

Title: Improving Health Communication during the Transition from Pediatric to Adult Diabetes Care

Funding: American Diabetes Association Pathway to Stop Diabetes Accelerator Award (1-18-ACE-27)

Clinicaltrials.gov ID: NCT03734107

Date of Document Submission: 3/27/2026

Last Finalized/Approved: 3/12/2024

1. Background and Specific Aims

Late adolescents and young adults (AYAs; ages 17-23) with type 1 diabetes (T1D) are at risk for significant acute and chronic complications directly related to their diabetes management, initiating a costly and potentially dangerous trajectory of suboptimal health that continues well into adulthood.¹⁻³ Inadequate self-care is the most consistent predictor of worsening glycemic control and related complications in this age group, particularly as youth assume independent responsibility for diabetes care and prepare for adulthood.^{4,5}

Effective communication with health care providers (HCPs) is a critical component of self-care skills in AYAs with T1D, serving as one indicator of readiness for adulthood and adult medical care.⁶⁻⁹ HCPs are typically targeted in communication interventions, yet communication is transactional and adolescents eventually must transition to an adult HCP. Research has demonstrated that patient participation in medical visits can be improved and is related to higher quality communication from HCPs, improved patient self-care, and better health outcomes.¹⁰⁻¹⁴ However, few interventions have targeted the patient communication skills necessary to effectively engage in health interactions, including effective planning, organization, disclosure of information, and collaborative data sharing.^{15,16} Enhancing AYA health communication skills prior to entrance into adult care may hasten the development of key self-advocacy skills needed for successful T1D management in adulthood.

A randomized trial of our well formulated intervention is critical prior to implementation and dissemination of this intervention in clinical care. We propose a rigorous mixed-methods randomized clinical trial (RCT) examining a multicomponent intervention to promote T1D self-care and glycemic outcomes in AYAs, targeting T1D-specific health communication skills. Our preliminary data suggest that in routine T1D visits, HCP talk exceeds AYA talk at a nearly 3:1 ratio and AYAs desire increased opportunity to discuss risky behaviors and receive anticipatory guidance related to T1D care in adulthood.^{17,18} Adapting existing communication interventions for youth and adults with chronic illness,^{11,15,19} we propose a brief, developmentally-appropriate behavioral intervention delivered to AYAs with T1D and supported by tailored text messaging and open-source, freely accessible glucose downloading software. PREP-DC (**P**lan, **R**eflect, and **E**ngage with **P**roviders for **D**iabetes **C**are) aims to augment AYA skills in three specific areas: 1) planning for clinic visits; 2) disclosing information and asking questions; and 3) utilizing and communicating glucose data. Intervention development is guided by Social Cognitive Theory (SCT), which addresses psychosocial factors and motivations influencing health behaviors and methods to promote sustained, translatable behavior change.²⁰

We will recruit 120 AYAs ages 17-23 to participate in the PREP-DC intervention. Assessments will be conducted pre-intervention, immediately post-intervention, and post-transfer to adult medical care for this RCT. In addition, participating AYAs and HCPs will participate in qualitative interviews to guide future iterations of the PREP-DC program. Results will support a multi-site pragmatic R01-level application designed to evaluate PREP-DC in the real world setting. Specific aims are:

Aim 1. *Determine initial efficacy of PREP-DC, an innovative intervention to promote communication skills in AYAs with T1D.* 120 AYAs with T1D and associated HCPs will be recruited for participation. Up to 20 participants will complete a pilot of this intervention. 100 AYAs with T1D will be randomized to intervention (n=50) or standard care (n=50). Assessments will be conducted pre-intervention, 4 months post-baseline (immediately after intervention), and after transfer to adult medical care (expected to be ~8 months post-baseline).

Hypothesis 1.1: The intervention will be associated with high feasibility (e.g. ≥80% retention) and acceptability (e.g. ≥80% rating high satisfaction).

Hypothesis 1.2: In comparison to standard care at the first follow-up period (~4 months post-baseline), AYAs in the intervention group will evidence: 1) higher quality health communication (e.g. higher rated engagement, more questions, more disclosure); 2) better T1D self-care (better adherence, higher transition readiness).

Hypothesis 1.3: In comparison to standard care at the second follow-up period (~8 months post-baseline; post-transfer to adult diabetes care), AYAs in the intervention will evidence: 1) better glycemic control (lower A1c; lower mean glucose level); 2) shorter gap in time between the last visit in pediatric diabetes care and the first visit in adult diabetes care; 3) better T1D self-care (better adherence); 4) fewer reported complications (e.g. emergency department visits; missed school/work days).

Aim 2. *Obtain AYA and HCP feedback on PREP-DC and identify potential moderators of the PREP-DC intervention in preparation for integration into clinical practice.* Participants (20 AYAs and associated HCPs) will participate in interviews regarding satisfaction with and utility of the PREP-DC program. Interviews will be coded for thematic content to evaluate program satisfaction and potential modifications for future versions of

PREP-DC. We will examine potential moderators of intervention impact (e.g., HCP communication quality, executive function, self-efficacy) to further evaluate PREP-DC and potential components that could be augmented in a multisite trial to improve T1D self-care and reduce complications during this crucial period of development.

Results from this study will have public health implications for supporting AYAs as they transition to independent care, a specific area of interest of the Clinical and Translational Science Institute at Children's National (CTSI-CN). PREP-DC has the potential to equip AYAs with the communication skills necessary to promote optimal self-care and navigate the adult health care system, initiating a successful trajectory of engagement with adult diabetes HCPs.

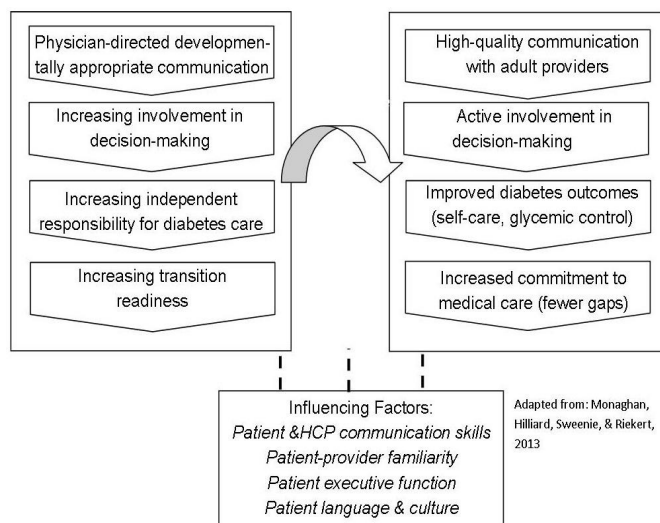
2. Significance

Glycemic Control and Adherence Deteriorate across Adolescence. Type 1 diabetes (T1D) is a common chronic illness, affecting 1 in every 500 youth under age 20.²¹ Adolescents and young adults (AYAs; ages 17-23) with T1D are at risk for poor glycemic control.²²⁻²⁵ Registry studies suggest as few as 9-14% of AYAs ages 15-24 meet standard recommendations for glycemic control (e.g., A1c<7.5%),^{26,27} and nearly 50% experience T1D-related acute and chronic complications.^{2,23,28} Youth who are not engaged with the health care system are at highest risk for poor glycemic control.^{29,30} *To improve health in this vulnerable group, behaviors that contribute to glycemic control and engagement in health care, including content and quality of communication with health care providers (HCPs), must be targeted.*

Health Communication is a Critical T1D Self-Care Skill. Although physiologic factors contribute to suboptimal glycemic control during adolescence,³¹ decrements in glycemic control are largely driven by decreased self-care behaviors.^{5,32,33} Self-care refers to a set of skilled behaviors to manage one's illness, including interacting with HCPs, self-monitoring, adhering to treatment regimens, preventing complications, and managing disease effects on daily functioning.³⁴ Comprehensive models predicting disease self-care behaviors identify effective communication with HCPs as a novel target to improve self-care,³⁵⁻³⁷ with high quality communication with HCPs improving motivation for health, related disease self-care, and more distal outcomes.^{16,38} Effective patient-HCP communication predicts increased adherence to disease care regimens,^{12,39,40} with meta-analytic data finding a 19% higher risk of nonadherence when health communication is poor.³⁹ Communication is not one-sided and the patient contribution to health care interactions is essential to consider.^{13,41} Increased patient participation, disclosure, problem solving, and positive affect leads to improved self-care and better health outcomes in adults with chronic illness.^{12,42-46} One adult study found that patients initiated 84% of active participation behaviors in medical visits and, in turn, greater patient participation elicited higher quality HCP communication.¹³ Communication skills may be particularly important for AYAs who are preparing for adulthood and adult medical care.^{6,47} *Enhancing the self-care dimension of communication can lead to improved health outcomes.*^{12,48-51} *This has not been evaluated in AYA patients with T1D, a prime target for intervention given their developing skills related to communication and managing the health care system.*

AYA Health Communication Skills are Underdeveloped. National policy statements on transition from pediatric to adult medical care, including the American Academy of Pediatrics' Clinical Report,⁸ highlight health communication skills as a critical component of transition readiness.⁵²⁻⁵⁴ Yet, little attention has been paid to the promotion of AYA health communication skills – including planning/preparation and information disclosure – and their resulting impact on the development of effective, life-long self-care skills.^{7,55} Patient difficulty with communication is viewed by HCPs as a significant barrier to successful transition to adult care.^{9,56,57} Further, AYA “ownership of care” is a determinant of expected success in adult medical care.⁹ A recent study with AYA patients with irritable bowel disease (IBD) found that self-care skills generally improve with age; however, communication with HCPs, including answering and asking questions during medical visits, did not improve.⁵⁸ Our research has found that HCP talk outnumbers AYA talk 3 utterances: 1 utterance, and engagement in risk behaviors that may directly impact T1D care and glycemic control is not consistently disclosed.¹⁸

Figure 1: Patient-HCP Interactions during the AYA Period



Planning is a key component of executive functioning, and this cognitive capacity is related to glycemic control in youth with diabetes.^{59,60} Applying planning skills to medical visit preparation and identification of discussion topics may facilitate AYA-HCP communication, yet few AYAs routinely do this.^{61,62} AYAs report difficulty disclosing information to HCPs, including risky behavior and adherence barriers.^{63,64} For example, a recent sexual health survey found that only 60% of sexually active adolescents consistently disclosed this information to their primary care provider.⁶⁵ These communication skills are important intervention targets during the AYA period: improvements may lead to increased engagement with and success in adult medical care (Figure 1).⁶ *Enhancing AYA communication skills is an understudied mechanism that may lead to improved T1D outcomes during the vulnerable period before entering adult health care.*⁶⁶⁻⁶⁸ *We are missing a unique opportunity to positively impact AYA self-care.*

Health Communication is Amenable to Change. Promotion of effective communication skills may have a direct impact on health care interactions and later health behavior. Recent research has recognized the limitations of only training HCPs when targeting communication, and is, therefore, shifting to intervene upon patient communication skills. Porter et al. developed and piloted the COPE intervention, an online program to improve how oncology patients communicate emotional concerns with HCPs. Patient satisfaction with the intervention was high, and nearly half of participants felt that the intervention was very likely to improve how they talked with their oncologists.¹⁵ A coaching intervention targeting pain in cancer patients resulted in increased pain disclosure and, through better tailoring of treatment regimen, a decrease in pain symptoms (adjusted OR = 2.61).⁶⁹ Additionally, priming adolescents with a mental health screener prior to a primary care visit increased adolescent disclosure of mental health symptoms.⁷⁰ *Emerging research suggests that patient communication skills can be improved, resulting in improved patient and HCP health communication and care.*^{14,71}

Health Communication Training Targets. AYA-focused communication training is informed by existing communication interventions^{15,72} and preliminary data on health communication in AYAs with T1D [see preliminary studies]. The current intervention will be designed to augment AYA skills in three specific areas: 1) planning for clinic visits; 2) disclosing information and asking questions to HCPs; and 3) utilizing and communicating glucose data. The intervention is designed to provide concrete, supportive steps to enhance communication. Intervention development is guided by Social Cognitive Theory (SCT), which addresses psychosocial factors and motivations influencing health behaviors and methods to promote sustained behavior change.²⁰ Core elements of SCT relevant to this intervention include knowledge of health and communication behaviors, perceived communication self-efficacy, outcome expectations including the belief that information disclosure will result in better T1D care, goal setting, and identifying facilitators of change (e.g., parent support). SCT has successfully informed intervention development for youth with T1D and their caregivers.^{73,74}

In summary, communicating with HCPs and disclosing health needs are necessary skills for adulthood and may directly result in improved T1D care and glycemic outcomes. Yet no interventions have directly targeted these skills in AYAs with T1D.⁷ Equipping AYAs with specific skills to optimize communication in health care settings has the potential to improve communication and preclude declines in self-care. The evaluation of a targeted communication intervention for AYAs with T1D is warranted.

3. Innovation

This proposed study is innovative because it: (1) targets *patient* health communication in an understudied population of AYAs with T1D; (2) incorporates quantitative and qualitative evaluation of a novel intervention; and (3) utilizes cutting-edge technologies to deliver the intervention and effect behavior change.

This study addresses the practical problem of deterioration in self-care in AYAs with an in-depth examination of a central skill encompassed in self-care. AYAs are an innovative yet logical target for communication skills training, as communication expectations increase with age – yet communication skills do not increase as linearly – and these patients are preparing to enter a strikingly different adult health care system.^{57,75,76}

Research also suggests that pediatric HCPs demonstrate relatively high usage of patient-centered communication techniques, reinforcing our target of AYA communication rather than HCP communication.^{43,77}

This study proposes AYA communication as a mechanism to positively impact T1D adherence and glycemic control. Multi-informant quantitative and qualitative data will be collected and evaluated to assess intervention satisfaction and impact on measures of T1D health. To capture a busy population of AYAs, we will deliver intervention content via novel technologies, including phone, text messaging, video conferencing, and tools for glucose downloading and integration (e.g., Tidepool, Glooko, etc.).^{15,78,83} Communication skills will be further reinforced through joint review of the AYA's own medical visit. Communication feedback directly from audio-recorded medical interactions has been piloted with adult oncology patients and found promising.¹⁵ As a package, the PREP-DC intervention is highly translatable and promotes key self-care skills needed by all adolescents with T1D preparing for adulthood and adult medical care.

4. Experimental Approach

This application proposes to evaluate the PREP-DC intervention.

4.a. Preliminary Studies

AYA-HCP health communication contributes to T1D self-care. Dr. Monaghan is currently examining AYA-HCP health communication as part of a longitudinal study with AYAs with T1D (K23DK099250; 9/2013-9/2017).¹⁸ In this study, 75 AYAs with T1D (55% female; M age = 17.81 years; 51% Caucasian; M T1D duration = 8.16 years) participated in a longitudinal study examining communication with pediatric HCPs. Participants had 4 consecutive clinic visits recorded as part of study procedures, along with paired self-report and medical record review data on satisfaction with care, adherence, self-efficacy, clinic attendance, and biometric information. Baseline data indicate that T1D is poorly controlled in this sample, with a mean A1c of 8.86% (± 2.23) and 70% with an A1c above current recommendations ($A1c < 7.5\%$). Baseline data demonstrate the importance of the AYA-HCP relationship. Using AYA-report on the Health Care Climate Scale – Brief (HCC)⁴³, higher quality care (e.g. encouraging questions, having choices for T1D management) is associated with better T1D adherence which, in turn, predicts better glycemic control (e.g., lower A1c; model $p < .05$).

Clinic recording was an integral component of this study, and 73 of 75 participating AYAs (97%) and all HCPs approached (6 MDs, 2 NPs) agreed to audio recording. Initial coding using the Roter Interaction Analysis System (RIAS) has been completed for 70 baseline clinic visits. Mean clinic visit duration was 21.28 ± 10.12 min (range = 2.63–48.98 min). HCP talk exceeded AYA talk at a 3:1 ratio (M HCP utterances = 379.90 ± 180.10 vs. M AYA utterances = 128.83 ± 94.94). Trends suggest AYA contributions alter visit communication. For example, AYA and HCP utterances were correlated ($r = .74$, $p < .001$) yet more AYA utterances (but not HCP utterances) were associated with higher rated patient-centeredness of the visit ($r = .24$, $p < .05$). Higher A1c ($p < .05$) and AYA executive functioning (EF) difficulties ($p < .05$) were associated with lower HCP warmth. Disclosure of risky behavior is also a concern: 41% of AYA participants reported some alcohol use in the past 30 days but alcohol was only discussed in 9% of the medical visits. *Preliminary data demonstrate success in recruiting and retaining AYAs, recording clinic visits, and evaluating AYA-HCP communication. Data inform appropriate targets for intervention, including disclosure of risky behavior and executive function skills (e.g., planning).*

AYA communication preferences. We completed interviews with a subset of AYA patients who completed the longitudinal study described above to gain insight into AYA-HCP communication and factors that AYAs with T1D value when working with HCPs.¹⁷ Twenty AYAs with T1D (M age = 18.8 ± 1.5 yrs; 70% female; 65% Caucasian; M A1c = $8.5\% \pm 1.7$; 71% of eligible AYAs) participated in an interview (M length = 13.9 ± 5.1 min). Interviews were recorded, transcribed, and coded by two independent coders to identify themes. Themes emerged related to HCP interactions, support for autonomy, comfort with disclosure, and difficulties communicating when glycemic control was poor. AYAs requested involvement in decision making and perceived higher-quality communication when they could share information about their lives outside of diabetes. AYAs reported comfort disclosing risky behavior or concerns related to transfer to adult care; however, few reported initiating these conversations. AYAs perceived less support when their glycemic control was poor, and struggled to share concerns when they were not meeting their treatment goals. Changing HCPs in pediatric care was associated with greater AYA communication challenges. Results suggest AYAs desire collaborative, consistent HCP relationships but did not initiate conversations about topics of key interest to AYAs (e.g., risky behavior, transition). *Qualitative data demonstrate the success of this investigator in conducting mixed-methods research with AYAs and applying qualitative results to inform intervention efforts, including focusing on disclosure, T1D self-care goals, and maintaining communication when changing HCPs.*

Text Messaging for T1D Adherence. Dr. Monaghan, Dr. Streisand [mentor], and colleagues collaborated on a pilot study on text messaging with 23 adolescents with T1D (M age=15.09 yrs; 56% female).⁷⁹ Adolescents received 2-3 texts/day x 6 weeks with psychoeducational tips and queries about daily T1D care (eating, BG monitoring, physical activity, mood, sleep). Adolescents and parents completed follow-up questionnaires and an interview. Adolescents responded to the majority of texts (M response rate=78.0%± 24.0, range=30-100%). Feedback was positive; adolescents indicated the text messages motivated behavior change. Participants also requested text message assistance to support clinic engagement and T1D care, including appointment reminders. *Data demonstrate interest in and feasibility of a text message intervention component.*

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> - Age 17-23- Diagnosed with T1D for ≥ 1 year - Fluent in English - Text message access - Within 6-8 months of planned transfer to adult diabetes care 	<ul style="list-style-type: none"> - Other major chronic illness (e.g. cancer) - Major psychiatric disorder - Pervasive developmental disorder or cognitive limitations

4.b. Participants. One hundred and twenty AYAs (ages 17-23; ~50% female; ~40% minority; English fluency; T1D duration ≥1 year; within 6-8 months of transfer to adult diabetes care) and a primary caregiver (as available) will be recruited. We anticipate that ~70% of the estimated 400+ available AYA patients will meet these criteria. We expect to recruit equal numbers of males and females. Our recent studies with this population have

successfully recruited AYA samples comprising of 40 – 50% non-Caucasian participants, ensuring a diverse sample for evaluation of intervention effects. AYA participants must have consistent access to a device with text messaging capability. As AYAs are high users of technology,⁸⁰ we do not anticipate that this will be a barrier to participation. We will document reasons for ineligibility and/or non-participation in this pilot. Primary caregivers will be enrolled as available to report on AYA communication and T1D care. Ten HCPs will also be consented to allow for recording of clinic visits and completion of HCP-report data (n=10).

4.c.Enrollment. We will employ methods for enrolling subjects that have been evaluated and refined in our prior work with AYA with T1D, resulting in successfully enrolling ~65% of AYAs reached for recruitment. Our longitudinal trial on health communication on which this work is based has outstanding retention, with ~85% of participants attending follow-up visits and completing study procedures to date. AYAs will be recruited into the proposed RCT prior to a regularly scheduled clinic visit. The principal investigator will obtain clinic lists, send a letter that describes the study, and follow up by phone to determine eligibility and interest. Potential participants will also receive informed consent forms; those not interested can contact the study team to decline enrollment. Potentially eligible AYAs will be screened by phone to determine eligibility; parents can provide information for AYAs under age 18 and AYAs ages 18 and up can provide their own eligibility information. AYAs and their parents interested in participating will provide initial verbal consent on the phone. Once verbal consent has been obtained, AYAs and a parent (if applicable) will be e-mailed instructions for accessing REDCap – a secure, web-based survey tool⁸¹ – to provide informed consent and complete the baseline assessment. In addition to completing the consent form online prior to questionnaire completion, participating AYAs and a parent (if applicable) will complete written consent in person at a clinic visit. If research staff cannot meet with the participant in person at their next clinic visit (e.g. the participant has a telehealth appointment), then the AYA and parent (if applicable) will complete an e-consent form on REDCap via telephone or a secure, HIPAA-compliant videoconferencing platform (Zoom) with a research staff member, in place of verbal and written consent. Consent forms will include a description of the study procedure and state that: (a) information collected will be confidential and not be released to AYAs, caregivers, or HCPs, (b) subjects will be randomized to the intervention or standard care group at a 1:1 ratio (c) subjects will receive modest compensation (e.g., ClinCards) for completing the study, (d) study withdrawal can occur at any time, and (e) data will be destroyed at any time upon request. The participant will verify that they are the legally authorized representative or individual to sign the e-consent form. A copy of the written consent will be printed and mailed to the participant. Only research staff will obtain consent via structured scripts.

4.d. PREP-DC procedures. At baseline, AYA participants will: complete questionnaires on health communication, engagement in health care, executive function, readiness for independence, and T1D self-care; have their medical visit recorded (if the visit is conducted in person); and have their BG meter and/or continuous glucose monitor data downloaded or recorded. Participant biometric data and BG data will be collected in ways consistent with usual clinical care (e.g., CliniPro, Dexcom website). If participants cannot obtain a lab-drawn A1c value (e.g. participant has telemedicine appointment), the study team will mail them a self-collection A1c kit (e.g. CoreMedica A1c kit) to obtain A1c value remotely. The self-collection A1c kit will not contain any identifying information, and only a random study ID will be used to identify the participant's A1c sample. The participants will be sent their A1c value via email after we receive the information from

CoreMedica. Participants will also be introduced to free, open-source software platforms designed for personal use by patients with diabetes to download, integrate, and share glucose data (e.g. Glooko, Tidepool), but participants will not be required to use these software platforms for the study.⁸² Participants will also be given access to a password-protected study website containing information about the study and additional resources for diabetes management. The baseline visit will take approximately 45 minutes for AYAs. HCPs will complete a questionnaire on AYA communication and engagement in the medical visit, which will take approximately 5 minutes.

For the purposes of the initial pilot, all AYAs will then receive the PREP-DC intervention. For the RCT (target recruitment: 100 participants), after completion of the baseline study visit, participants will be randomized to the intervention or standard care group at a 1:1 ratio. AYAs randomized to standard care will receive standard diabetes education and care, including resources for transition to adult diabetes care. AYAs randomized to the intervention group will receive the PREP-DC intervention. Building upon our own work as well as existing health communication research, we will integrate several key strategies for behavior change including identification of communication preferences, tailored reflection, brief text message reminders and assessments, the use of a communication plan, and improved glucose review.

PREP-DC	Session 1 (1 month post-baseline)	Session 2 (2 months post-baseline)	Session 3 (3 months post-baseline)
Topics	<ul style="list-style-type: none"> Communication preferences Communication skills overview Communication review of medical clinic visit – with guided opportunities to identify areas for improvement 	<ul style="list-style-type: none"> Review and troubleshoot glucose data Downloading and uploading glucose data Set goals with CDE 	<ul style="list-style-type: none"> Taking control of T1D – glycemic control data Planning for medical clinic visits Review of texted communication topics Creation of communication plan
	Text messages to support intervention content, communication plans. Sent 3x/week for 3-4 months.		
	Glucose data downloading for 3-4 months. Reviewed remotely and shared with HCP at next clinic visit.		

Specifically, prior to their next clinic visit, AYAs will complete three intervention sessions over the phone or via video conferencing (Zoom) and receive weekly targeted text messages. Each intervention session is expected to take 45-60 minutes. The first session will review results of a communication preferences questionnaire and provide guided reflection on their communication with HCPs. Participants and the interventionist will jointly review their most recent medical visit through edited audio review. The clinic visit will have been reviewed by the interventionist prior to this first intervention session to identify areas where the AYA patient demonstrated high-quality communication (e.g. asking questions, disclosing information) and areas for improvement (e.g. missed opportunities to ask questions, engage in decision making). This technique of editing and reflecting on clinic visits has been effectively utilized with adults with cancer.¹⁵ The second session will be conducted by a certified diabetes educator (CDE) and will focus on reviewing and troubleshooting glucose data. Participants and the CDE will jointly review personal and/or mock glucose data and troubleshoot decisions around diabetes care situations that many AYAs face. Participants will also set diabetes management goals with the CDE (e.g. uploading BG data, checking BG levels). The third session will focus on promoting executive functioning skills through glucose data review and use of a communication plan to prepare for medical visits and organize information. AYA participants and the interventionist will review T1D adherence and complete a communication plan for the next medical visit, setting goals related to asking questions and disclosing concerns, including adherence related concerns. Throughout the 12-16 week intervention period, AYA participants will also receive text messages via Mosio, a secure, HIPAA- compliant text messaging platform, 3x/week to support intervention content and provide reminders. To facilitate communication, one message/week will ask AYAs to document concerns as they arise in preparation for their next clinic visit. These concerns will be compiled and given to the AYA at their clinic visit as part of the communication plan. AYAs will not be required to participate in this text message service and have the option to opt out at any point during the study. AYAs will also be encouraged to download glucose devices to personal use software platforms (e.g., Tidepool, Glooko) 1x/month or more to facilitate data review.

At the next medical clinic visit (~3-4 months post-baseline), participants will complete follow-up psychosocial and health outcome measures. As in the baseline visit, participant biometric data and BG data will be collected. For any follow-up visits, if participants cannot obtain a lab-drawn A1c value, the study team will mail them a

self-collection A1c kit. The participants will be sent their A1c value via email after we receive the information from CoreMedica. Participants with additional clinic visits prior to transfer to adult medical care will complete a brief set of questionnaires and provide glucose data. Participants will sign an optional release form for their adult diabetes care provider and complete additional follow-up assessments after transfer to adult medical care (expected to be ~8 months post-baseline). If participants sign the release of information form, their adult diabetes care providers will be asked to complete a brief online questionnaire reporting on participants' biometric data. If participants do not sign the release of information form, they are still able to participate in the study and the research team will not contact their adult diabetes care provider. Clinic visits are typically scheduled every 3-4 months, and data collection will therefore coincide with AYAs' regular visits. To increase retention, we will use strategies employed in our other projects including contacting the AYA by text to remind them about the data collection. Follow-up questionnaires are expected to take 30 minutes (AYA: 30 minutes; HCP: 5 minutes). Through REDCap Survey, follow-up questionnaires can be administered online, increasing the likelihood of completion.

AYA participants will receive modest incentives for baseline and follow-up questionnaire completion. Participants who complete baseline questionnaires will receive \$50; participants who complete follow-up questionnaires will receive \$50 at the first follow-up and \$100 at the second follow-up. Participants who complete questionnaires online before their clinic visit will receive an additional \$10 at their baseline visit and first follow-up visit. Participants who complete their interview will receive an additional \$10. Additionally, participants who bring in glucose data to baseline and follow-up clinic visits will receive a \$25 incentive/visit. Participants who complete remote A1c data collection procedures will receive a \$25 incentive/visit (maximum total incentive = \$480). Participants will receive compensation via ClinCard, a prepaid reloadable debit card. Adult care providers will receive modest compensation (e.g., a one-time \$25 gift card) for completing the brief online questionnaire about the participant's biometric data.

4.e. Measures. Biometric data, including A1c values and other clinical data (height, weight, complications), will be collected from participants at baseline and follow-up. Recording of the clinic visit, patient-reported outcomes, and related HCP-report measures will be completed at each visit as well. Health communication will be assessed by the Roter Interaction Analysis System (RIAS), a well-validated method to codify medical interactions in primary and specialty care.⁸³⁻⁸⁸ We have an ongoing relationship with the RIAS coding team and, as a coding framework has already been developed for this population, clinic visits can be coded quickly. We also will utilize a coding framework examining motivational interviewing principles, as guided by an expert consultant Dr. Kathryn Pollak. AYAs will also complete the Health Care Preferences questionnaire, a validated measure that AYA preferences for interacting with HCPs, including domains of respect, power, closeness, communication with parents, and communication about personal issues.^{89,90} AYA responses will inform personal preferences for health care delivery and contribute to the tailoring of PREP-DC. The Independent Behavior During Consultations scale (IBDC; AYA and HCP report) assesses AYA's communication, including asking and answering questions and disclosure.^{10,91} Assessment of engagement in care complements communication measures. The Health Care Climate questionnaire (HCC; AYA report)⁹² evaluates patient-centered care.⁴³ The HCC is reliable and valid; we are using a modified version (9 items) found to be significantly associated with glycemic control in adolescents with T1D.^{43,92} Executive function is assessed with the BRIEF or the BRIEF-A (Adult Version; AYA), a well-validated assessment of key domains of executive function. Readiness for independence will be assessed using the Self-Management of Diabetes - Adolescent scale (SMOD-A; AYA report),⁹³ a reliable scale that assesses support, degree of responsibility for care, and communication with HCPs.⁹⁴ The Transition Readiness assessment for Emerging Adults with Diabetes Diagnosed in Youth (READDY; AYA report) captures skills thought to predict success in adult medical care, including disease management and advocacy (including communication). This survey is unpublished but was received from the survey creators (Corathers & Frazier personal communication, 2016). The Youth Risk Behavior Survey (YRBS; AYA report) is a questionnaire utilized by the Centers for Disease Control (CDC) to assess health-related behaviors in youth and young adults. We are using a modified version (25 items) to assess health behaviors related specifically to diabetes management. The Diabetes Management Questionnaire (DMQ; AYA report) is a reliable measure that evaluates adherence to diabetes management for young people with T1D.⁹⁵ We are using a modified version (20 items) to ask specifically about AYA self-management of diabetes. Diabetes distress will be assessed with the two item Diabetes Distress Scale (DDS), and self-efficacy will be assessed using the Self-Efficacy for Diabetes Scale. Accuracy and congruence of discussions during clinical encounters between health care providers and young adults will be assessed using a Discussion Recall questionnaire (AYA and HCP report) (based on a survey designed by Bodner et al.).¹⁰⁰ In

addition, self-care data will be obtained by downloaded glucose values for the 30 days prior to a clinic visit. Health outcomes include assessment of hemoglobin A1c, the most widely accepted measure of glycemic control and represents average glucose over the preceding 6-12 weeks.⁹⁶ Further, AYA participants will complete a satisfaction survey related to their experience in the intervention, similar to what we have done in other intervention studies.^{74,97} In response to the COVID-19 pandemic experienced in spring, 2020, we also will assess participant's anxiety related to COVID-19 and any changes to their mood or diabetes management behaviors as a result of COVID-19. Further, in response to the FDA approval of the Pfizer COVID-19 vaccine, we will track participant's COVID-19 vaccine status to better understand perspectives on vaccination.

Qualitative interviews will be completed with a purposeful subset of AYA participants (n=20) and HCPs to gain in-depth understanding of the feasibility and acceptability of the PREP-DC intervention, including specific factors predictive of high-quality health communication and perceived impact of PREP-DC on communication and health outcomes. Process evaluations such as this offer critical feedback on the applicability, translatability, and strengths/weaknesses of the intervention and identify opportunities for refinement. We have developed interview guides for AYA and HCP participants, asking interviewees what they thought about the PREP-DC intervention, if/how they think it worked to promote better T1D management and glycemic control, parts of the intervention that were more or less effective, and applicability to improve transition to adult diabetes care.⁹⁸ In response to the COVID-19 pandemic experienced in spring, 2020, we also will inquire about any changes to their diabetes care or transition timeline resulting from COVID-19 and related restrictions. Interview guides will ensure that similar areas of content are collected across subjects, providing more focus than a conversational approach but allowing adaptability. Standard, open-ended interview questions will be incorporated to facilitate data collection and analyses.

4.f. Training & Fidelity Checks. PREP-DC will be primarily delivered by the PI and a trained research coordinator with a social science background. All intervention sessions will be recorded, and independent fidelity checks will be conducted on ~35% of all intervention sessions. Fidelity checks will include a direct comparison of session objectives and content per the treatment manual with the content discussed in each session. Adherence coefficients will be calculated on an ongoing basis in order to determine the need for additional modification of session content. Indices of treatment utilization (i.e., dose) include interventionist reporting of the duration and frequency of participation for each session, utilization of the strategies presented (e.g. completing communication plan), and text message response. Pediatric clinic visits will be reviewed and coded for AYA communication based on a standardized coding framework.

5. Data Analyses. Data will be entered into REDCap, an online data management system. In the proposed study, the health communication measures (e.g., RIAS, HCC) and some outcome measures (e.g., DMQ) have multi-item based scales/subscale or composite scores (see Measures). Item and scale reliabilities of these measures will be assessed using item-to-total correlation and Cronbach's α , respectively, before evaluating the proposed specific aims. Missing data will be identified and addressed. Measure total scores will be used for analyses, and AYA reports will be used as the primary independent and dependent variables. Various advanced statistical models are proposed to assess intervention efficacy.

Aim 1. Determine initial efficacy of PREP-DC. Feasibility will be assessed by evaluation of study recruitment and retention (>80% completing the intervention in its entirety), satisfaction (>80% reporting overall satisfaction, improved communication with HCP, likely to recommend PREP-DC to others), and satisfaction with and use of components (medical clinic review, text messaging, videoconferencing, communication plan). Paired t-tests will be used to assess changes from baseline to the first follow-up (~4 months post-baseline) to the second follow-up (~8 months post-baseline; post transfer to adult care). To test how the PREP-DC intervention affects health outcomes indirectly through improving health communication and related T1D self-care, we propose implementing a moderated mediation model, in which health communication is measured at the first follow-up, and T1D self-care and health outcomes are measured at the second follow-up (post-transfer to adult care). This model allows for changes in health communication in pediatric care to predict changes in diabetes health indicators post-transfer to adult care. We will control for the baseline measures (e.g. A1c) and hypothesized covariates (e.g. T1D duration, sex, ethnicity), and the residualized scores of those measures will then be used in the moderated mediation model. The specific indirect effects of the intervention on health outcome (e.g. through health communication and then self-care) will be evaluated.⁹⁹ Our proposed sample for the RCT (n=100) is sufficient for these analyses. Accounting for attrition (up to 20%), power analysis results show a sample size of n=80 achieves 85% power to detect a small effect size (0.30) in a paired t-test at a significance level of $\alpha=0.05$.

Aim 2. Obtain AYA and HCP feedback on PREP-DC and identify potential moderators of the PREP-DC intervention in preparation for integration into clinical practice.. Qualitative coding will evaluate AYA themes related to intervention experience and perceived impact. Interviews will be transcribed and coded for content. Coding, sorting, and integration of the major themes will be accomplished as outlined by Charmaz,⁹⁸ and supported by the use of contextual software Atlas.ti. Thematic prevalence will be determined as the relative importance of codes (the proportion of interviews to which a code is applied). Data saturation will be met when new information produces little or no change to the codebook. Study findings will be enriched by this in-depth qualitative material to illustrate major barriers and facilitators to changing health communication as perceived by AYAs. AYA report will be integrated to provide a detailed evaluation of intervention components and delivery to inform future iterations of the intervention. We will identify potential moderators of intervention response. While executive function is not expected to change as a result of the intervention, PREP-DC does incorporate skills associated with executive function. Therefore, scores on the BRIEF (the measure of executive function) will be evaluated descriptively as a potential moderator of intervention impact.

5. Timeline. This study can be successfully completed in the proposed funding period (1 year pilot; 5 year RCT). The RCT timeline is in the table below.

We have the full support of the CNMC Diabetes Program for the execution of this proposed intervention.

6. Future Directions. Promotion of health communication skills in AYA with T1D in pediatric care has the potential to initiate a more successful transfer into adult diabetes care, a key component of the vision for CTSI-CN v2.0. The proposed intervention builds on a successful program of communication research in AYAs with T1D and incorporates elements successfully piloted in adolescents with diabetes and adults with chronic illness (e.g. text messaging; communication plan). Results from the proposed pilot and innovative RCT will equip AYAs with critical communication skills necessary for successful independent self-care. Evaluation of health communication in youth with T1D has been well-received by NIH/NIDDK, with two current descriptive proposals funded on this topic by the principal investigator. This proposed research extends findings from an active NIH/NIDDK K23 award (PI: Monaghan; Lead Mentor: Streisand; 9/2013-6/2017). The proposed study is well-aligned with CTSI-CN's mission to improve clinical care and prevent chronic complications in a common chronic illness with onset in childhood.

TASK	YEAR 1		YEAR 2		YEAR 3		YEAR 4		YEAR 5	
	1-6	7-12	1-6	7-12	1-6	7-12	1-6	7-12	1-6	7-12
Study start up	X									
Recruitment		X	X	X	X	X	X			
Data collection		X	X	X	X	X	X	X	X	
Data analyses								X	X	X
Dissemination										X

REFERENCES

1. Bryden KS, Peveler RC, Stein A, Neil A, Mayou RA, Dunger DB. Clinical and psychological course of diabetes from adolescence to young adulthood: a longitudinal cohort study.[see comment]. *Diabetes Care*. 2001;24(9):1536-1540.
2. Johnson B, Elliott J, Scott A, Heller S, Eiser C. Medical and psychological outcomes for young adults with Type 1 diabetes: no improvement despite recent advances in diabetes care. *Diabet Med*. 2014;31(2):227-231.
3. Monaghan M, Helgeson V, Wiebe D. Type 1 diabetes in young adulthood. *Current Diabetes Reviews*. 2015;11:239-250.
4. Helgeson V, Siminerio L, Escobar O, Becker D. Predictors of metabolic control among adolescents with diabetes: a 4-year longitudinal study. *Journal of Pediatric Psychology*. 2009;34(3):254-270.
5. Hood K, Peterson C, Rohan J, Drotar D. Association between adherence and glycemic control in pediatric type 1 diabetes: a meta-analysis. *Pediatrics*. 2009;124(6):e1171-e1179.
6. Monaghan M, Hilliard M, Sweenie R, Riekert K. Transition readiness in adolescents and emerging adults with diabetes: the role of patient-provider communication. *Curr Diab Rep*. 2013;13(6):900-908.
7. Nobile C, Drotar D. Research on the quality of parent-provider communication in pediatric care: implications and recommendations. *J Dev Behav Pediatr*. 2003;24(4):279-290.

8. American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians Transitions Clinical Report Authoring Group. Clinical report - Supporting the health care transition from adolescence to adulthood in the medical home. *Pediatrics* 2011;128(1):182-200.
9. Paine CW, Stollon NB, Lucas MS, et al. Barriers and facilitators to successful transition from pediatric to adult inflammatory bowel disease care from the perspectives of providers. *Inflammatory bowel diseases*. 2014;20(11):2083-2091.
10. van Staa A, Sattoe J, Strating M. Experiences with and outcomes of two interventions to maximize engagement of chronically ill adolescents during hospital consultations: a mixed methods study. *J Pediatr Nurs*. 2015;30(5):757-775.
11. Harrington J, Noble LM, Newman SP. Improving patients' communication with doctors: a systematic review of intervention studies. *Patient Education and Counseling*. 2004;52(1):7-16.
12. van Dam HA, van der Horst F, van den Borne B, Ryckman R, Crebolder H. Provider-patient interaction in diabetes care: effects on patient self-care and outcomes. A systematic review. *Patient Educ Couns*. 2003;51(1):17-28.
13. Street Jr. RJ, Gordon HS, Ward MM, Krupat E, Kravitz RL. Patient participation in medical consultations: Why some patients are more involved than others. *Medical Care*. 2005;43(10):960-969.
14. Kravitz RL, Tancredi DJ, Grennan T, et al. Cancer Health Empowerment for Living without Pain (Ca-HELP): effects of a tailored education and coaching intervention on pain and impairment. *PAIN®*. 2011;152(7):1572-1582.
15. Porter L, Pollak K, Farrell D, et al. Development and implementation of an online program to improve how patients communicate emotional concerns to their oncology providers. *Support Care Cancer*. 2015;23:2907-2916.
16. Street RLJ, Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling*. 2009;74:295-301.
17. Baumann K, Simms M, Cogen F, Monaghan M. Health communication experiences of youth with type 1 diabetes. Pediatric Academic Societies; April, 2016; Baltimore, MD.
18. Monaghan M. Cognitive development and communication with providers among young adult with type 1 diabetes. 76th Annual Scientific Sessions of the American Diabetes Association; 2016; New Orleans, LA.
19. Kinnersley P, Edwards A, Hood K, et al. Interventions before consultations for helping patients address their information needs (Review). *The Cochrane Collaboration* 2009;1:1-82.
20. Bandura A. Health Promotion by Social Cognitive Means. *Health Education & Behavior*. 2004;31(2):143-164.
21. SEARCH for Diabetes in Youth Study Group, Liese A, D'Agostino RJ, et al. The burden of diabetes mellitus among US youth: prevalence estimates from the SEARCH for Diabetes in Youth Study. *Pediatrics*. 2006;118(4):1510-1518.
22. Northam E, Lin A, Finch S, Werther G, Cameron F. Psychosocial well-being and functional outcomes in youth with type 1 diabetes 12 years after disease onset. *Diabetes Care*. 2010;33(7):1430-1437.
23. Bryden K, Dunger D, Mayou R, Peveler R, Neil H. Poor prognosis of young adults with type 1 diabetes: A longitudinal study. *Diabetes Care*. 2003;26(4):1052-1057.
24. Rewers A, Chase H, Mackenzie T, et al. Predictors of acute complications in children with type 1 diabetes. *Journal of the American Medical Association*. 2002;287(19):2511-2518.
25. Simmons J, Chen V, Miller K, et al. Differences in the management of type 1 diabetes among adults under excellent control compared with those under poor control in the T1D exchange clinic registry. *Diabetes Care*. 2013;36(11):3573-3577.
26. McKnight JA, Wild SH, Lamb MJE, et al. Glycaemic control of Type 1 diabetes in clinical practice early in the 21st century: an international comparison. *Diabet Med*. 2015;32(8):1036-1050.
27. Miller K, Foster N, Beck R, et al. Current state of type 1 diabetes treatment in the U.S.: updated data from the T1D Exchange Clinic Registry. *Diabetes Care*. 2015;38(6):971-978.
28. Cengiz E, Xing D, Wong J, et al. Severe hypoglycemia and diabetic ketoacidosis among youth with type 1 diabetes in the T1D Exchange clinic registry. *Pediatric Diabetes*. 2013;14(6):447-454.

29. Osan JK, Punch JD, Watson M, et al. Associations of demographic and behavioural factors with glycaemic control in young adults with type 1 diabetes mellitus. *Internal medicine journal*. 2016;46(3):332-338.
30. Pyatak EA, Sequeira PA, Whittemore R, Vigen CP, Peters AL, Weigensberg MJ. Challenges contributing to disrupted transition from paediatric to adult diabetes care in young adults with Type 1 diabetes. *Diabet Med*. 2014.
31. Amiel SA, Sherwin RS, Simonson DC, Lauritano AA, Tamborlane WV. Impaired insulin action in puberty. A contributing factor to poor glycemic control in adolescents with diabetes. *New England Journal of Medicine*. 1986;315(4):215-219.
32. Helgeson VS, Snyder PR, Seltman H, Escobar O, Becker D, Siminerio L. Brief report: Trajectories of glycemic control over early to middle adolescence. *Journal of Pediatric Psychology* 2010;35(10):1161-1167.
33. Pai ALH, Ostendorf HM. Treatment adherence in adolescents and young adults affected by chronic illness during the health care transition from pediatric to adult health care: a literature review. *Children's Health Care*. 2011;40(1):16-33.
34. Clark N, Gong M. Management of chronic disease by practitioners and patients: Are we teaching the wrong things? *BMJ*. 2000;320(7234):572-572.
35. DiMatteo MR. The role of effective communication with children and their families in fostering adherence to pediatric regimens. *Patient Education and Counseling*. 2004;55(3):339-344.
36. Modi AC, Pai AL, Hommel KA, et al. Pediatric self-management: a framework for research, practice, and policy. *Pediatrics*. 2012;129(2):e473-485.
37. Schulman-Green D, Jaser S, Martin F, et al. Processes of self-management in chronic illness. *Journal of Nursing Scholarship*. 2012;44(2):136-144.
38. Street Jr RL. How clinician–patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling*. 2013;92(3):286-291.
39. Zolnieriek KB, DiMatteo MR. Physician communication and patient adherence: A meta-analysis. *Medical Care*. 2009;47(8):826-834.
40. Ratanawongsa N, Karter AJ, Parker MM, et al. Communication and medication refill adherence: The diabetes study of northern california. *JAMA internal medicine*. 2013;173(3):210-218.
41. Verlinde E, De Laender N, De Maesschalck S, Deveugele M, Willems S. The social gradient in doctor-patient communication. *International Journal for Equity in Health*. 2012;11:12.
42. Swedlund MP, Schumacher JB, Young HN, Cox ED. Effect of communication style and physician-family relationships on satisfaction with pediatric chronic disease care. *Health Commun*. 2012;27(5):498-505.
43. Croom A, Wiebe DJ, Berg CA, et al. Adolescent and parent perceptions of patient-centered communication while managing type 1 diabetes. *J Pediatr Psychol*. 2011;36(2):206-215.
44. Henry SG, Fuhrel-Forbis A, Rogers MA, Eggly S. Association between nonverbal communication during clinical interactions and outcomes: a systematic review and meta-analysis. *Patient Educ Couns*. 2012;86(3):297-315.
45. Heisler M, Bouknight RR, Hayward RA, Smith DM, Kerr EA. The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management. *Journal of General Internal Medicine*. 2002;17(4):243-252.
46. Rost K. The influence of patient participation on satisfaction and compliance. *Diabetes Educ*. 1989;15(2):139-143.
47. Schwartz LA, Brumley LD, Tuchman LK, et al. Stakeholder validation of a model of readiness for transition to adult care. *JAMA pediatrics*. 2013;167(10):939-946.
48. Towle A, Godolphin W, Van Staaldin S. Enhancing the relationship and improving communication between adolescents and their health care providers: a school based intervention by medical students. *Patient Educ Couns*. 2006;62(2):189-192.
49. Rao JK, Anderson L, Inui T, Frankel RM. Communication interventions make a difference in conversations between physicians and patients: A systematic review of the evidence. *Medical Care*. 2007;45(4):340-349.

50. Tran AN, Haidet P, Street RLJ, O'Malley KJ, Martin F, Ashton CM. Empowering communciation: A community-based intervention for patients. *Patient Education and Counseling*. 2004;52:113-121.
51. Greenfield S, Kaplan S, Ware JJ, Yano E, Frank H. Patients' participation in medical care: Effects on blood sugar control and quality of life in diabetes. *Journal of General Internal Medicine*. 1988;3(5):448-457.
52. Sable C, Foster E, Uzark K, et al. Best practices in managing transition to adulthood for adolescents with congenital heart disease: The transition process and medical and psychosocial issues: A scientific statement from the American Heart Association. *Circulation*. 2011;123(13):1454-1485.
53. Viner RM. Transition of care from paediatric to adult services: One part of improved health services for adolescents. *Archives of Disease in Childhood*. 2008;93(2):160-163.
54. Peters A, Laffel L, American Diabetes Association Transitions Working Group. Diabetes care for emerging adults: Recommendations for transition from pediatric to adult diabetes care systems. *Diabetes Care*. 2011;34:2477-2485.
55. Sawicki GS, Whitworth R, Gunn L, Butterfield R, Lukens-Bull K, Wood D. Receipt of health care transition counseling in the national survey of adult transition and health. *Pediatrics*. 2011;128(3):e521-529.
56. Sonneveld HM, Strating MM, van Staa AL, Nieboer AP. Gaps in transitional care: what are the perceptions of adolescents, parents and providers? *Child Care Health Dev*. 2013;39(1):69-80.
57. Ferris M, Cohen S, Haberman C, et al. Self-Management and Transition Readiness Assessment: Development, Reliability, and Factor Structure of the STARx Questionnaire. *J Pediatr Nurs*. 2015;30(5):691-699.
58. Whitfield EP, Fredericks EM, Eder SJ, Shpeen BH, Adler J. Transition readiness in pediatric patients with inflammatory bowel disease: A patient survey of self-management skills. *Journal of pediatric gastroenterology and nutrition*. 2015;60(1):36-41.
59. Duke DC, Harris MA. Executive Function, Adherence, and Glycemic Control in Adolescents with Type 1 Diabetes: a Literature Review. *Current Diabetes Reports*. 2014;14(10):1-10.
60. McNally K, Rohan J, Pendley J, Delamater A, Drotar D. Executive functioning, treatment adherence, and glycemic control in children with type 1 diabetes. *Diabetes Care*. 2010;33(6):1159-1162.
61. van Groningen J, Ziniel S, Arnold J, Fishman LN. When independent healthcare behaviors develop in adolescents with inflammatory bowel disease. *Inflammatory bowel diseases*. 2012;18(12):2310-2314.
62. Sawicki GS, Kelemen S, Weitzman ER. Ready, Set, Stop: Mismatch Between Self-Care Beliefs, Transition Readiness Skills, and Transition Planning Among Adolescents, Young Adults, and Parents. *Clinical Pediatrics*. 2014;53(11):1062-1068.
63. Beresford BA, Sloper P. Chronically ill adolescents' experiences of communicating with doctors: A qualitative study. *Journal of Adolescent Health*. 2003;33(3):172-179.
64. Klein JD, Wilson KM. Delivering quality care: Adolescents' discussion of health risks with their providers. *Journal of Adolescent Health*. 2002;30:190-195.
65. Alexander SC, Fortenberry JD, Pollak KI, et al. Disclosure of Sexual Intercourse by Teenagers: Agreement Between Telephone Survey Responses and Annual Visit Disclosures. *Clinical Pediatrics*. 2015;54(6):529-533.
66. van Staa A, Jedeloo S, van der Stege H, On Your Own Feet Research Group. "What we want": Chronically ill adolescents' preferences and priorities for improving health care. *Patient Preference and Adherence*. 2011;5:291-305.
67. van Staa A, van der Stege H, Jedeloo S, Moll HA, Hilberink SR. Readiness to transfer to adult care of adolescents with chronic conditions: Exploration of associated factors. *Journal of Adolescent Health*. 2011;48(3):295-302.
68. Jedeloo S, van Staa A, Latour JM, van Exel JA. Preferences for health care and self-management among dutch adolescents with chronic conditions: A Q-methodological investigation. *International Journal of Nursing Studies*. 2010;47:593-603.
69. Kravitz RL, Tancredi DJ, Jerant A, et al. Influence of Patient Coaching on Analgesic Treatment Adjustment: Secondary Analysis of a Randomized Controlled Trial. *Journal of Pain and Symptom Management*. 2012;43(5):874-884.

70. Gadomski AM, Fothergill KE, Larson S, et al. Integrating mental health into adolescent annual visits: impact of previsit comprehensive screening on within-visit processes. *Journal of Adolescent Health*. 2015;56(3):267-273.
71. Street RL, Tancredi DJ, Slee C, et al. A pathway linking patient participation in cancer consultations to pain control. *Psycho-Oncology*. 2014;23(10):1111-1117.
72. Roter D, Larson S, Shinitzky H, et al. Use of an innovative video feedback technique to enhance communication skills training. *Medical Education* 2004;38:145-157.
73. Holmes CS, Chen R, Mackey E, Grey M, Streisand R. Randomized clinical trial of clinic-integrated, low-intensity treatment to prevent deterioration of disease care in adolescents with type 1 diabetes. *Diabetes Care*. 2014;37(6):1535-1543.
74. Monaghan M, Hilliard ME, Cogen FR, Streisand R. Supporting parents of very young children with type 1 diabetes: results from a pilot study. *Patient Education and Counseling*. 2011;82(2):271-274.
75. Hilliard ME, Perlus JG, Clark LM, et al. Perspectives from before and after the pediatric to adult care transition: a mixed-methods study in type 1 diabetes. *Diabetes Care*. 2014;37(2):346-354.
76. Ritholz MD, Wolpert H, Beste M, Atakov-Castillo A, Luff D, Garvey KC. Patient-provider relationships across the transition from pediatric to adult diabetes care: a qualitative study. *Diabetes Educ*. 2014;40(1):40-47.
77. Reiss JG, Gibson RW, Walker LR. Health Care Transition: Youth, Family, and Provider Perspectives. *PEDIATRICS*. 2005;115(1):112-120.
78. Chen J, Mullins CD, Novak P, Thomas SB. Personalized Strategies to Activate and Empower Patients in Health Care and Reduce Health Disparities. *Health Education & Behavior*. 2016;43(1):25-34.
79. Herbert LJ, Mehta P, Monaghan M, Cogen F, Streisand R. Feasibility of the SMART Project: a text message program for adolescents with type 1 diabetes. *Diabetes Spectrum*. 2014;27(4):265-269.
80. Pew Internet and American Life Project. Cell internet use 2012. 2012; <http://www.pewinternet.org/Reports/2012/Cell-Internet-Use-2012/Key-Findings.aspx> Accessed September 14, 2012.
81. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*. 2009;42(2):377-381.
82. Neinstein A, Wong J, Look H, et al. A case study in open source innovation: developing the Tidepool Platform for interoperability in type 1 diabetes management. *J Am Med Inform Assoc*. 2016;23:324-332.
83. Roter DL, Hall JA. Studies of doctor-patient interaction. *Annual Review of Public Health* 1989;10:163-180.
84. Roter D, Larson S. The Roter interaction analysis system (RIAS): utility and flexibility for analysis of medical interactions. *Patient Educ Couns*. 2002;46(4):243-251.
85. Brown JD, Krupnick J. Therapeutic alliance in pediatric primary care: Preliminary evidence for a relationship with physician communication style and mothers' satisfaction. *J Dev Behav Pediatr*. 2010;31(2):83-91.
86. Johnson RL, Roter D, Powe NR, Cooper LA. Patient race/ethnicity and quality of patient-physician communication during medical visits. *American Journal of Public Health*. 2004;94(12):2084-2090.
87. Cox ED, Smith MA, Brown RL, Fitzpatrick MA. Assessment of the physician-caregiver relationship scales (PCRS). *Patient Educ Couns*. 2008;70(1):69-78.
88. Roter DL, Hall JA, Katz NR. Relations between physicians' behaviors and analogue patients' satisfaction, recall, and impressions. *Medical Care*. 1987;25:437-451.
89. Britto M, DeVellis R, Hornung R, DeFries G, Atherton H, Slap G. Health care preferences and priorities of adolescents with chronic illness. *Pediatr* 2004;114(5):1272-1280.
90. Britto MT, Slap GB, DeVellis RF, et al. Specialists understanding of the health care preferences of chronically ill adolescents. *J Adolesc Health*. 2007;40(4):334-341.
91. van Staa A, Sattoe J. Young adults' experiences and satisfaction with the transfer of care. *J Adolesc Health*. 2014;55:796-803.
92. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care*. 1998;21(10):1644-1651.

93. Schilling L, Dixon J, Knafl K, et al. A new self-report measure of self-management of type 1 diabetes for adolescents. *Nurs Res.* 2009;58(4):228-236.
94. Keough L, Sullivan-Bolyai S, Crawford S, Schilling L, Dixon J. Self-management of Type 1 Diabetes Across Adolescence. *Diabetes Educ.* 2011;37(4):486-500.
95. Mehta SN, Nansel TR, Volkening LK, Butler DA, Haynie DL, & Laffel LMB. Validation of a contemporary adherence measure for children with type 1 diabetes: the Diabetes Management Questionnaire. *Diabetic Med.* 2015;32(9):1232-1238.
96. American Diabetes Association. Standards of Medical Care in Diabetes - 2015. *Diabetes Care.* 2015;38(S1):S1-S93.
97. Monaghan M, Clary L, Mehta P, et al. Checking In: A Pilot of a Physician-Delivered Intervention to Increase Parent-Adolescent Communication About Blood Glucose Monitoring. *Clinical Pediatrics.* 2015.
98. Charmaz K. *Constructing Grounded Theory: A Practical Guide through Qualitative Analysis.* London: Sage Publications, Ltd; 2006.
99. Sobel M. Asymptotic confidence intervals for indirect effects in structural equation models. *Sociological Methodology.* 1982;13:290-312.
100. Bodner ME, Lyna P, Østbye T, et al. Accuracy and congruence of physician and adolescent patient weight-related discussions: Teen CHAT (Communicating health: Analyzing talk). *Patient Educ Couns.* 2018;101(12):2105-2110.