attitudes, psychosocial, and behavioral outcomes and assess its cost-effectiveness. The results showed that the RG-I had higher knowledge and perceived benefits concerning reproductive health, and PC along with fewer perceived barriers to receiving PC. For cost-effectiveness, it was determined that *READY-Girls* could improve and reduce costs of adverse reproductive health outcomes.[11] In addition, both studies included general PC information from the March of Dimes that discussed engaging in healthy behaviors before planning a pregnancy (e.g., taking folic acid, stopping

tobacco/alcohol/illicit drug use, maintaining a healthy weight and recommended testing for STIs); but did not include information on using condoms to prevent STIs.[31]

However, it was never determined whether the *RGPC* could impact risk-taking behaviors, condom use, and STI acquisition post-intervention. Given the risk of acquiring STIs in the adolescent population, and the compounding effect of STIs in diabetes, prevention of STIs is paramount in this population. Therefore, the purpose of this secondary analysis was to evaluate the short-term effect (baseline to 3 months) of receiving *RGPC* on risk-taking behaviors, condom use, and STIs among adolescent females with T1D compared to those who received standard care. We hypothesize at 3 month post-intervention data point, those adolescents who received *RGPC* (RG-I) would report decreased risk-taking behaviors, increased condom use, and decreased STIs compared to the standard care control group (RG-C).

Research Design and Methodology

The study was a secondary analysis of data obtained from the two previous RCTs of *READY-Girls*.[11, 30] Because both of these RCTs had similar research designs, used the same measures and were independent, data were pooled. Paper and pencil questionnaires were completed in by all subjects in both studies at baseline, immediate post-intervention, and at 3 months. However, for the purpose of the secondary analysis, behavioral and clinical outcomes were limited to the 3 month follow-up. Data were examined from a pooled sample consisting of 136 subjects, 76 in the *READY-Girls* group (RG-I) and 60 in the standard care control group (RG-C). The participants were recruited from two university based diabetes clinics from eastern Massachusetts and western

Pennsylvania. Protocols for both studies were approved by the institution review board (IRB) and original consent and assent for the adolescents were obtained at the time of the studies. A third IRB was obtained for the secondary analysis.

Measures

Outcome variables for the secondary analysis included general risk-taking behaviors, sexual activity, birth control methods, and STIs. Items for these variables were combined in a Reproductive Health Attitudes and Behavior (RHAB) questionnaire.[32] This measurement was modified from the "Pregnancy and Diabetes Interview Schedule" that was validated and created by Janz.[33] In addition, demographic items were also chosen.

Risk-taking behaviors (e.g., substance use and unsafe sex) included 5 dichotomous (yes/no) items on episodes of unprotected sex, having more than 1 sex partner, and "ever" using tobacco, alcohol and illicit drugs. Sexual behavior consisted of both dichotomous (yes/no) and continuous items, for example, "Have you ever had vaginal sex?" and age of sexual debut. The main item for birth control was "Which birth control methods are you using most frequently: condoms?" STIs were measured with a dichotomous item (yes/no), "Have you ever been diagnosed with an STI?" In addition, types of STIs were listed as categorical items. Lastly, we analyzed nominal and categorical items for demographic characteristics of age, race, annual income, educational level, insurance, and religion.

Analysis

Data were analyzed using SPSS for Windows.[34] A descriptive analysis of all baseline variables of interest was performed to assess data accuracy and describe sample characteristics and identify data anomalies (e.g., outliers, missing data, underlying statistical assumptions). One outlier was identified for the total number of sexual partners. The total number of sex partners was categorized to limit the influence of this outlier (no sex partners, 1 sex partner, 2 or more sex partners). Additionally, sensitivity analyses were conducted to investigate the robustness of findings. Via sensitivity analyses, no differences were found among the other variables when the outlier was removed.

Independent *t*-tests were performed on continuous variables (age, age of first date, age of sexual debut) to compare the means, standard deviations, ranges, for each group. Chi-square and Fisher's exact tests were computed to determine differences between the RG-I and RG-C groups on categorical baseline demographic characteristics. Marginal modeling with generalized estimating equations was performed to investigate main effects between groups (group), and over time (time) as well as the interaction between groups by time on risk-taking behaviors, condom use, and STIs. Overall means were computed for each group at baseline and three months. Level of significance was set at $p<.05$.

There was some missing data by 3 months post-intervention. Attrition of 28 subjects (21%) occurred for the three month follow-up accounting for < 10.3% of missingness across baseline and 3 months. It was assumed that the data was missing at random (MAR) related to the developmental age of the subjects and was not related to the outcome variables being studied. [35] The missingness did not appear to be related to the outcome of interest. Because the goal of the study was to

examine the risk-taking behaviors of these particular subjects rather than all adolescents in general, missingness is considered ignorable, therefore MAR. This allowed for a more unbiased estimation to be made using observed data within each group [36]. We expected the subjects to be independent from one study to the next and since analysis of the same subjects are being tested longitudinally; the data was highly correlated.

There were no difference between groups at baseline. However, there were significant differences between groups of those who were missing by 3 months post-intervention on risk-taking behaviors such as smoking, drug use, and having >1 sexual partner. A Mann-Whitney *U* test was conducted to evaluate the differences of those subjects who dropped out by three months would have more risk taking behavior, on average, than the subjects who completed both baseline and three months follow-up. The results of the test were in the expected direction and significant except for having more than 1 sexual partner, smoking use: $z = -2.92$, $p < .05$, drug use: $z = -3.97$, $p < .05$, >1 sexual partner: $z = -.314$, $p > .05$. The subjects without the three month follow-up had an average rank of 95.36, 94.57, and 115.35, while the overall group had an average rank of 126.12, 126.02, 118.91, respectively.[37]

Results

Sample Characteristics

The pooled sample (n=136) had a mean age of 16.9 years and most of the subjects were white. The majority of the subjects were currently in high school and lived with their parents. As for sexual behavior, 25% (n=36) were sexually active at baseline and 29% (n=39) were at 3 months,

with a mean age of sexual debut at 15.4 years (SD 1.44). There were no differences between groups on these variables at baseline (p>.05). See Table 1 for baseline group comparisons on demographics.

Risk-taking Behaviors

At baseline, no significant differences were found between groups on sexual risk-taking behaviors or other risk-taking behaviors (Table 2). Although more subjects in the RG-I compared to the RG-C were sexually active (n= 20, 33% vs. n=16, 21%), this was not significant (p=.09).

When comparing groups over time, there were no significant differences between groups on sexual risk-taking behaviors or other risk-taking behaviors (Table 3). However, a significant increase was noted within groups over time on the following item: "Ever voluntarily had vaginal sex?" (p=.002). See Table 3.

Condom Use and Other Birth Control Methods

At baseline, no significant differences were found between groups on birth control use (Table 2). Condoms were the most frequently used birth control method in both groups over time (baseline: RG-I 88%, RG-C 95%; 3 months: RG-I 86%, RG-C 90%). When comparing groups over time, there were no significant differences between groups on most frequent birth control use (Table 2). However, a significant increase was noted within groups over time in the item: "Ever used condoms with sex?" (p=.024). See Table 3.

STI Outcomes

At baseline, only 3 of the pooled sample had reported a diagnosis of an STI (Table 2). Two were in the RG-I and 1 was in the RG-C. At 3 months, an additional subject in the RG-C reported an STI. The following STIs were reported: HSV, chlamydia, gonorrhea, and HPV. Therefore, there were no significant changes between groups over time.

Discussion

This study evaluated the short-term efficacy (baseline to 3 months) of receiving *RGPC* on risk-taking behaviors, condom use, and STIs among adolescent females with T1D compared to those who receive standard care. Although there were no significant findings between groups in our outcomes, there were some changes at 3 months post-intervention in both groups regarding sexual risk-taking behaviors and condom use. The sexual behavior that increased was sexual debut. This behavior is likely to increase over time during adolescence and young adulthood, however, significant changes within 3 months was unexpected.[38] These increased sexual behaviors could explain the significant rise in condom use.

No effects of *RGPC* emerged on risk-taking behaviors, condom use, and STIs among adolescent females with T1D. This finding may be due to the following reasons. Firstly, 75% of our subjects were not sexually active, therefore the data collection period of 3 months may be too short to detect changes in sexual debut. Secondly, *RGPC* targets female teens with diabetes starting at puberty and focuses on the importance of preventing unplanned pregnancies, benefits of tight metabolic control before conception, how to plan a pregnancy that is safe and wanted,

effective use of birth control and to decrease risky sexual behaviors related to reproductive health.[14] *RGPC* has been effective for what it was intended to do. However, *RGPC* does not directly target the outcomes of this secondary analysis, namely, general risk-taking behaviors such as, substance use or STIs. Although these topics are mentioned, they are brief and peripheral in the context of reproductive health for women with diabetes.[39] And because no spillover effect of *RGPC* were found on risk-taking behaviors or STIs, these additional topics from evidence-based interventions[40-41] should be incorporated in PC for adolescents, including future versions of *READY-Girls*.

It should be noted that some general PC information was also provided to all subjects (both RG-I and RG-C in both studies). They all received March of Dimes pamphlets discussing healthy behaviors to adopt before and during a pregnancy, such as, taking folic acid, decreasing the use of smoking cigarettes/alcohol consumption/illicit drug, getting tested for STIs, and avoiding STIs by limiting sex partners.[31] Even with these additional pamphlets regarding general PC, it appears to have been insufficient to directly impact the targeted outcomes for this secondary analysis. Information about using condoms as a barrier method to avoid an unplanned pregnancy or STI was not included in the March of Dimes pamphlets. However, it was discussed in *RGPC* and is usually found in most sex education programs[42]. PC information is focused on pregnancy planning to prevent problems, whereas, sex education emphasizes preventing pregnancies and STIs.[43] Also, sex education in the general adolescent population has reduced risk-taking behaviors, increased condom use and STIs.[42-43] Therefore, it is imperative to include information about the importance of condoms because condoms are the only barrier method when used correctly, other than abstinence, that can prevent both STIs and unplanned pregnancies.[28] Furthermore, results of this

study indicated that condoms were the most frequent type of birth control method for both groups over time; and using condoms was significant at the 3 month follow-up. Another type of birth control that was the third the most frequently reported method by the pooled sample, and of particular concern, was withdrawal. According to Planned Parenthood, withdrawal does not prevent STIs and 27% of women who use this method, will become pregnant each year.[44] Therefore, the effectiveness of each method of birth control, especially condoms, should be included in all PC discussions with women of reproductive age.

As for other risk-taking behaviors, there were no significant differences between groups. Some adolescents in the study reported "ever" engaging in some risk-taking behaviors, such as, smoking cigarettes, drinking alcohol, and illicit drug use. These findings seems to coincide with another study, whereby, adolescents with chronic illness are just as likely to experiment with risk-taking behaviors as compared to healthy peers.[16]

In regards to STIs, there were too few subjects in these adolescent RCT studies that had diagnoses of STIs to allow for any meaningful analyses other than descriptive. Therefore, this variable was underpowered and statistical significance could not be determined. This low incidence of STIs is unlike other studies in which adolescents with chronic illnesses were more likely to be diagnosed with STIs.[17, 45-46]

The results of this study must be interpreted in the context of the following limitations. First, this was a secondary analysis. The adolescent RG-RCTs were not designed to examine the efficacy of the outcome variables in these analyses. The measures for the targeted outcomes for the secondary analysis could have been more robust. For example, the frequency for some items was determined by the term "ever" which was a broad dichotomous variable rather than a

continuous variable with a specific time line. The measures should also include specific items that target both sexual risk-taking behaviors and STIs. For example, the items only pertained to engaging in vaginal sex. Future studies should include items on oral sexual activity, since approximately 45% of adolescents (ages 15-19 years) reported having had oral sex with a partner of the opposite sex which can lead to contracting STIs.[47] Secondly, the data collection time point of 3 months post-intervention for observing changes in sexual debut may be too short. Longer time periods could capture more behavior changes. Regarding the sites, although precautions were taken for privacy, contamination could have occurred between the RG-I and RG-C because the subjects were recruited from diabetes clinics where the study was conducted. Also, the subjects completed self-reported questionnaires in the diabetes clinics. Self-reporting may have led to underreporting of risk-taking and sexual behaviors, as well as, STI diagnoses. Another limitation was that the sample size of sexually active subjects in our pooled sample was too small to conduct a comparative analysis with sufficient statistical power. We had expected the number of sexually active subjects in our study to be higher. But instead they had a later sexual debut compared to other adolescents with chronic illness.[19] A larger pool of sexually active subjects could have possibly been recruited if the adolescent RCT had included additional sites. Other limitations are related to data analysis, which was affected by the amount of missing data in the adolescent *READY-Girls* studies which has been discussed in the analysis section.

Nevertheless, despite these limitations, the adolescent studies were multi-site RCTs in our population of interest, and had the same recruitment criteria and measures to allow for data to be pooled. Although *READY-Girls* didn't target general risk-taking behaviors and STIs, it is the only PC program for adolescent females with diabetes. Our results highlight the need for continued

focus on receiving early PC among adolescents with diabetes and to include risk-taking behaviors and the prevention of STIs.

Implications

Because the ADA[13] recommends that adolescents with diabetes should receive preconception counseling at puberty prior to sexual debut, this is an ideal time to also include more information on general risk-taking behaviors, the benefits of condom use if sexually active, and STI prevention. *RGPC* could also benefit from these additions.

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Table 1. Descriptive and Comparison Statistics for Participant Characteristics in Pooled Sample and Between READY-Girls (n=76) and Control Group (n=60)

Characteristics	Pooled Sample (n=136)	READY-Girls n=76	Control Group N=60	*p*
Age (years) (M/SD/range)	16.9/1.5/13-20	16.8(1.5)	17.1(1.5)	.162
Age at sexual debut (years) (M/SD/range)	15.4/1.4/13-19	15.5/1.5	15.4/1.5	.840
Age at first date in years (M/SD/range)	14.4/1.4/10-17	14.5/1.3	14.1/1.4	.193
Ethnicity: (n/%)				.448
Caucasian	108(79.4)	62(82.1)	45(77.6)	
African American	7(5.1)	3(4.2)	4(6.9)	
Other	16(11.8)	7(9.7)	9(15.5)	
Religion: n(%)				.255
Catholic	56(41.2)	35(47.3)	21(35.0)	
Protestant	28(20.6)	14(18.9)	14(23.3)	
Other/none	51(37.5)	25(33.8)	9(15.5)	
Education: n(%)				.076
≤High school	101(74.2)	53(75.7)	48(85.7)	
>High school	25(18.4)	17(24.3)	8(14.3)	
Living arrangements: n(%)				.610
Parents	131(96.4)	72(96)	58(96.7)	
Other	5(3.6)	4(5.3)	2(3.4)	
Annual household income				.351
<$20000	7(5.1)	3(8.1)	4(17.3)	
≥$20000	53(39.0)	34(91.9)	19(82.6)	

*$p<.05$

Table 2. Risk-Taking Behaviors, Birth Control (BC) Use, and STI diagnosis between READY-Girls (n=76) and Control Group (n=60) at Baseline

Substance Use	READY-Girls n(%)	Control Group n(%)	*p*-value
"Ever" smoked cigarettes	20(26.3)	17(28.3)	.490
"Ever" used alcohol	32(42.1)	22(40.7)	.298
"Ever" used illicit drugs	11(14.5)	13(21.7)	.203
Sexual Behavior			
"Ever" had sex	16(21.3)	20(33.3)	.085
"Ever" Unprotected sex	11/20(69)	12/20(60)	.425
>1 sexual partner	10/14(71)	10/15(68)	.550
Most Frequently use BC method(s):			
Condoms	12(75.0)	14(70.0)	.519
Birth control pills	10(62.5)	6(37.5)	.451
Withdrawal	0	5(25.0)	.041*
Abstinence	1(6.3)	2(10.0)	.240
Nothing	5(31.3)	7(35.0)	.551
STI diagnosis	2(12.5)	1(5.0)	.415

*$p<.05$

Table 3. Comparison Sexual Activity, Risk-taking Behaviors, and STIs Between READY-Girls and Control Group Based on Marginal Modeling with Generalized Estimating Equations (GEE)

Behavior/Outcome	READY-Girls Estimated proportion		Control Group Estimated proportion		*p*-value: Groups Time Group by time
	Baseline	3 months	Baseline	3 months	
Voluntarily had sex	0.21±.047[a]	0.33±.057	0.33±.061	0.40±.066	.179 .002* .303
Currently sexually active	0.11±.035	0.19±.049	0.20±.052	0.23±.060	.229 .058 .280
>1 sex partner	0.17±.043	0.14±.041	0.20±.052	0.17±.053	.604 .217 .842
"Ever" unprotected sex	0.14±.040	0.20±.048	0.20±.052	0.22±.058	.498 .179 .565
"Ever" used condoms	0.18±.044	0.28±.054	0.32±.060	0.34±.065	.179 .024* .138
"Ever" smoked cigarettes	0.26±.051	0.25±.051	0.28±.058	0.21±.055	.883 .196 .340
"Ever" used alcohol	0.42±.057	0.41±.060	0.37±.062	0.38±.069	.572 .996 .799
"Ever" used illicit drugs	0.14±.040	0.17±.045	0.22±.053	0.18(.052	.502 .977 .317
"Ever" diagnosed with STI	0.03±.018	0.04±.024	0.02±.017	0.04±.026	.775 .171 .699

[a]Values reported are the proportions (means and standard errors) of subjects with the outcome

*p-values reported for group, time, group*time effects, $p<.05$

7.0 MANUSCRIPT 2: ADOLESCENT HEALTH BELIEFS AS PREDICTORS OF FUTURE SEXUAL RISK-TAKING BEHAVIORS AND OUTCOMES IN ADULT WOMEN WITH DIABETES USING A LONGITUDINAL COHORT SAMPLE

Running Title: Health beliefs and risk-taking behaviors

University of Pittsburgh School of Nursing

440 Victoria Building Health Promotion and Development

3500 Victoria St Pittsburgh PA 15261

412-624-6953 (work)

412-624-8521 (fax)

jlt92@pitt.edu

Adolescent Health Beliefs as Predictors of Future Sexual Risk-Taking Behaviors and Outcomes in Adult Women with Diabetes Using a Longitudinal Cohort Sample

Corresponding author: Jennifer Thurheimer

University of Pittsburgh School of Nursing

USA, Pittsburgh, PA 15261

Susan M. Sereika

University of Pittsburgh School of Nursing

USA, Pittsburgh, PA 15261

Julie Downs

Carnegie Mellon University Social and Decision Sciences

USA, Pittsburgh PA 15624

Sandra Founds

University of Pittsburgh School of Nursing

USA, Pittsburgh, PA 15261

Denise Charron-Prochownik

University of Pittsburgh School of Nursing

USA, Pittsburgh, PA 15261

Abstract

Background: Adolescents often engage in risk-taking behaviors, such as, unprotected sex. These behaviors can lead to unplanned pregnancy, reproductive health complications, or sexually transmitted infections (STIs). Given that health beliefs may predict health behaviors, the purpose of this study was to determine if adolescent health beliefs predict the long-term health behaviors of sexual risk-taking behaviors, birth control use, and STIs in adult women with type 1 diabetes.

Design/setting: A secondary analysis with original adolescent health belief data and recent adult follow-up data of 39 women with diabetes who participated as adolescents in randomized control trials using the Expanded Health Belief Model (EHBM), namely susceptibility, severity, barriers, and self-efficacy. Data were conducted using online surveys to assess sexual risk-taking behaviors, condom use, and STIs as adults.

Results: The sample was on average 24 years (SD=4.4), all white, 64% had a husband/boyfriend, and 74% were sexually active. Adolescents with higher perceived susceptibility were more likely as adults to plan a pregnancy (p=.035), and less likely to have unprotected sex (p=.035). Adolescents with higher perceived susceptibility and self-efficacy were more likely to use birth control as adults (p=.031; p=.048) respectively. Adolescent health beliefs were not predictive of number of sexual partners, consistent birth control use, or STIs as adult women.

Conclusion: Some health beliefs as adolescents appear to be associated with avoidance of some sexual risk-taking behaviors and greater birth control use as adult women. Some EHBM constructs for adolescents predicted sexual risk behaviors as adults. Identification of adolescent health beliefs can assist in tailoring education towards the importance of decreasing risky behaviors, condoms use, and preventing STIs.

Keywords: adolescent females, health beliefs, reproductive health, risk-taking behaviors, STIs

Introduction

Adolescence is a period of physical, cognitive, emotional, and sexual growth. The beliefs and attitudes that form during this critical developmental phase can influence future behaviors, such as risky sexual activity. Identifying predictors during adolescence could have implications for interventions to alter beliefs that lead to long-term risky or protective behaviors.

However, to our knowledge, there have been no longitudinal cohort studies to link adolescent beliefs to adult risky sexual behaviors. In a systematic review by Hiltabiddle (1), relationships between health beliefs, condom use and sexually transmitted infections (STIs) during adolescence were examined. In this review, positive attitudes and higher levels of self-efficacy towards condoms were associated with frequency of condom use. There were no significant relationships between attitudes and preventing STIs. Furthermore, no studies have examined the relationship of adult health beliefs to risky behaviors.

For women with diabetes, family planning vigilance and safer sex practices can prevent reproductive health and metabolic complications (2-4); therefore, early identification of health beliefs that could predict the prevention of unplanned pregnancy and risky sexual behaviors is imperative. Adolescent females with diabetes perceive their risk to be low for unplanned pregnancies and pregnancy related complications (5). However, studies of women with diabetes have shown that up to 75% of pregnancies are unplanned (6, 7), increasing their risks for pregnancy-related and fetal complications (4). The beliefs and attitudes in women with diabetes towards unplanned pregnancy and contraception use have predicted family planning behaviors (7, 8). For example, in women with diabetes, consistent birth control use was associated with positive attitudes and beliefs towards birth control (8), and they were more likely to seek preconception

care to plan a pregnancy when they perceived benefits to themselves and their baby (7). However, perceived barriers towards their ability to conceive resulted in unplanned pregnancies (9). The studies above were only conducted in adult women as cross-sectional or having short data collection periods.

With regard to beliefs and risky sexual behaviors in adolescent with chronic illness, they were as likely as their healthy peers to engage in risky sexual behaviors (10) and have lower rates of contraception use (11). These behaviors can lead to STIs and unplanned pregnancy and in women with diabetes, these conditions could lead to severe reproductive health complications. Yet, adolescent females with diabetes were unaware of their increased risks for pregnancy-related complications and the benefits of tight metabolic control to prevent them (5, 12). They also perceive birth control to be "dangerous" or cause adverse side effects because of their illness (13), which puts them at greater risk for STIs and unplanned pregnancy. Positive attitudes about birth control in adolescent female with diabetes have been shown to be associated with the use of effective family planning and greater self-efficacy was associated with lower barriers to using birth control (14). Beliefs and attitudes of adolescent females with diabetes were influenced by a preconception counseling intervention to enhance knowledge about diabetes and pregnancy, reproductive health complications, and promoted safer sexual practices and contraception (15-17). However, in these studies, the measure of health beliefs, attitudes and behaviors were limited to a short 3 or 9 month post-intervention period. It is not known if these positive adolescent health beliefs could continue into adulthood and influence adult risky sexual behavior. Until now, no studies have examined the prediction of longitudinal health beliefs in women with diabetes.

Theoretical Framework

The Expanded Health Belief Model (EHBM) is the most frequently utilized model to predict health behaviors (18). It theorizes that one's behaviors are influenced by her beliefs regarding health outcomes (19-21). The EHBM guided the intervention and measurements for the adolescent preconception counseling studies (15-17). The EHBM describes six main beliefs (constructs) that influence behavior change: Perceived Susceptibility, Perceived Severity, Perceived Benefits, Perceived Barriers, Cues to Action, and Self-Efficacy (14, 20-22). Perceived susceptibility is a person's perception of acquiring a risk while, perceived severity is the belief of the seriousness of that risk (21). Perceived benefits is one's opinion that a behavior change will decrease their risk, and perceived barriers is the assessment of obstacles that may deter a behavior change (8). Cues to action are events, people, or things that trigger a change in behavior (21). Self-efficacy is the belief or confidence in a person's own ability to perform a behavior that will change an outcomes (23). According to EHBM, when an individual has a high susceptibility and high severity towards having an unplanned pregnancy; high self-efficacy, high perception of benefit and low perception of barriers for getting birth control, there is a high likelihood of effective use of condoms, and low likelihood of risky sexual behavior, STIs and unplanned pregnancy. However, it is not known if there is any carry-over effect of these beliefs during adolescence impact long-term sexual risk-taking behaviors into adulthood. Therefore, the purpose of this study was to determine if adolescent health beliefs (e.g., susceptibility, severity, barriers, and self-efficacy) regarding sexual risk predict long-term sexual risk-taking behaviors, birth control use and STIs in the same cohort of subjects 10-15 years later as adult women. This study combined: 1) original adolescent health belief data, 2) 15 year adult follow-up data of women with diabetes who participated as adolescents

in studies (3, 15-16) using the EHBM, and 3) data from an additional expanded follow-up study that measured sexual risk-taking behaviors, condom use, and STIs as adults.

Methods

Study Subjects

The women in this sample were between the ages of 18 and <45 years of age with type 1 diabetes (T1D) and were participants in a longitudinal cohort follow-up study (hereafter termed the "adult follow-up study"). The subjects were eligible for the recent adult follow-up study if they participated in one of three randomized control trials (RCTs) about preconception counseling (PC) as adolescents (13-20 years of age). These 3 studies have been reported elsewhere (15-17). For the approximate 15 year adult follow-up study conducted from 2010 to 2013, the participants completed bi-annual online questionnaires for 18 months to examine distal outcomes of pregnancy planning behaviors, pregnancy outcomes and metabolic control.

During adolescence, these women received a PC program called *R*eproductive-health *E*ducation and *A*wareness of *D*iabetes in *Y*outh for *G*irls [*READY-Girls*, (24)]. *READY-Girls* (RG) focused on diabetes, pregnancy, family planning, and tight metabolic control, but did not directly target risk-taking behaviors or STIs. The inclusion criteria for the *READY-Girls* RCTs (RG-RCTs) as adolescent patients were <20 years, having T1D for at least 1 year, and fluent in English; exclusion criteria were a history of another chronic illness or mental retardation, or pregnant at the time of recruitment.

Design/Measurements

For this investigation, data at 3-month post-intervention time point on adolescent health beliefs collected were obtained from the previous RG-RCTs and merged with the baseline data from the adult follow-up study. Items on health beliefs from the adolescent studies that were consistent across the RG studies were included. Items/scales chosen were based on adolescent's perceptions of risky sexual activity and constructs from the EHBM (25) and related to the, namely, susceptibility and severity to unplanned pregnancy, barriers to birth control (BC), and self-efficacy for waiting to have sex with birth control. Other constructs were not included in these analyses since these items were not measured consistently across each of the RG-RCTs.

EHBM constructs were measured as: susceptibility was ordinally scaled with response choices ranging 1 to 10 (1 = not at all to 10 = a lot) for the question, "If you had unsafe sex, would you worry that you might get pregnant?" Severity had an ordinal scale, ranging 1 to 10, (1 = not bad at all to 10 = very bad) for the question, "How bad would it be to have these things happen to you: To have an unplanned pregnancy?"

Across all RG studies, one item was consistently used to measure barriers to BC, one item remained consistent across all RG-RCTs. This barriers item also had an ordinal scale, ranging 1 to 10, (1 = not hard at all to 10 = very hard) for the question, "How hard would it be to do these things: To get some type of birth control?' Lastly, self-efficacy had an ordinal scale again ranging 1 to 10 (1 = not sure at all to 10 = very sure) for the question, "How sure are you that you could do these things: To wait to have sex until you have birth control?"

The outcome variables are birth control, condom use, sexual risk behavior, and STIs. *Birth control* data, such as a list of birth control methods, most frequently and currently used methods, were taken from the adult follow-up study at baseline from the same adult subjects for analysis. *Condom use* was listed among the birth control methods. However, items on risk-taking behaviors and STIs were not included in the adult follow-up study. Therefore, an expanded follow-up study using a cross-sectional design was conducted using a self-reported online survey from years 2013 to 2014 to measure the variables of risk-taking behaviors and STIs that were missing from the adult follow-up survey. For the expanded follow-up study, participants were contacted by either email or a mailed letter requesting completion of an additional five minute on-line survey. The survey questions on sexual risk-taking behaviors and STIs items were taken from a questionnaire used in all three *READY-Girls* RCT studies. *Sexual risk behavior and STI* included 7 items and responses were dichotomous (yes/no). The list of items and item descriptives are listed in Table 4 and Table 6. In addition, a *risk behavior score* (RBS) was computed from the summation of the 7 sexual risk-taking behaviors items. Participants responded yes/no (dichotomous variable) to the following items: not using birth control, not frequently using condoms, not currently using condoms, having unprotected sex, having unplanned pregnancy, having more than one sexual partner, and diagnosed with an STI. Descriptives of RBS are provided in Table 5.

Analysis

SPSS for Windows (26) was used to analyze the data. Descriptive and exploratory analyses were conducted to describe all participant characteristics. EHBM constructs, and outcomes were examined to identify any data anomalies (e.g., outliers, missing data, multicollinearity, etc.) that

may invalidate the planned logistic and linear regression analyses. Simple and multiple logistic regression were performed to determine if adolescent health beliefs (e.g., susceptibility, severity, risk perception, barriers, and self-efficacy) measured at 3 months post-intervention data predicted long-term outcomes of sexual risk-taking behaviors, condom use, and STIs as adult women. Women's current age was included as a covariate to evaluate any confounding effects on the adolescent health beliefs. Regression coefficients from logistic regression analyses of binary outcomes (e.g., unprotected sex) were exponentiated to yield odds ratios. Regression coefficients from linear regression analyses were reported as unstandardized coefficients. For both, 95% confidence intervals were obtained. The level of statistical significance was set at $p<.05$.

Results

Only a sample of 39 subjects who had participated in the RG-RCTs were eligible for the five minute online survey from the total sample of 102 of the adult follow-up study. The mean age of the women was 24 years. All the women were white and the majority had some college education. One third of the sample was married and 8 subjects had at least one biological child. As for sexual history, most of the women reported having had sexual intercourse with a mean age of sexual debut at 17.9 years. More than half of the women currently were sexually active and using some type of birth control to prevent pregnancy. See Table 7 for a complete list of demographics.

In regards to health beliefs, as an adolescent, having higher levels of perceived susceptibility to an unplanned pregnancy was associated with being less likely to have unprotected sex (p=.035), unplanned pregnancies (p=.035) and current BC use (p=.031) as an adult woman. Women who reported higher self-efficacy were more likely to use some type of birth control

method (p=.048). In a multiple regression analysis to examine the effects of the constructs in the EHBM on each of the targeted outcomes, the only marginally significant relationship was perceived susceptibility as adolescents with fewer episodes of unprotected sex as adults (p=.051). All of these findings are in the expected direction of the EHBM. However, perceived barriers as adolescents to getting birth control was positively associated with women being less likely to be currently using birth control (p=.031). Although adolescent health beliefs predicted sexual risk behaviors, it did not predict the number of risk-taking behaviors (RBS), condom use or STIs. See Tables 8, 9 and 10 for a complete list of health beliefs.

Conclusion

This study examined whether adolescent health belief constructs including susceptibility, severity, barriers and self-efficacy predicted long-term sexual risk-taking behaviors, birth control use, including condoms, and STIs in the same cohort of adult women with T1D. To our knowledge, this is the first long-term follow-up study to link health beliefs to predict female sexual risk behavior in the same cohort. Overall, our results suggest that some adolescent health beliefs were associated with safer sexual behaviors in adulthood. This is beneficial since health beliefs are alterable and can change risky sexual behavior. Decreasing risky sexual behaviors, such as unprotected sex, and increasing birth control use, can prevent STIs or unplanned pregnancies and complications. The only major constructs of EHBM that appear to be significantly associated in the expected direction with sexual risky behavior was perceived susceptibility; and susceptibility

and self-efficacy were associated with birth control use. Moreover, perceived susceptibility was significant at the simple and multiple regression analyses. Therefore, further exploration of susceptibility through the use of a qualitative method, such as, in-depth interviews, may provide additional insight into these associations. None of the constructs were associated with STIs. As adults, the women in our sample appeared to use some type of birth control, engage in protected sex, and plan their pregnancy, when as an adolescent, they had higher levels of perceived susceptibility to an unplanned pregnancy and greater self-efficacy to using birth control use.

Our results are supported by the literature. We did not find that perceived susceptibility or severity to contracting an STI predicted frequent use of condoms as a birth control method (1). In our study, positive attitudes and higher levels of self-efficacy towards birth control were also associated with currently using some method of birth control (5, 8, 14). However, in our study, susceptibility was a significant predictor of safer sexual behavior which was not found in previous studies (8, 14). Benefit was a strong predictor in both of these studies but was not examined in this study because the items were not consistently measured across the 3 RG-RCTs.

The majority of our results followed the expected direction of the EHBM except for the finding related to barriers. The women in our sample who had low barriers to birth control as adolescents were less likely to currently use some type of contraception. The barriers to accessing contraception for adolescents may be very different from those barriers for adults. This may also be explained in that many women with diabetes believe they may have difficulty conceiving; therefore contraception is not needed (27). Moreover, there may be a carry-over effect from adolescent to adulthood through a misunderstanding that some more effective birth control methods cannot be used in women with diabetes (13).

This study had some limitations; therefore caution should be used with interpretation of the results. Because this was a secondary analysis, most of the data had already been collected and some of the major variables of interest for this paper, namely risky sexual behavior or STIs, were not the focus of the adult follow-up study. The adolescent health belief items focused on unplanned pregnancy or birth control methods, but not specific to condoms. Therefore, the expanded follow-up study was conducted to allow for selection of additional variables of sexual risk-taking behaviors and STIs. However, the follow-up survey only asked about vaginal intercourse and did not include specific items on sexual risk-taking behaviors, such as, engaging in other types of sexual contact (e.g. oral or anal sex) which may result in contracting STIs. These additional items should be included in future studies.

Health beliefs of the adult women with T1D were not collected in either the adult follow-up or expanded follow-up study and could have provided further explanation for our findings. The construct perceived benefit was not measured consistently in the adolescent studies and was not included in these analyses. Therefore, a longitudinal design with repeated measures over time, assessing all of the health beliefs from EHBM, could predict a more accurate relationship among the outcome variables. Also, the inclusion of participants with type 2 diabetes (T2D), using an additional survey or a qualitative method, such as, in-depth interviews, may further provide information on the impact of health beliefs on sexual risk-taking behaviors, condom use and STIs.

The small sample size was another limitation for our study. Some assumptions of the analyses (e.g., multiple regression) were not met, and therefore, the results should be interpreted with caution. A larger sample would help to confirm these findings. Approximately 152 subjects, would be necessary for sufficient power for detection of predictors for a true regression model. In

addition with a larger sample, a path analysis could have been performed to determine if beliefs predicted sexual risk-taking behaviors and in turn these behaviors predicted STIs or unplanned pregnancy.

There are limitations with the EHBM as a framework for this secondary analysis. The EHBM does not incorporate peer influence or emotions which can impact the adolescents' ability to objectively evaluate personal risks in making decisions (1). Due to their cognitive development, adolescents are preoccupied with the immediate consequences of their involvement in risky sexual behavior, therefore, deterring rational decision-making skills on which the EHBM is based. Moreover, this in turn can influence early beliefs, attitudes and behaviors (29).

Also, these women had participated in the preconception intervention studies *READY-Girls* as adolescents. *READY-Girls* targets female adolescents starting at puberty and focuses on the importance of preventing unplanned pregnancies, benefits of tight metabolic control before conception, how to plan a pregnancy that is safe and wanted, effective use of birth control and to decrease risky behaviors related to reproductive health (15). However, *READY-Girls* does not target general sexual risk-taking behaviors, such as multiple partners, or emphasizes using barrier methods, such as condoms, to prevent STIs. And avoiding STIs is important for women in our target population. These women are in a higher risk category, since young adults ages 15–24 years account for nearly half (9.1 million) of new STIs cases each year in the U.S. (30). STIs can have serious health consequences in the general population; and for women with diabetes, it can cause reproductive health complications similar to those associated with uncontrolled blood sugars, such as, preterm labor, miscarriage or birth defects (31).

In conclusion, this is the first longitudinal study of women with diabetes to examine beliefs and sexual behaviors over time in the same cohort. Adolescent health beliefs appear to influence sexual behaviors and birth control into adulthood. Our findings support the need for initiating preconception counseling during adolescence at puberty, prior to sexual debut, as recommended by the American Diabetes Association (2). The use of effective contraceptive methods combined with barrier methods, such as condoms, are important topics to be addressed in all women, particularly in those with diabetes to decrease reproductive health complications, encourage safe and wanted healthy pregnancies, and prevent STIs. Future studies should be conducted with larger sample size and a more diverse population, including T2D, to allow for generalizability and need to target risky behaviors and STIs.

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Table 4. Sexual Risk Behavior, Birth Control Use, and STIs Items

Sexual Risk Behavior	Have you had sex without using birth control, that is, when you're not trying to get pregnant? Have you had more than one sexual partner? Have you had an unplanned pregnancy?
Birth Control Use	Are you using birth control now? Which birth control method(s) are you using most frequently: Condoms? In the last 6 months, which of these did you use to keep from getting pregnant: Condoms?
STIs	Have you ever been told you have a sexually transmitted infection (STI)?

Table 5. Risk Behavior Summation Score (RBS)

Risk Behavior Items (scale 0-7)	M±SD(range) or n(%)
Not using birth control	15(38.5)
Not frequently using condoms	19(48.7)
Not currently using condoms	22(56.4)
Had unprotected sex	18(46.2)
Had an unplanned pregnancy	7(17.9)
>1 sex partner	26(66.7)
STI diagnosis	4(10.3)
Risk Behavior Summation Score	3.0±1.29 (1-6)

Mean, standard deviation and range are reported for the RBS.

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Table 6. Description of Adolescent Health Belief Items

Question (scale 1-10)	M±SD (range)
Susceptibility How much do you worry that you could have an unplanned pregnancy	4.5±3.65 (1-10)
Severity How bad would it be to have an unplanned pregnancy	8.9±1.70 (2.86-10)
Barrier How much of a problem is it for you to get birth control	6.3±3.64 (1-10)
Self-Efficacy How confident are you to delay sex if birth control is not available	9.2±1.33 (4.29-10)

Means, standard deviations and ranges are reported.

Table 7. Characteristics of participants (N=39)

Characteristic	M±SD(min-max) or n(%)
Age (18-33)	24.8±4.43
Age of sexual debut (15-26)	17.9±2.69
Age of 1st date (12-21)	15.3±1.95
Length of diabetes (5-26)	15.3±5.66
Race	
White	39(100)
Marital status (n=28)	
Husband/boyfriend	25(64.1)
Income	
<$40000	8(20.6)
≥$40000	31(79.4)
Education Level	
High School graduate	3(7.7)
Some college	12(30.7)
College graduate	11(28.2)
Some graduate school	2(5.1)
Graduate school completed	9(23.1)
Have biological children	9(23.1)
Currently sexually active	29(74.3)

Table 8. Simple and multiple linear regression of Health Belief Constructs and risk behavior score

Health Belief Constructs	Simple Regression		Multiple Regression	
	Unstandardized Regression Coefficient	p	Unstandardized Regression Coefficient	p
Susceptibility	[a] b = -0.066, 95%CI =(0.582, 1.858)	.252	b = -0.034, 95%CI =(-0.190, 5.340)	.659
Severity	b = 0.102, 95%CI =(-0.148, 0.352)	.415	b = -0.067, 95% CI =(0.831, 1.204)	.512
Barrier	b = 0.073, 95%CI =(-0.042, 0.188)	.206	b = 0.048, 95%CI =(-0.109, 0.205)	.540
Self-Efficacy	b = 0.077, 95%CI =(-0.244, 0.397)	.632	b = 0.044, 95%CI =(-0.292, 0.379)	.793

[a]Unstandardized regression coefficients reported as b=beta and CI=Confidence Interval,
**p<.05*

Table 9. Simple logistic regression of adolescent health beliefs on adult sexual risk behavior, birth control (BC) and sexually transmitted infections (STIs)

Health Belief Construct	Risk Behavior or Outcome						
	Current BC use	Frequent BC use: Condoms	Current BC use: Condoms	Unprotected Sex	Unplanned Pregnancy	>1 sex partner	STI diagnosis
Susceptibility	1.230[a] (.983, 1.53); .031*	1.002 (0.823, 1.221); .981	0.917 (0.770, 1.093); .333	0.787 (0.629, 0.984); .035*	0.741 (0.550, 1.000); .035*	0.941 (0.761, 1.163); .574	0.975 (0.703, 1.353); .882
Severity	1.190 (0.995, 1.430); .057	1.187 (0.778, 1.788); .411	1.030 (0.705, 1.505); .878	1.247 (0.815, 1.908) .309	0.899 (0.749, 1.079) .251	1.055 (0.898, 1.238) .516	1.000 (0.753, 1.340) .980
Barriers	1.291 (1.024, 1.628); .031*	0.737 (0.503, 1.078); .116	0.732 (0.503, 1.066) .104	1.112 (0.781,1.582); .556	1.034 (0.652,1.638); .888	0.817 (0.550, 1.216); .319	1.019 (0.572, 1.816); .948
Self-efficacy	1.203 (1.001, 1.445); .048*	0.516 (0.259,1.028); .060	0.721 (0.423,1.228); .229	1.007 (0.622,1.630); .977	0.893 (0.747, 1.068); .217	0.619 (0.300, 1.276); .194	0.740 (0.389,1.409); .360

[a] Unadjusted or crude odds ratios, 95% CI=confidence interval, p value based on Wald test *p<.05

Table 10. Multiple logistic regression of adolescent health beliefs on adult risk behavior, birth control (BC) use and sexually transmitted infections (STIs)

Health Belief Construct	Current BC use	Frequent BC use: condoms	Current BC use: condoms	Unprotected sex	Unplanned pregnancy	>1 sex partner	STI diagnosis
Susceptibility	0.839[a] (0.645, 1.092); .193	0.924 (0.711, 1.201); .556	0.904 (0.698, 1.172); .447	0.765 (0.585, 1.001); .051*	0.744 (0.513, 1.080); .120	0.784 (0.558, 1.102); .162	0.707 (0.350, 1.431); .335
Severity	1.130 (0.761, 1.679); .545	1.240 (0.758,2.027); .391	1.284 (0.797, 2.068); .305	1.420 (0.809, 2.494) .222	0.786 (0.475, 1.301) .350	2.462 (0.918, 6.602) .073	10.460 (0) .998
Barriers	0.852 (0.648, 1.119); .249	0.846 (0.653, 1.095); .205	0.804 (0.620, 1.044) .101	0.956 (0.744,1.228); .724	0.830 (0.615,1.119); .222	0.769 (0.535, 1.103); .154	1.043 (0.686, 1.584); .844
Self-efficacy	1.159 (0.699, 1.923); .567	0.460 (0.206,1.026); .058	0.668 (0.357,1.250); .207	0.872 (0.500,1.522); .630	1.364 (0.572, 3.251); .491	0.366 (0.092, 1.234); .100	0.359 (0.093,1.384); .137

[a] Adjusted odds ratios , 95% CI=Confidence Interval, p value based on Wald test
*p<.05

8.0 MANUSCRIPT 3: RISK-TAKING BEHAVIORS, CONDOM USE, AND SEXUALLY TRANSMITTED INFECTIONS IN WOMEN WITH TYPE 1 DIABETES

University of Pittsburgh

School of Nursing

3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401

February 23, 2015

Nancy K. Lowe, CNM, PhD, FACNM, FAAN
Editor of JOGNN
University of Colorado Denver
College of Nursing C288-28
13120 East 19th Avenue
Aurora, CO 80045

Dear Dr. Lowe,

I would like to submit a research manuscript for consideration by JOGNN. The manuscript reports on the examination of risk-taking behaviors, condom use, and sexually transmitted infections (STIs) in women with diabetes. The manuscript is approximately 21 double spaced pages [4100 words] in length with references/tables and is in the format stipulated by the Author Guidelines for JOGNN.

Corresponding author: Jennifer Thurheimer PhD, MEd, RN
University of Pittsburgh School of Nursing
440 Victoria Building Health Promotion and Development
3500 Victoria St Pittsburgh PA 15261
jlt92@pitt.edu

Susan M. Sereika, PhD
Professor Health and Community Systems
Director, Center for Research and Evaluation
University of Pittsburgh School of Nursing

Julie Downs, PhD
Associate Professor Social and Decision Sciences
Carnegie Mellon University

Sandra Founds, PhD
Associate Professor Health Promotion and Development
University of Pittsburgh School of Nursing

Denise Charron-Prochownik, PhD, RN, CPNP, FAAN
Professor and Chair, Health Promotion and Development
University of Pittsburgh School of Nursing

The authors have seen and approved this manuscript.

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Please feel free to contact me and I look forward from hearing from you.

Respectfully,

Jennifer Thurheimer, PhD
University of Pittsburgh School of Nursing
jlt92@pitt.edu

Title page:

Risk-Taking Behaviors, Condom Use, and Sexually Transmitted Infections in Women with Type 1 Diabetes

Corresponding author: Jennifer Thurheimer, PhD
University of Pittsburgh School of Nursing
440 Victoria Building Health Promotion and Development
3500 Victoria St Pittsburgh PA 15261
jlt92@pitt.edu

Susan M. Sereika, PhD
Professor Health and Community Systems
Director, Center for Research and Evaluation
University of Pittsburgh School of Nursing

Julie Downs, PhD
Associate Professor Social and Decision Sciences
Carnegie Mellon University

Sandra Founds, PhD
Associate Professor Health Promotion and Development
University of Pittsburgh School of Nursing

Denise Charron-Prochownik, PhD
Professor and Chair, Health Promotion and Development
University of Pittsburgh School of Nursing

Abstract

Objective: To describe the self-reported risk-taking behaviors, condom use and sexually transmitted infections (STIs) in adult women with type 1 diabetes, which confers a higher risk of reproductive health complications

Design: Cross-sectional, descriptive study

Participants and Setting: Convenience sample of 75 adult women from a diabetes registry; some of whom participated in previous preconception counseling (PC) studies as adolescents.

Methods: Online survey to measure risk-taking behaviors (substance use, and unsafe sex), birth control use and STIs.

Results: Mean age was 24.2 years, 92% (n=69) were white, 79% (n=59) had some college, and 64% (n=48) had a husband/boyfriend. Seven percent (n=5) reported >7 alcoholic beverages weekly, 31% (n=23) had passed out from alcohol consumption, and 39% (n=29) had used illicit drugs. Eighty-three percent (n=62) had been sexually active, with a median age of sexual debut of 18.0 years (SE=0.43). Thirty-six percent (n=27) reported having had unprotected sex when not planning a pregnancy. The three most frequently used birth control methods were oral contraceptives (45%), condoms (41%), and withdrawal (23%). Eight percent (n=6) reported having been diagnosed with an STI. Overall, there were no significant differences in the outcome variables for women who participated in the adolescent PC studies.

Conclusions: Some of the participants reported having engaged in some risky behaviors that could interfere with reproductive health and result in STIs or unplanned pregnancies. The episodes of unprotected sex and the use of the withdrawal method were of particular concern. Studies

including a more diverse sample of women with diabetes are necessary to inform future educational interventions to target risky behaviors.

Keywords: reproductive health, diabetes, risk-taking behaviors, birth control methods, STIs

Call-outs

1. Risk-taking behaviors (substance use, unsafe sexual practices) can negatively impact diabetes and lead to additional reproductive health complications.

2. Women with diabetes who are involved in risk-taking behaviors and ineffective contraceptive use could contract STIs or unplanned pregnancies which could lead to reproductive health complications.

3. For all women, especially women with diabetes, preconception counseling is warranted and should begin at puberty prior to sexual debut and include information on risk-taking behaviors

For women, diabetes poses challenges throughout their life particularly in relation to both reproductive and sexual health (Stenhouse, 2012). Women should be made aware of their risks of reproductive health complications and ways to avoid them. Most general preconception counseling (PC) for women discusses family planning, safe sexual practices, contraception, and sexually transmitted infections (STIs) [Williams et al., 2012]. However, diabetes-specific PC for women with diabetes focuses on family planning as well, but also includes information on preparation of pregnancy and the effects of uncontrolled blood sugars and the need for tight glycemic control to decrease complications (Kitzmiller et al., 1996; Nankervis, 1998; Schroeder et al., 2000). However, other topics such as unsafe sexual practices (e.g., unprotected sex and multiple sex partners), risk-taking behaviors (e.g. alcohol, tobacco and illicit drug use) and STIs can interfere with reproductive health and further compound risks for complications in women with diabetes. These topics are not routinely mentioned in PC for women with diabetes.

Risk-taking behaviors, such as substance use and unsafe sexual practices, can negatively impact the management of diabetes. Tobacco users with diabetes and smoke daily are at a 50-75% greater risk for morbidity and mortality (Schwab, Doerfer, Hallermann et al., 2008). Alcohol use causes hypoglycaemia and illicit drugs can cause hyperglycaemia or ketoacidosis (Ng, Darko,& Hillson, 2004). These behaviors, compounded with diabetes, pose a greater threat to the individual's health than by themselves. The consequences of these behaviors are not consistent with diabetes adherence and are likely to divert financial resources away from healthy food, health care, and necessary medical supplies (Frey, Guthrie & Loveland-Cherry, 1997).

With regards to reproductive health, since alcohol and illicit drug use can alter cognition and decision-making, these behaviors have been linked to unprotected sex (Herrick et al., 2011). Unprotected sex can result in STIs. Young adults ages 15–24 years account for nearly half (9.1

million) of the 18.9 million new cases of STIs each year in the U.S. (Weinstock et al., 2004). Women are at an increased risk of contracting an STI compared to men [Center for Disease Control (CDC), 2008]. Many STIs can be asymptomatic in women, delaying diagnosis and treatment. Delayed treatment can lead to irreversible reproductive health issues. Additionally, STIs cause many of the same complications of uncontrolled diabetes (e.g., birth defects such as brain damage, bone/joint deformities, or pre-term labor), thus can compound problems for these women (CDC, 2008). Studies have shown that adolescents with chronic illness are more likely to report ever having an STI when compared to adolescents without chronic illness (Suris et al., 1996; Valencia & Cromer, 2000; Sawyer et al., 2007). However, the incidence of STI cases in women with diabetes is unknown.

Unprotected sex can also lead to an unplanned pregnancy. Up to 70% of diabetic pregnancies are unplanned (Kjaer, 1992; St. James, 1993). With uncontrolled blood sugars, pregnancy-related complications such as preeclampsia, increase the incidence of major congenital malformations and mortality of the infant (Kitzmiller et al., 1996; Pettitt & Jovanovic, 2007). Both maternal and fetal complications can require lengthy, complex, and costly hospitalizations (Herman et al., 1999).

Adolescent females with diabetes perceive their risk to be low for STIs (Weinstock, 2004), unplanned pregnancies and pregnancy related complications (Charron-Prochownik et al., 2006). Whether these beliefs extend into adulthood is yet to be determined. Furthermore, they appear to have lower rates of contraception use and engage in more risk-taking behaviors (Scaramuzza et al., 2010; Chuang, Velott & Weisman, 2010; Fennoy, 1989) increasing their chances for serious health consequences. Perhaps their behaviors are related to beliefs that having a chronic illness will make it more difficult to conceive (Chuang et al., 2010; St. James et al., 1993).

Prevention is key to prevent reproductive health complications. Therefore, providing information on avoiding risky behaviors, using condoms, and STI prevention during preconception counseling for women with diabetes would be beneficial. Information on types of birth control such as abstinence, condoms, and combination methods that provide protection from both STIs and unplanned pregnancies is essential. Studies have shown that regular use of condoms can decrease the risk of STI transmission, specifically HIV, by 69% (Zieman, Barbieri, & Eckler, 2014). Yet, only half of adolescent females with T1D who were sexually active used condoms or other forms of birth control compared to 61% in the general population (Schwartz et al., 2010). However, consistent use of condoms and risk-taking behaviors are less known among adult women with diabetes. Therefore, the purpose of this study was to describe the self-reported risk-taking behaviors, condom use and STIs in women with type 1 diabetes (T1D).

Methods

Descriptive methods were used to report on data taken from two studies with the same cohort of women, both were web-based questionnaires, one was administered every six months for 18 months via an online portal and the other was an expanded follow-up study using a cross-sectional survey. Women in this sample were between the ages of 18 and <45 years of age with T1D. First they were participants in a longitudinal web-based cohort follow-up study, hereafter termed the "adult follow-up study" (Sereika et al., 2014). Subjects for the adult follow-up study were recruited from two groups of women. The first group of women had been eligible for adult follow-up study if they had participated as an adolescent (age: 13-20 years) in one of three randomized controlled trial (RCTs) to receive a PC intervention called *R*eproductive-health *E*ducation and

*A*wareness of *D*iabetes in *Y*outh for *G*irls (*READY-Girls*), hereafter this group is termed FRG. (Charron-Prochownik et al., 2008; Rodgers et al., 2010; Charron-Prochownik et al., 2013). *READY-Girls* focused on diabetes and birth control, but only peripherally mentioned risk-taking behaviors and STIs. All of the participants in the *READY-Girls* studies also received March of Dimes (2015) pamphlets for general PC, which discussed taking folic acid, avoiding tobacco/alcohol/illicit drug use, and getting screened for STIs. Women were eligible for the second (comparison) group, hereafter termed FCG, if they were < 45 years, patients with T1D from an original pediatric diabetes registry at a university-based hospital, and using insulin. Exclusion criteria for the adult follow-up study were non-English speaking, and history of another chronic illness or mental retardation. As mentioned above, the subjects were asked to complete a web-based questionnaire every six months to examine distal outcomes of pregnancy planning behaviors, pregnancy outcomes and metabolic control.

Within the questionnaire for the adult follow-up study, birth control items (e.g., birth control method, type, frequency, consistency) were the same as those included in the adolescent *READY-Girls* RCTs (RG-RCTs), and therefore, were used in these analyses for this paper. However, the items on risk-taking behaviors and STIs in the adolescent RG-RCTs were not included in the adult follow-up study. Therefore, an expanded follow-up study using a cross-sectional design was conducted using a self-reported online survey to measure risk-taking behaviors and STIs as measured in the original RG-RCTs. The survey was brief consisting of 30 items and expected to take no more than 5 minutes to complete. Participants in the adult follow-up study were contacted by either email or a mailed letter requesting completion of the brief self-reported survey.

Risk-taking behaviors consisted of 6 dichotomous items, asking whether the respondent had "ever" smoked cigarettes, drank alcohol, passed out from alcohol, driven while drinking, taken illicit drugs, or had more than one sexual partner. Two additional questions elicited continuous values for the number of cigarettes smoked per day and of drinks consumed per week, for those reporting past smoking or drinking. Twelve dichotomous items on sexual behavior (2 items), birth control use (7 items), and STIs (3 items) are listed in Table 11. The protocol and survey were approved by the university institutional review board.

Descriptive analyses, using frequencies and percentages, were performed on demographic characteristics, risk-taking behaviors, birth control use, and STIs. Only baseline data on birth control use from the adult follow-up study were used in these analyses. In order to examine the age of sexual debut for the entire sample, Kaplan-Meier estimation was used to estimate the medians by censoring the age of sexual debut for those women who were not yet sexually active at the time of the survey. Analysis of variance and chi-square test of independence were conducted to examine whether participating in the *READY-Girls* studies had confounding effects on the outcome variables. For age of sexual debut, Kaplan-Meier estimation and log rank statistics were used for the estimation of medians and the comparison of groups considering the censoring of age of sexual debut for women who were not yet sexually active at the time of the expanded follow-up survey. [To conduct these comparisons, the sample was categorized into three groups: received *READY-Girls* (FRG-I), controls and received *READY-Girls* at the end of the RCTs (FRG-C), and matched comparison of adult women who did not receive *READY-Girls* (FCG)].

Results

A sample of 75 subjects was recruited for the brief online survey from the total sample of 102 of the adult follow-up study. The mean age was 24.2 years (18-33 years) and the majority was white, which is expected with T1D (ADA, 2014). Average duration of diabetes was approximately 15 years. Sixty-four percent of the sample reported having a husband/boyfriend, with 25% (n=19) being married. Twenty-one percent reported having biological children. Most of the participants reported sexual activity, with a median age of sexual debut of 18 years (SE=.043). See Table 12 for a complete list of demographics.

For this group of women with T1D in regard to risk-taking behaviors, a third reported to "ever" smoking cigarettes with a fifth of the sample being current smokers. A third reported having passed out from alcohol consumption, and 5% had driven a car under the influence of alcohol. A third of these women also reported to "ever" using illicit drugs, including marijuana.

Furthermore, out of the 75 subjects, 64% (n=48) were currently sexually active. Half (n=39) were using birth control to avoid a pregnancy, but only 16% chose a BC method to prevent STIs. Despite the 39 subjects who were avoiding pregnancy using birth control, a third reported having had unprotected sex in the past 6 months. See Table 13 for the complete list of risk-taking behaviors.

Regarding birth control methods, the three most frequently used birth control methods and methods currently being used were oral contraceptives, condoms, and withdrawal. See Table 14 for a complete list of BC methods (ordered in descending level of effectiveness). Moreover, 23% reported using a combination method. However, the online survey did not include questions regarding the type of combination methods used, and therefore could not be reported.

For STIs, among the 75 subjects, 6 had "ever" been diagnosed with an STI and 2 had been diagnosed with more than one. Types of STIs are listed in Table 15.

The results of the analyses examining the confounding effects of *READY-Girls* indicated no significant differences among the three groups (FRG-I, FRG-C, and FCG) on any of the outcome variables. Although the item "ever driven drunk" had a p=.05, the expected cell counts were less than 5, and therefore inconclusive. The only two characteristics that were significantly different were mean duration of diabetes in years (FRG-I =17.8, FRG-C=15.8, FCG=12.8, p=.02); and median age of sexual debut in years (FRG-I =19.0, FRG-C=17.0, FCG=18.0, p=.02).

Discussion

This paper described the risk-taking behaviors, condom use, and STIs in women with T1D. Some women in this sample reported having engaged in some risky behaviors that could interfere with reproductive health which could result in STIs or unplanned pregnancy.

In regards to risk-taking behaviors, approximately one fourth of the women currently use tobacco. Although tobacco has harmful effects for anyone, it can cause more serious medical consequences in smokers with diabetes. Smoking interferes with metabolic control by raising blood sugars and can also lead to blood clots, heart disease or stroke for those women on birth control (CDC, 2014). Women with diabetes who smoke and become pregnant are at a greater risk for miscarriages, stillbirths, or premature labor as well (CDC, 2014). As for alcohol use, a glass per day of wine is encouraged for adult women with diabetes to reduce their risk for heart disease (ADA, 2014). Even though most women in the study were low to moderate consumers of alcoholic

beverages, approximately a third of our sample had experienced unconsciousness from over-consumption of alcohol or reported the use of illicit drugs. The harmful effects of alcohol and illicit drug use on metabolic control and diabetes management is well documented (Diabetes Health, 2003). Alcohol causes hypoglycemia by impairing production, storage, and release of glycogen while certain illicit drugs increases liver glycogen metabolism resulting in hyperglycemia (Diabetes Health, 2003). These substances also impair judgment and decision-making. Studies have shown high correlation between substance abuse and unprotected sex, which can result in contracting an STI or an unplanned pregnancy (Townshend, Kambouropoulos et al., 2014).

Although several studies have indicated that females with chronic illness have an earlier sexual debut of approximately 13 years (Alderman, Lauby, & Coupy, 1995; Suris et al., 2004) compared to their healthy peers of 15 years (Mosher & Jones, 2005; Martinez, Copen, & Abma, 2011), our sample had a later sexual debut of 18 years. This discrepancy could be due in part to the women in our sample having received *RGPC* as adolescents. We have previously reported that adolescents who received *RGPC* had a later sexual debut (Sereika et al., 2014). Furthermore, our comparative analyses that examined the confounding effects of *RGPC* on our outcome variables confirmed these findings. The women who received *RGPC* (FRG-I) during adolescence had a later sexual debut of 19.0 years compared to 17.0 years in the control group (FRG-C) and 18.0 years in the adult comparison group (FCG). The FRG-C group also had the opportunity to watch the *READY-Girls* DVD at the end of the RG-RCT study as an adolescent, but many chose not to. They were also given a book to take home at the end of the study, however, these adolescents were never followed to determine whether they actually read the book and received the information (Charron-Prochownik et al., 2006).

The majority of our sample was married or had a boyfriend and was currently sexually active. Most of these women reported using some birth control method, yet 36% reported having had unprotected sex. This statistic is concerning for women with diabetes who are expected to be extra vigilant in family planning. Furthermore, condoms were only used by 41% of the sample. Condoms are the only barrier method of birth control, other than abstinence, that can prevent both STIs and unplanned pregnancies. There are more effective methods of birth control to protect from pregnancy, such as hormonal contraceptives (6-9% failure rate), IUD (.2% failure rate), or barrier methods of diaphragm/cervical cap (12% failure rate), or sponge (12%). However, these barrier methods do not protect from STIs (CDC, 2014). Condoms have an 18% failure rate when used alone, yet can be highly effective in conjunction with another method, such as, spermicide or hormonal birth control (CDC, 2014). However, less than half of the women used condoms or a combination method to decrease their risk for STIs. Furthermore, withdrawal was the third most frequently used for birth control method in our sample. This finding was concerning, given that withdrawal is an ineffective method of birth control and does not protect from STIs (Planned Parenthood, 2014). Moreover, 27 women out of 100 who use the withdrawal method will become pregnant each year (Planned Parenthood, 2014). Women with diabetes should be extra vigilant in family planning to avoid these outcomes (Sereika et al., 2014).

Out of the 75 women in our sample, 8% have been diagnosed with an STI. For women with diabetes, STIs can further compound their risks for reproductive health complications (CDC, 2008).

In summary, some women in our sample reported tobacco, alcohol, and illicit drug use, engaged in episodes of unprotected sex, and although condoms were used as a frequent method, withdrawal was also reported as a frequent form of birth control. Conversely, only a few women

in this sample had had an STI. Consistent with earlier findings *READY-Girls* did not have any confounding effects on any of the outcome variables (Thurheimer et al., 2012).

These findings should be interpreted with limitations. First, the study conducted secondary analysis from the adult follow-up study and could not control for sample recruitment or measures. Also, variables of the adult follow-up study may not meet the objectives or include specific questions required by a secondary analysis. Therefore, the expanded adult study was conducted to allow for selection of additional variables. However, regarding sexual activity, participants were only asked to report engaging in "ever" having vaginal sex. An item should be added to future studies on engaging in unprotected oral sex since over 80% of sexually active youth reported having had oral sex at least once with a partner of the opposite sex, which may result in contracting STIs (American Sexual Health Association, 2015). Second, the sample was convenient and recruited from a university-based hospital in western Pennsylvania limiting generalizability to our findings. The sample was racially homogenous with most being white which reflects the demographics for T1D (ADA, 2014). Inclusion of women with type 2 diabetes (T2D) could expand further studies to include a more diverse sample. Also, our sample size was small, therefore may not be representative of the target population. Third, the survey used the term "ever" in the questions providing little indication of frequency and duration of risk-taking behaviors. Fourth, many of these women had participated in a previous study as adolescents where they had received a preconception counseling program tailored to females with diabetes called *READY-Girls*. *READY-Girls* targets female adolescents starting at puberty and focuses on the importance of preventing unplanned pregnancies, benefits of tight metabolic control before conception, how to plan a pregnancy that is safe and wanted, effective use of birth control and to decrease risky behaviors related to reproductive health (Charron-Prochownik et al., 2006). However, *READY-*

Girls does not target general risk-taking behaviors such as, tobacco, alcohol, illicit drug use or STIs. Future studies should be conducted with larger sample size and a more diverse population to allow for greater generalizability.

Implications for Clinical Practice

This study suggests that some women with diabetes are involved in risk-taking behaviors, and ineffective contraceptive use which can lead to STIs and also unplanned pregnancy. Although these behaviors can impact reproductive health for all women, it can be especially harmful for those who have a chronic illness. It is essential that all women of reproductive age should receive PC to avoid STIs and unplanned pregnancies, including women with diabetes. However, women with diabetes require a special kind of PC to also include the benefits of tight metabolic control to prevent reproductive health complications and plan future pregnancies (Charron-Prochownik et al., 2008). PC should start at puberty, prior to sexual debut as supported by the American Diabetes Association (2014) to decrease the risk for these consequences.

Healthcare providers, especially nurses, nurse practioners and nurse midwives have a unique opportunity to educate adolescent women on the importance of reproductive health and family planning, including delaying sexual debut (e.g., practicing abstinence), using safe sexual practices if sexually active to avoid STIs and unplanned pregnancies, maintaining tight metabolic control, planning a pregnancy when they are ready, and limiting risky behaviors that can be detrimental to their health. Starting at puberty, information in regard to avoiding risk-taking behavior and the prevention of STIs should be included in routine PC for all women with diabetes.

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Table 11 Survey Questions on Risk-taking Behaviors, Condom Use and STIs

Risk-Taking Behaviors	Have you ever smoked cigarettes? If yes, how many per day? Have you ever drunk alcohol? If yes, how many (# glasses or cans) per week? Have you ever passed out from alcohol? Have you ever driven while drinking? Have you ever taken recreational drugs (including marijuana)?
Sexual Behaviors	Have you had more than one sexual partner? Have you ever had vaginal intercourse? In the last 6 months have you had sexual intercourse that was not forced?
Birth Control Use	Have you ever used birth control (BC)? Do you use a single method or a combination of BC methods each time you have sex? Have you had sex without using birth control, that is, when you're not trying to get pregnant? Are you using birth control now? Which birth control method(s) are you using most frequently: condoms? Why do you choose this method?
STIs	Have you ever been told you have a sexually transmitted infection (STI)? Have you had more than one STI diagnosis? Which STI(s) were you diagnosed with?

Table 12. Sample Characteristics of Participants (n=75)

Demographics:	**Mean±S.D (range) or n%**
Age (years)	24.2 ± 4.5 (18-33)
Race: White African American American Indian	 73 (97.3) 1(1.3) 1(1.3)
Education: At least some college	23(30.7)
Age at T1D diagnosis (years)	9.5 ± 5.4 (1-16)
Duration of T1D (years)	14.5 ± 6.5 (0-30)
Relationship Status: Current boyfriend or husband	48 (64)
"Ever" had sex	62(82.8)
Age at sexual debut[a]	18.0 ± 0.4
Currently sexually active	48(64)
Have biological children	22 (31.8)
Private health insurance	52 (69.3)
Income: < $40,000/year ≥ $40,000/year	 19(25.3) 38 (50.6)
Religion: Roman Catholic	32 (42.7)

[a]Means and medians were calculated using event history analysis where women who were not yet sexually active were treated as censored at the time of the expanded follow-up survey.
Point and standard error are reported for means and medians.

Table 13. Description of Risk-taking Behaviors (n=75) and Unsafe Sexual Practices

Risk-Taking Behaviors	**n%**
"Ever" smoking tobacco"	23 (30.7)
"Current" smoker	16 (21.3)
"Ever" drank alcohol	66 (88.0)
"Current" use of alcohol	50 (66.7)
> 7 drinks/week	5 (6.7)
"Ever" passed out from alcohol consumption	23 (30.7)
"Ever" driven while drinking	4 (5.3)
"Ever" illicit drug use	29 (38.7)
Unsafe Sexual Practices	
>1 lifetime sexual partner	48 (64.0)
"Ever" unprotected sex	27 (36.0)
Unprotected sex in last 6 months	10 (13.3)

Table 14. Description of Birth Control (BC) Methods: Current (last 6 months) and Most Frequent

Birth Control (BC) Use	n(%)
"Ever" used BC	54 (72.0)
Currently using BC	40 (53.3)
Using BC to prevent STIs	12 (16.0)
Most frequently used method(s)	
Abstinence	3 (4.0)
IUD	2 (2.7)
Plan "B"	4 (5.3)
Combination	16 (21.3)
Oral contraceptives	34 (45.3)
Condoms	31 (41.3)
Withdrawal	17 (22.7)
Currently using method(s)	
Abstinence	3 (4.0)
IUD	17 (22.7)
Plan "B"	3 (4.0)
Combination	17 (22.7)
Oral contraceptives	28 (37.3)
Condoms	27 (36.0)
Withdrawal	16 (21.3)

Table 15. Description of Sexually Transmitted Infections (STIs), Diagnosis and Type

Adverse Outcomes	**n (%)**
"Ever" diagnosed with an STI	6(8.0)
Types of STIs:	
Gonorrhea	1(1.3)
Human Papillomavirus (HPV)	4(5.3)
Chlamydia	1(1.3)
More than 1 STI diagnosis	2(2.7)

APPENDIX A

[ADDITIONAL SURVEY OF EXPANDED FOLLOW-UP STUDY]

University of Pittsburgh School of Nursing

3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401

October 8, 2013

Dear Participant

You are currently participating in the University of Pittsburgh research study called the **READY-Girls Follow-up Study**. We are requesting that you complete an additional short survey with approximately 10-15 questions through a weblink called REDCap. You will only complete the survey once and will take about 5 minutes to complete. The survey will ask questions about risk taking behavior. Your decision to participate in this study will have no effect on your care at Children's Hospital or any of the UPMC hospitals.

Click on this link below, https://www.ctsiredcap.pitt.edu/redcap/surveys/ , it will take you directly to the survey. Please remember to enter your 3 digit username (subject ID) which is the three numbers you have been using for the current study. You can take this survey at any time. Please try to answer all the questions. Upon completion of this additional survey, we will reimburse you $10 by gift card for your participation. We appreciate your contribution to this study. Please contact Jennifer Thurheimer MSN, MEd, BSN with any questions at jlt92@pitt.edu.

Thank you for your continued participation in our main follow-up study and we hope you'll consider completing the short survey as well. By taking part of these studies, you are assisting our research team to help women with diabetes have healthier lives, pregnancies and babies.

Sincerely,

The READY-Girls Research Team

Please read the following questions and write your answer in the spaces provided or answer yes or no:

Behaviors:

Sexual Activity

1. How old were you when you had your first menstrual period? ____years
2. At what age, if at all, did you have your first date, or begin going out with someone?_____years
3. Have you voluntarily had vaginal sex (intercourse; "gone all the way") with someone of the a)opposite sex ___yes no___
   b)same sex ___yes no___

Have you ever had any other sexual contact? ____yes no_____

If yes:

3a) how old were you when you first voluntarily had vaginal sex____years

3b) The first time you had voluntarily vaginal sex, did you use any method of birth control?____yes no_____

If yes:

3c) what method(s) did you use the first time you had sex?_____

3d) Have you ever been told you have a sexually transmitted infection(STI)? ____yes no_____

If yes:

3e) what age were you when you were first diagnosed with a STI(s)? _____years

If yes:

3f) Have you had more than 1 STI diagnosis and at what ages (years)?

3g) Which STI(s) were you diagnosed with:

1. AIDS __yes
2. Gonnorhea ___yes
3. Syphillis ___yes
4. Genital warts/human papillomavirus (HPV) __yes
5. Herpes simplex virus (HSV) ___yes
6. Chlamydia ___yes
7. Other; please list: _____

Please read the following questions and answer yes or no:

Risk Profile

Have you ever…..

4. Brushed your teeth daily? ____yes no____
5. Flossed teeth at least every other day? ____yes no____
6. Done self breast exam at least every other month? ____yes no_____
7. Had more than 1 sexual partner? ____yes no_____

   If yes:

   7a) total number of partners _____

8. Smoked cigarettes? ____yes no_____

   If yes:

   8a) how many per day? _____

9. Drunk alcohol? ____yes no_____

   If yes:

   9a) how many per week (# of glasses or cans) _____

9b) have you ever passed out from alcohol? _____yes no____

9c) do you drive while drinking? ____yes no____

10) taken recreational/street drugs (including marijuana)? ___yes no____

11) exercised regularly? ____yes no___

12)maintained a balanced diet? ____yes no____

13)wear seatbelts? ____yes no____

14)have a tattoo(s)? ____yes no____

15) Body pierced in place(s) other than your ears? ____yes no____

APPENDIX B

[IRB SECONDARY ANALYSIS]

Memorandum

University of Pittsburgh

Institutional Review Board

To: Jennifer Thurheimer

From: Christopher Ryan, Ph.D.,

Vice Chair Date: 11/15/2014

IRB#: PR014010121

Subject: Effects of Preconception Counseling (PC) on Risk-Taking Behaviors, Condom Use, and Sexually Transmitted Infections (STIs) in Adolescent Females with Diabetes

The above-referenced protocol has been reviewed by the University of Pittsburgh Institutional Review Board. Based on the information provided to the IRB, this project includes no involvement of human subjects, according to the federal regulations [§45 CFR 46.102(f)]. That is, the investigator conducting research will not obtain information about research subjects via an interaction with them, nor will the investigator obtain identifiable private information. Should that situation change, the investigator must notify the IRB immediately.

Given this determination, you may now begin your project.

Please note the following information:

- If any modifications are made to this project, use the "Send Comments to **IRB** Staff' process from the project workspace to request a review to ensure it continues to meet the determination.
- Upon completion of your project, be sure to finalize the project by submitting a "Study Completed" report from the project workspace.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX C

[IRB EXPANDED FOLLOW-UP STUDY]

Memorandum

University of Pittsburgh

Institutional Review Board

To:DeniseCharron Prochownik

From:Christopher Ryan , Vice

Chair Date: 8/28/2013

IRB#: RENI3080180 /PR010120019

Subject: Long term effects of receiving preconception counseling in early adolescence

Your renewal for the above referenced research study has received expedited review and approval from the Institutional Review Board under:
45 CFR 46.110.(2)(a) blood sample-
nonpregnant adult 45 CFR 46.110.(5) clinical
data
45 CFR 46.110.(7) characteristics/behaviors
Please note the following
information:
Approval
Date: 8/28/213
Expiration Date: 9/26/2014

Please note that it is the investigator's responsibility to repmt to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events.. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month** prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute

APPENDIX D

[SPECIFIC AIM 2A RESULTS]

Specific Aim 2a

Is there a difference as adults (in the adolescent cohorts of READY-Girl subjects) between the intervention group [FRG-I] (n =19) and the control group [FRG-C] (n =13) on adult risk-taking behaviors, condom use, and STIs?

Table 16. Characteristics of Follow-up READY-Girls (FRG-I) vs. Follow-up Control (FRG-C)

Characteristic	FRG-I (n=19)	FRG-C (n=13)	Test Statistic	p
M±SD(min-max)			t	
Age (18-33)	26.5±2.70	26.1±2.40	.484	.632
Age of sexual debut (14-26)	19.2±2.82	16.8±1.60	2.75	.010**
Age of 1st date (12-22)	15.8±2.15	14.1±1.90	2.61	.014**
Length of diabetes (0-30)	17.8±5.26	15.8±4.13	1.37	.181
n(%)				
Race (n=28)				
White	17(100)	11(100)		
Marital status (n=28)				
Husband/boyfriend	14(82.4)	10(90.9)		.482
Income (n=28)				
<$40000	7(41.2)	6(54.5)		.104
≥$40000	13(76.4)	5(45.5)		
Education Level (n=28)				
High School graduate	0	2(18.2)		.101
Some college	0	3(27.3)		
College graduate	9(52.9)	3(27.3)		
Some graduate school	2(11.7)	0		
Graduate school completed	6(35.3)	3(27.3)		

*t-statistics reported, **p<.05*

Table 17. Risk-Taking Behaviors and STIs between Follow-up READY-Girls (FRG-I) and Follow-up Control groups (FRG-C)

Behavior Outcome n(%)	FRG-I (n=19)	FRG-C (n=13)	p
Sexual Behavior			
"Ever" had sex	18(94.7)	13(100.0)	.594
Currently sexually active	15(78.9)	11(84.6)	.360
"Ever" unprotected sex	12(63.2)	4(30.7)	.114
>1 sex partner	10(52.6)	11(84.6)	.205
Diagnosed with an STI	3(15.8)	0	.195
Substance Use			
"Ever" smoked cigarettes	6(31.6)	7(53.8)	.186
Current smoker	4(21.1)	4(30.8)	.424
"Ever" used alcohol	18(94.7)	11(84.6)	.356
>4 drinks/wk	7(36.8)	1(7.7)	.143
"Ever" passed out from drinking	7(36.9)	4(30.8)	.604
"Ever" driven while drinking	2(10.5)	2(15.4)	.493
"Ever" used illicit drugs	7(36.8)	6(46.2)	.435

***p<.05*

Table 18. Birth Control Use, Current and Frequent Methods Between Follow-up READY-Girls (FRG-I) and Follow-up Control groups (FRG-C)

Birth Control (BC) n%	FRG-I (n=17)	FRG-C (n=11)	*p*
Currently using BC	11 (64.8)	10 (90.9)	.189
Most frequently used methods(s)			
Oral contraceptives	13 (76.5)	7 (63.6)	.376
Condoms	8 (47.1)	7 (63.6)	.320
Withdrawal	5 (29.4)	3 (27.3)	.624
Currently used method(s) (n=26)			
Oral contraceptives	10 (66.7)	7 (63.6)	.598
Condoms	5 (33.3)	8 (72.7)	.055
Withdrawal	4 (26.7)	3 (27.3)	.655
Combination BC	4 (26.7)	1 (9.1)	.245
Reason for using BC			
Protection from STIs	1 (5.9)	3 (27.3)	.153

***p<.05*

APPENDIX E

[SPECIFIC AIM 3B RESULTS]

Specific Aim 3b

What is the consistency of self-report regarding risk-taking behaviors items from adolescence to adulthood?

Table 19. Comparing Risk-Taking Behaviors Responses Over Time

Behavior/Outcome	Number of Same Responses	Observed Percentage	95%CI (Lower Limit, Upper Limit)
"Ever" smoked cigarettes (n=5)	2	40	-27.9, 107.9
"Ever" drank alcohol (n=12)	10	83	59.7, 106.3
"Ever" used illicit drugs (n=2)	2	100	-
"Ever" had sex (n=8)	8	100	-
"Ever" used birth control (n=7)	6	86	58.2, 113.8
"Ever" had unprotected sex (n=2)	2	100	-
>1 sex partner (n=5)	5	100	-
	Adolescent Response M±SD	**Adult Response M±SD**	**Difference M±SD; CI**
Age of sexual debut in years (n=7)	15.9±1.46	16.0±0.82	-0.14±1.35; -1.39, 1.10
Age of 1st date/boyfriend in years (n=27)	14.8±1.02	14.4±1.19	0.30±1.10; -0.14, 0.74

Means, standard deviations, and confidence intervals reported.

APPENDIX F

[ADDITIONAL ANALYSES]

Table 20. Correlations of Risk-Taking Behaviors of Adult Women with Diabetes

Correlations[c]

		Have you ever been told you have a sexually transmitted infection (STI)?	Have you voluntarily had vaginal sex (intercourse; gone all the way) with someone of the opposite sex?	Have you ever had sex without using birth control?	In your life, have you ever tried to get pregnant?	risksumscore	etohwk3	Have you ever: Taken recreational/street drugs (including marijuana)?	How many biological children do you have?
Have you ever been told you have a sexually transmitted infection (STI)?	Pearson Correlation	1	.042	-.271*	-.047	.165	.151	-.012	.092
	Sig. (2-tailed)		.717	.018	.687	.154	.193	.919	.428
	Sum of Squares and Cross-products	7.934	.118	-4.211	-.421	6.276	1.632	-.145	1.855
	Covariance	.106	.002	-.056	-.006	.084	.022	-.002	.025
Have you voluntarily had vaginal sex (intercourse; gone all the way) with someone of the opposite sex?	Pearson Correlation	.042	1	-.077	.050	.097	.069	.107	.065
	Sig. (2-tailed)	.717		.510	.668	.404	.554	.359	.577
	Sum of Squares and Cross-products	.118	.987	-.421	.158	1.303	.263	.461	.461
	Covariance	.002	.013	-.006	.002	.017	.004	.006	.006
Have you ever had sex without using birth control?	Pearson Correlation	-.271*	-.077	1	.288*	-.018	-.263*	.031	-.108
	Sig. (2-tailed)	.018	.510		.012	.880	.022	.792	.352
	Sum of Squares and Cross-products	-4.211	-.421	30.526	5.053	-1.316	-5.579	.737	-4.263
	Covariance	-.056	-.006	.407	.067	-.018	-.074	.010	-.057
In your life, have you ever tried to get pregnant?	Pearson Correlation	-.047	.050	.288*	1	-.155	-.013	-.255*	.418**
	Sig. (2-tailed)	.687	.668	.012		.182	.912	.026	.000
	Sum of Squares and Cross-products	-.421	.158	5.053	10.105	-6.632	-.158	-3.526	9.474
	Covariance	-.006	.002	.067	.135	-.088	-.002	-.047	.126
risksumscore	Pearson Correlation	.165	.097	-.018	-.155	1	.192	.723**	-.058
	Sig. (2-tailed)	.154	.404	.880	.182		.097	.000	.618
	Sum of Squares and Cross-products	6.276	1.303	-1.316	-6.632	182.039	9.947	42.408	-5.592
	Covariance	.084	.017	-.018	-.088	2.427	.133	.565	-.075
etohwk3	Pearson Correlation	.151	.069	-.263*	-.013	.192	1	.107	.102
	Sig. (2-tailed)	.193	.554	.022	.912	.097		.356	.381
	Sum of Squares and Cross-products	1.632	.263	-5.579	-.158	9.947	14.737	1.789	2.789
	Covariance	.022	.004	-.074	-.002	.133	.196	.024	.037
Have you ever: Taken recreational/street drugs (including marijuana)?	Pearson Correlation	-.012	.107	.031	-.255*	.723**	.107	1	-.165
	Sig. (2-tailed)	.919	.359	.792	.026	.000	.356		.154
	Sum of Squares and Cross-products	-.145	.461	.737	-3.526	42.408	1.789	18.882	-5.118
	Covariance	-.002	.006	.010	-.047	.565	.024	.252	-.068
How many biological children do you have?	Pearson Correlation	.092	.065	-.108	.418**	-.058	.102	-.165	1
	Sig. (2-tailed)	.428	.577	.352	.000	.618	.381	.154	
	Sum of Squares and Cross-products	1.855	.461	-4.263	9.474	-5.592	2.789	-5.118	50.882
	Covariance	.025	.006	-.057	.126	-.075	.037	-.068	.678

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

c. Listwise N=76

Table 21. Associations of Risk-Taking Behaviors in Women with Diabetes

Behavior	"Ever" had an STI	"Ever" had sex	Unprotected sex	>1 sex partner	"Ever" smoked cigarettes	Current smoker	"Ever" drank alcohol	Currently use alcohol	"Ever" used illicit drugs
"Ever" had an STI	0	6(100) .31	5(83.3) .07	5(83.3) .59	3(13) .26	2(33.3) .56	6(100) .45	2(33.3) .64	2(33.3) .58
"Ever" had sex	6(100) .31	0	32(100) .01*	45(72.6) .01*	23(37.1) .01*	16(21.3) .03*	57(86.4) .04*	18(85.7) .07	29(100) .01*
Unprotected sex	5(83.3) .07	32(100) .01*	0	22(53.7) .02*	13(40.6) .04*	9(28.1) .12	30(98.8) .79	30(93.8) .79	13(40.6) .50
>1 sex partner	5(83.3) .59	45(72.6) .01*	22(53.7) .02*	0	19(42.2) .01*	15(33.3) .01*	40(88.9) .43	13(28.9) .61	20(44.4) .01*
"Ever" smoked cigarettes	3(13) .26	23(37.1) .01*	13(40.6) .04*	19(42.2) .00*	0	16(69.9) .01*	22(95.7) .17	7(30.4) .40	18(78.3) .01*
Current smoker	2(33.3) .56	16(21.3) .03*	9(28.1) .12	15(33.3) .01*	16(69.9) .01*	0	15(93.8) .36	6(37.5) .46	11(68.8) .01*
"Ever" drank alcohol	6(100) .45	57(86.4) .04*	30(93.8) .57	40(88.9) .43	22(95.7) .17	15(93.8) .36	0	21(31.8) .00*	28(42.4) .07
Currently use alcohol	2(33.3) .64	18(85.7) .07	30(93.8) .79	13(28.9) .61	7(30.4) .40	6(37.5) .46	21(31.8) .00*	0	10(34.5) .16
"Ever" used illicit drugs	2(33.3) .58	29(100) .01*	13(40.6) .50	20(44.4) .01*	18(78.3) .01*	11(68.8) .01*	28(42.4) .07	10(34.5) .16	0

**p<.05*

Table 22. Characteristics of READY-Girls (FRG-I), Control (FRG-C), and Comparison Group (FCG)

Demographics	FRG-I (n=17) M±SD or n(%)	FRG-C (n=11) M±SD or n(%)	FCG (n=40) M±SD or n(%)	*p*
Age in years	26.5±4.26	26.1±2.4	22.6±4.3	.62
Race: Caucasian African American	17(100.0)	11(100.0)	39(97.5) 1 (2.5)	.69
Education Level: some college/college graduate	10(58.8)	6(54.5)	24(60.0)	.13
Duration of diabetes in years	17.8±5.3	15.8±4.1	12.8±7.0	.02*
Marital status: husband/boyfriend	14(82.4)	10(90.9)	24(60.0)	.07
Age of sexual debut	19.2±2.8	16.8±1.6	17.5±2.5	.02*
Insurance: Private	17(100)	7(63.6)	29(72.5)	.63
Income: >$40000	8(47.1)	4(36.4)	20(50.0)	.42
Have biological children	4(23.5)	2(18.2)	8(20.0)	.92
Sexually Active	15(88.2)	11(100)	22(55.0)	.52

**Significance at p*<.05

Table 23. Comparisons of Risk-Taking Behaviors, STIs, and Unplanned Pregnancy in READY-Girls (FRG-I), Control (FRG-C), and Comparison Group (FCG)

Risk Behaviors	FRG-I (n=19) n(%)	FRG-C (n=13) n(%)	FCG (n=43) n(%)	*p*
"Ever" smoked cigarettes Current Smoker	6(31.6) 4(21.1)	7(53.8) 4(30.8)	10(23.3) 8(18.6)	.11 .22
"Ever" drank alcohol Current alcohol use "Ever" driven drunk "Ever" passed out from alcohol	18(94.7) 7(36.8) 2(10.5) 7(36.8)	11(84.6) 9(69.2) 2(15.3) 4(30.1)	37(86.1) 13(30.2) 0 12(27.9)	.57 .37 .05* .89
"Ever" used illicit drugs	7(36.8)	6(46.2)	16(37.2)	.83
Unprotected sex	10(52.6)	4(30.1)	13(30.2)	.43
>1 sex partner	11(57.9)	12(92.3)	25(58.1)	.07
"Ever" had an STI	3(15.8)	0	3(6.9)	.25
>1 STI	1(5.2)	0	1(23.3)	.08
Unplanned pregnancy	4(21.1)	1(7.6)	4(9.3)	.55

**Significance at p<.05*

Table 24. Comparisons of Birth Control Methods in READY-Girls (FRG-I), Control (FRG-C), and Comparison Group (FCG)

Birth Control (BC)	FRG-I (n=17) n(%)	FRG-C (n=11) n(%)	FCG (n=27) n(%)	*p*
Currently using BC	13(76.9)	7(63.6)	19(72.2)	.39
Type of BC:				
Abstinence	0	0	2(7.4)	.34
Oral Contraceptives	13(76.5)	7(63.6)	14(51.9)	.26
Condoms	8(47.1)	7(63.6)	16(59.3)	.63
Plan B	2(11.1)	0	2(7.4)	.50
Withdrawal	5(29.4)	3(27.3)	9(33.3)	.92
Use BC to prevent STIs	1(5.9)	3(27.3)	8(29.6)	.16
Use combination BC	4/14(28.6)	1/11(9.1)	11/22(50)	.06
Most Frequent BC used:				
Abstinence	0	0	3/25(12)	.19
Oral Contraceptives	10/15(66.7)	7/11(63.6)	11/25(44)	.31
Condoms	5/15(33.3)	8/11(72.7)	14/25(56)	.13
Plan B	1/15(6.7)	0	2/25(8)	.64
Withdrawal	4/15(26.7)	3/11(27.3)	9/25(36)	.78

**Significance at p<.05*

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