

**TRANSDISCIPLINARY VERSUS USUAL CARE FOR TYPE 1
DIABETES IN ADOLESCENCE (PART 2):
RANDOMIZED, CONTROLLED TRIAL**

NIH GRANT # 1-DP3-DK113235

MANUAL OF PROCEDURES

November 19, 2018

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CHAPTER 1

BACKGROUND AND STUDY SUMMARY

1.0. SPECIFIC AIMS

Large epidemiologic studies show that <25% of adolescents with type 1 diabetes (T1D) achieve targeted glycohemoglobin levels advocated by the American Diabetes Association ($\leq 7.5\%$) or International Society of Pediatric and Adolescent Diabetes ($\leq 7.0\%$). Optimal self-management of T1D requires daily insulin replacement by multiple injections or insulin pump, 4-6 daily blood glucose checks, regulation of carbohydrate intake and physical activity, prevention/correction of glycemic fluctuations and perhaps use of a continuous glucose monitor. This regimen places pervasive affective, behavioral, cognitive and social demands on adolescents with T1D and their families and psychosocial variables greatly impact their success in T1D self-care. Struggling with maintaining adequate glycemic control is essentially normative among adolescents, suggesting that conventional systems of care are not meeting the needs of this population. A substantial, growing literature provides an evidence base for psychosocial screening and behavioral intervention strategies targeting improved coping with the demands of T1D, but this evidence base has not penetrated fully into routine T1D care. Rigorous integration of this evidence into routine care for T1D could yield many benefits. Behavioral barriers to effective care are major concerns of all stakeholders, but conventional care is not well-equipped to address these issues. Concomitantly, the supply of board-certified pediatric endocrinologists is not keeping pace with growth of the T1D patient population, amplifying the need to validate alternative delivery systems that multiply the effective workforce of T1D health professionals. We will develop and test a novel Transdisciplinary Care (TC) approach (conjoint TC visits conducted by an Advanced Practice Nurse, Psychology Postdoctoral Fellow and Dietitian) to improve adolescents' T1D outcomes and justify a larger randomized controlled trial (RCT). In Year 1, crowdsourcing methods will engage youths with T1D, parents and health care providers (HCP) in planning a feasible, acceptable, safe and effective TC model that addresses youths' and families' psychosocial needs and capitalizes on the expertise of advanced practice nurses co-managing T1D with psychologists and dietitians. The Wallander et al. stress and coping model and the D'Zurilla and Goldfried problem solving model provide a sound conceptual framework for the TC model of care. The TC team will learn each discipline's skills in T1D management, develop a detailed TC manual to guide this work and others' future studies, see adolescents and parents together as a team, screen for potentially modifiable psychological impediments to T1D care, and promote families' coping resources by enhancing family-centered communication and problem solving, implementing empirically validated behavioral interventions and facilitating additional appropriate services for complex problems. Telehealth delivery of TC care carries several potential advantages, justifying a rigorous RCT in Years 2-3 comparing the effects of UC and of both Face-to-Face and Telehealth delivery of TC on glycemic control and treatment adherence (primary outcomes) as well as quality of life and other psychosocial variables (secondary outcomes). Qualitative and economic analyses will follow the RCT, providing perspectives on mechanisms of TC effects and its sustainability. Mixed qualitative and quantitative methods will validate an innovative model of T1D care for adolescents that could then be tested in a future definitive, multi-site RCT. We will address these specific aims:

SPECIFIC AIM 1. In Year 1, with methods used effectively in our ongoing DP3 study of parents of children <6 years old with T1D, we will engage separate "crowds" of adolescents with T1D, parents, and HCPs in planning/refining a feasible, safe, acceptable and efficacious Trans-Disciplinary care model (TC) for T1D in adolescence. This crowdsourcing effort should yield a TC model that meets the needs of all key stakeholder groups, ensuring its feasibility, acceptance and efficacy.

SPECIFIC AIM 2. With study oversight by a diverse stakeholder panel and guided by a detailed intervention manual, 150 families of adolescents treated for T1D at Nemours practices in the Delaware Valley or Florida will participate in a rigorous Randomized Controlled Trial (RCT) in years 2 and 3. The RCT will compare Usual

Care (UC) with Trans-Disciplinary Care delivered in In-Person clinic visits (TC-IP) or via Telehealth (TC-TH) on glycohemoglobin (HbA_{1c}), treatment adherence, health care use, T1D-related distress, quality of life, and treatment satisfaction. The proposed trial will yield substantial information that could justify a definitive future test of this model, inform methodological planning for subsequent studies, and determine if Telehealth or Face to Face delivery of TC would be more strongly justified for evaluation in future trials.

SPECIFIC AIM 3. Qualitative interviews of adolescents, parents, and health care providers completed at the midpoint and end of the RCT will identify possible mediators or moderators of TC efficacy and guide refinements to the TC model. We will interview third party payers about the feasibility of dissemination of the TC model into practice and collect health care cost data. These analyses will strengthen the justification for a future, larger trial of TC, and guide refinements to the TC model to further enhance its efficacy.

1.1 BACKGROUND

Barriers to T1D care Epidemiologic studies indicate that <25% of adolescents with T1D achieve the HbA_{1c} target of < 7.5%.¹⁻³ T1D care has advanced greatly in emphasizing the merits of long-term glycemic control and through reliance on technological advances (insulin pumps, continuous glucose monitors).⁴⁻¹¹ Adolescents achieve poorer T1D outcomes than other age groups,¹²⁻²⁶ partly due to pubertal insulin resistance.²⁷ But, many studies show that T1D care interacts with psychological variables at the levels of individuals,²⁸⁻⁹¹ dyads/families⁹²⁻⁹⁷ and broader social contexts.⁹⁸⁻¹¹⁴ Treatment adherence declines during adolescence^{26-50,92} and adolescents tend to derive less benefit from technological advances in care.^{8-22,44-48,92} Person-level characteristics of adolescents that impact T1D self-care include adjustment and behavioral problems,^{28-45,49,50,92} presence/absence of depression, anxiety disorders and eating disorders,^{47-90,93,115-118} social support from siblings and peers,^{91,98,99,101-114,119-123} and cognitive processes such as executive functioning and decisional competence.¹²⁴⁻¹³¹ Poor T1D self-care and poor glycemic control resist change, raising risks of major long term complications and psychiatric disorders. Parents of teens with T1D struggle to balance the benefits of youths' self-care autonomy with the risks of mismanaged T1D. This dilemma is a major stressor for parents that may manifest in distress and psychiatric disorders in youths and parents,^{71,132-146} caregiver "burnout" and premature parental withdrawal from involvement in care.^{93,136,147-159} Premature parental withdrawal is associated with many adverse outcomes.^{93,136,147-159} Healthy parent-adolescent teamwork, emotional affiliation and collaborative T1D problem solving are all associated with favorable outcomes.^{98-103, 148-168} Many features of families also predict T1D outcomes,^{96,160-170} which tend to be worse with single-parent family structure or low paternal involvement,¹⁶⁰⁻¹⁷⁰ low socioeconomic status,¹⁷⁰⁻¹⁷⁴ minority status,¹⁷¹⁻¹⁷⁶ higher family conflict,^{70,73,177-182} coercive parenting¹⁸³⁻¹⁸⁵ lower family cohesion¹⁸⁶ and more psychosocial dysfunction in family members.^{71,132,134-146} Little is known about how interactions with HCPs may affect T1D outcomes, but more frequent health care visits predict lower HbA_{1c}.¹⁸⁷⁻¹⁹⁰ Care encounters reflecting patient-centered communication predict greater satisfaction and agreement on the goals of care.¹⁸⁷⁻¹⁸⁹ Current models of care are ill-equipped to respond to these critical behavioral barriers to T1D care that affect so many patients and families. The tentative TC model was specifically designed to address these issues, using empirically validated tools for screening and intervention and it will be refined with deliberate stakeholder input. The proposed work rests on the observations that individual psychological characteristics of patients and parents, family/dyadic interactions around T1D care, and the broader social context of T1D management affect adherence and problem solving, which in turn affect T1D outcomes such as glycemic control, quality of life and health care use. T1D care that does not address these issues seriously cannot be broadly effective.

Psychologically informed T1D care Research on psychosocial influences on youths' T1D outcomes is penetrating T1D care guidelines,¹⁹¹ and many trials of psychosocial screening and intervention have been reported. Structured screening protocols have been validated in several large studies,¹⁹²⁻¹⁹⁴ showing that screening for psychosocial barriers to effective T1D care is feasible, acceptable and may enhance psychosocial outcomes. But, few T1D centers support routine psychosocial screening. Growing evidence also supports the efficacy of various psychological interventions,¹⁹⁵ including treatments for adolescents as individuals or in groups,^{120,196-205} using cognitive behavior therapy,^{195,200} motivational interviewing,^{198,206-209} and skills training targeting coping,²¹⁰⁻²¹² social interactions^{120,201-204} or diabetes problem solving.²¹³ Other

interventions treat families as the unit of treatment, including Behavioral Family Systems Therapy,²¹⁴⁻²¹⁹ Ellis' research on Multi-systemic Therapy,²²⁰⁻²²³ Anderson and Laffel's studies^{34,224-227} of family teamwork interventions and the recent Family Management of Childhood Diabetes trial²²⁸ that all targeted promotion of healthy youth-parent teamwork in T1D care. Investigators are now adapting these interventions for e-health delivery to enhance cost effectiveness and access.²²⁹⁻²⁴³ Few pediatric T1D centers have well-integrated programs that offer these evidence-based services routinely due to lack of availability of behavior change professionals with sound T1D expertise, insurance constraints, perceived stigma around such services, dilution of efficacy of these interventions when delivered in real-world settings, and inadequate communication between community mental health providers and T1D HCPs. The proposed work emphasizes use of screening and intervention methods that can be integrated into typical T1D care, targeting the prevention of common behavioral obstacles, the remediation of mild to moderate issues before they become entrenched and facilitation of intensive services for more complex problems. The proposed work is thus highly consistent with the encouragement of inter-professional care in the Affordable Care Act. As discussed below, telehealth delivery of T1D care^{230,234-243} and behavioral interventions¹⁹²⁻¹⁹⁵ carry many potential advantages, thus warranting consideration as a platform for delivering innovative care to adolescents with T1D and their families.

Models of T1D care Pediatric endocrinologists often direct T1D care supported by diabetes educators, nurses, dietitians, social workers or psychologists. Access to pediatric endocrinologists is concentrated in the Eastern U.S., (1 per 144 youth with T1D) but elsewhere this ratio is one per 300-350 patients²⁴⁴ and most also manage other endocrine problems. The supply of new pediatric endocrinologists is not matching the growth of these populations, and so new models are needed.²⁴⁴ Pediatric endocrinologists recognize psychological barriers to T1D care, but neither their training, workflow nor payment practices facilitate addressing those barriers. An alternative care model is needed to address behavioral barriers to T1D care by engaging parents and youth as key members of the care team, screening and prevention for psychosocial problems, promoting healthy problem solving and communication about T1D care, applying empirically validated intervention tools for families with mild/moderate barriers and obtaining more intensive services for families who need them.

Table 1. Comparison of Multidisciplinary, Interdisciplinary and Transdisciplinary models of care.

	MULTIDISCIPLINARY	INTERDISCIPLINARY	TRANSDISCIPLINARY
Professional activities	Additive	Interactive	Holistic
Knowledge of others' disciplines	Minimal	Incidental	Intentional and thorough
Interactions among disciplines	Distinct professional boundaries	Coordination of input from separate disciplines	Integration yields a whole exceeding sum of its parts
Boundaries between disciplines	Distinct and preserved	Blurred	Negligible
Expanded roles for all team members	Absent	Limited and passive	Integral to the model
Subordination of discipline in favor of achieving an integrated perspective	Absent	Limited and passive	Integral to the model

Engaging several disciplines in T1D care occurs on a spectrum of delivery models.²⁴⁵⁻²⁴⁹ **Multidisciplinary care**, typifying much U.S. T1D care, engages several disciplines, but each stays within its boundaries. **Interdisciplinary care** deliberately analyzes, synthesizes and harmonizes links between disciplines into a coordinated whole. **Transdisciplinary care** integrates the disciplines in a humanistic context transcending traditional boundaries. Put simply, inter-professional interaction is additive in Multidisciplinary Care, interactive in Interdisciplinary Care and holistic in Transdisciplinary Care. Research has supported TC models in scientific research initiatives involving multiple disciplines²⁴⁸⁻²⁵² and delivery of care for many clinical problems.²⁵³⁻²⁶⁸

Trans-Disciplinary Care (TC) is conjoint delivery of T1D care by a team of HCPs from different disciplines who share the knowledge base and tools of their respective professions. In this study, TC teams (Advanced Practice Nurse/APN, Registered Dietitian/RD and Psychology Post-Doctoral Fellow/Psy.

Fellow) will see families jointly at visits and collaborate in care delivery by integrating their respective knowledge and skills. Pediatric endocrinologists will monitor enrolled patients. A TC model will be refined iteratively based on stakeholder input and tested in a careful randomized controlled trial (RCT). We hypothesize that TC will achieve better T1D outcomes than Usual Care. **This application is based on the premise that current care is failing most adolescents and that careful user-centered design²⁶⁹ and testing of an innovative Transdisciplinary model of care can better address psychosocial barriers to T1D management, improving outcomes via better assessment of patients' needs and resources, better cross-discipline and parent-adolescent-HCP communication, and better collaboration with families to resolve problems that cross disciplines.** This work can validate an innovative TC model, justifying its testing in a larger RCT. A pilot evaluation of a telehealth intervention for teens with T1D delivered by a nurse-social worker team yielded excellent visit attendance among adolescents and self-care improvements in the intervention group.²⁷⁰ That care model did not employ evidence-based psychological principles and practices. We have based the TC model in a conceptual framework combining the Wallander et al²⁷¹ Chronic Disability Stress and Coping Model, treating the elements of TC as coping resources within that scheme; and the D'Zurilla and Goldfried Problem Solving model,²⁷² a framework that underlies our trials of Behavioral Family Systems Therapy for Diabetes²¹⁴⁻²¹⁹ and other intervention trials.^{213,220,224,225,228,273-277} TC will encourage constructive, patient-centered communication via Motivational Interviewing skills^{198,206-209} and it will promote active group problem solving. TC team members will use a toolbox of methods from prior studies to resolve common clinical problems^{198-202,205,213-220,224,228-243,273,274,278} Multi-systemic Therapy in T1D promotes engaging home, school, peer and health care systems in planning and delivery of that intervention,²²⁰⁻²²³ but that work has not emphasized changing health care delivery to better address psychosocial barriers to care. We expect that knowledge and skills of TC team members in one another's disciplines will be enhanced and that this will improve recognition, analysis and resolution of each adolescent's barriers to T1D self-care.

Growth of Telehealth Delivery of T1D Care and Psychological Interventions The promulgation of telehealth delivery of T1D medical care and behavioral health interventions is likely to continue.^{230-243,278} Telehealth delivery of TC could facilitate families' access to needed specialized care, capitalize on the emergence of systems for remote monitoring and communication of clinical data, and enable dissemination of TC across geographic and institutional boundaries. Thus, a key element of this application is comparison of TC delivered via conventional face to face encounters versus telehealth delivery, which will be achieved by relying on Nemours' established relationship with American Well, using its AW9 telehealth platform.

1.2. RESEARCH STRATEGY: INNOVATION

Fewer than 25% of adolescents with T1D achieve the HbA_{1c} target of $\leq 7.5\%$. If indeed "**every system yields exactly the results that it was designed to achieve**",²⁷⁹ the system of T1D care for adolescents requires re-thinking. Youth and their families face challenging affective, behavioral and cognitive impediments to valued T1D outcomes and typical T1D care is ill-equipped to address these issues. Few pediatric T1D centers address these challenges well since there are too few behavior change professionals with T1D expertise, reimbursement issues, stigmatization around such services, reduced efficacy of validated interventions in real-world settings, and barriers to communication between mental health providers and T1D HCPs. The proposed work would carefully plan and test a novel TC model that identifies and targets psychological barriers to optimal care and engages stakeholders in designing and testing the TC model. As in our ongoing grant (DP3-DK-108198) we will use crowdsourcing^{280,281} to elicit stakeholder input to design and test a TC model for adolescents with T1D that is acceptable, safe, and effective. We propose a novel intervention that could be more effective than usual multidisciplinary care. TC may reduce demands on pediatric endocrinologists, freeing them to care for endocrine problems that clearly require subspecialty expertise. Extensive stakeholder input, focused qualitative work before, during and after the RCT and the planned economic analyses also enhance the potential impact. Comparison of face to face with telehealth delivery of the TC model amplifies the novelty of this work. The proposed work could provide justification for similar trials with other medical conditions.

Crowdsourced Design of a Web Resource for Parents: Our use of crowdsourcing (DP3-DK-108198) to design and test a social media portal for parents of very young (<6 y.o.) children with T1D will be re-purposed in the proposed work. In the ongoing study, we have enlisted 170 Parent Crowd members and 32 U.S.

pediatric endocrinologists and other professionals as HCP Crowd members. A 6-member Family Advisory Council guides the research team. With expert input from Dr. Karen Aroian, Chatlos Endowed Professor of Nursing at the U. of Central Florida, the Parent Crowd answered open-ended questions and polls about their perspectives as parents of very young children with T1D. To date, 19 open-ended questions have been sent to the Parent Crowd, and a mean of 128 parents (74% of members) sent free-text replies averaging ~120 words. Also, 7 polls about narrower issues yielded similar response rates. Only 18 Parent Crowd members have not replied to a question or poll. Systematic coding has yielded a detailed taxonomy that will drive the content and functions of the planned website. The distribution of parallel open-ended questions to the HCP Crowd has just begun. We are systematically mapping the resulting content into website functions that will be iteratively refined with crowd input until a final website has been designed and built. Results to date support an adapted Social-Ecological Model framework for organizing the voluminous content that has been compiled. A randomized controlled trial of website use on parental coping and child outcomes will follow, including qualitative interviews of trial participants at the midpoint and end of the trial. This experience will facilitate the design and evaluation of a TC model of care that is planned with careful consideration of diverse views and is acceptable to all stakeholder groups. Application of these methods to crowdsourced design of the TC model should be even more successful given the much larger clinical population of adolescents with T1D.

Qualitative Interviews of Stakeholders: We have completed qualitative interviews of 6 adolescents with T1D, 6 parents, 5 HCPs and 3 administrators with expertise in health care reimbursement about the feasibility of TC. These interviews yielded very positive reactions to the TC model, and respondents offered constructive suggestions that could improve its feasibility and acceptability. Parents and adolescents were especially enthusiastic about the possibility of telehealth delivery of TC. Stakeholder input has been incorporated into our initial TC design and these interviews will guide continued qualitative work during the initial phase of this grant. Until notice of funding, responding to some complex points will be deferred to the initial planning phase of this grant. Dedication of major time and effort to address those points is not justified until funding is certain.

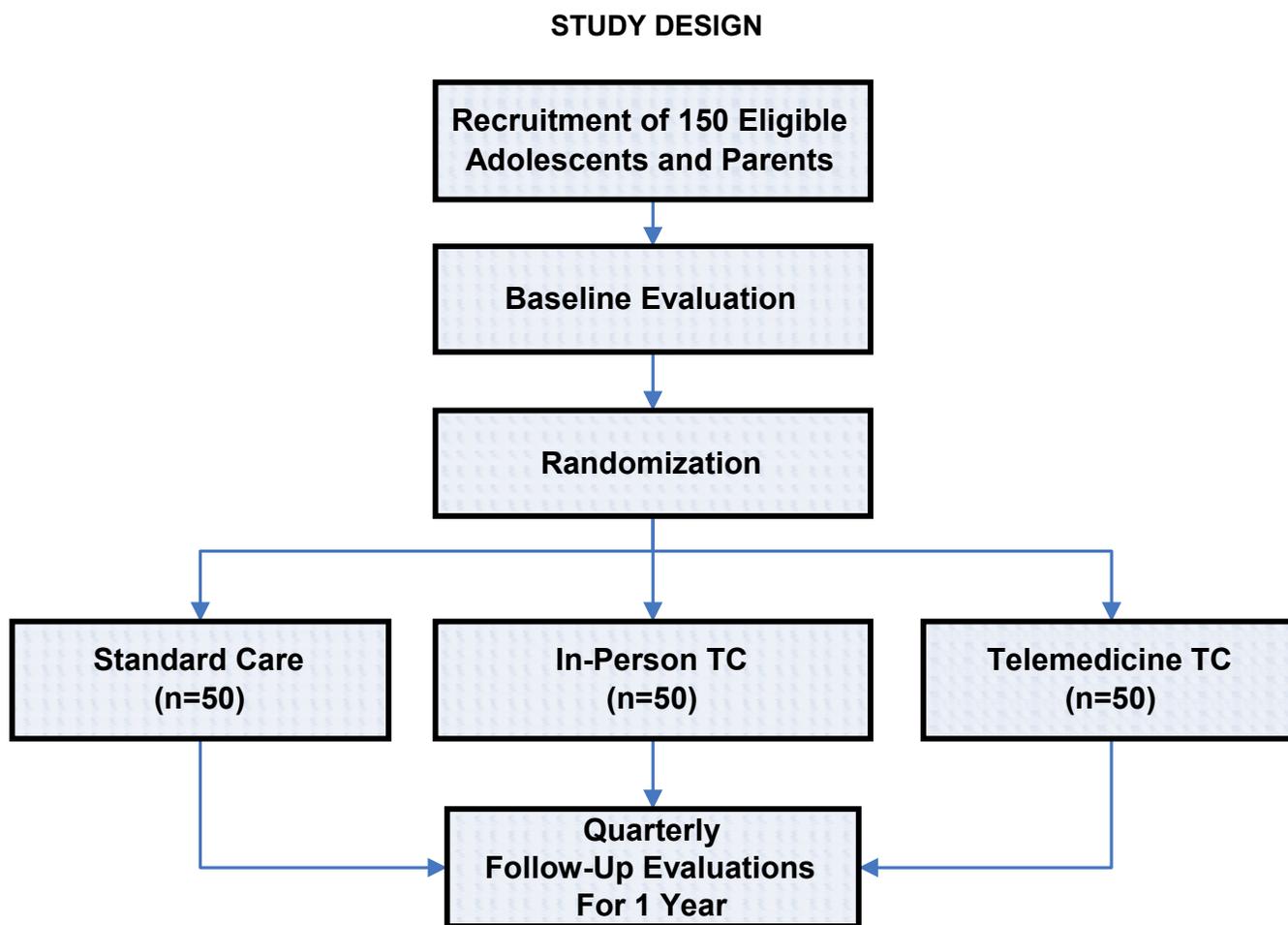
1.3. PROGRESS TO DATE

This grant award provides support for a 2-part research plan. Part 1 consisted of the refinement of the Transdisciplinary Care model for adolescents with type 1 diabetes that was achieved from September, 2016 through May, 2018. These steps in achievement of Specific Aim 1 occurred during that period:

- Recruitment, hiring and assignment of project staff including Psychologists, Dietitians and Advanced Practice Nurses
- Assignment of existing staff to Research Coordinator roles on the project
- Training of Transdisciplinary Care team members in one another's professional disciplines
- Role playing simulations of typical Transdisciplinary care clinic visits
- Distribution of 26 open-ended questions about experiences and perspectives related to T1D clinic visits among online communities consisting of 35 parents and 35 adolescents with T1D who served as advisors to the research team. Qualitative analysis of their responses will be used to guide refinements to the TC model and will be reflected in the recruitment of participants.
- Interaction with Nemours electronic medical record EPIC team to establish detailed procedures for the scheduling, documentation, and billing of research visits for TC participants.
- Consideration of alternative procedures for TC-Telehealth patients to obtain vital signs, height, weight, and blood samples for glycosylated hemoglobin assays at key points during the trial. Selection of the Vidyo platform as the principle means of implementing TC-Telehealth visits during the study, primarily because it permits screen-sharing capability that is not available through American-Well.
- Research Coordinators have been trained in use the EPIC Research Module for recruitment, scheduling, implementation of clinic visits, documentation and billing tasks for clinic visits associated with research studies. Only the four research coordinators will be able to schedule TC visits for study participants.
- Training materials are in development for parents and adolescents who are randomized to TC-Telehealth so that they are able to connect easily via the Vidyo platform and so they can share their device data downloads (e.g., insulin pump, glucose meter, CGM, etc.) with the TC team prior to scheduled visits.
- Nemours IRB#1 has approved the randomized, controlled trial. See IRBNet project #1211467.

1.4. Part 2: RANDOMIZED, CONTROLLED TRIAL

The diagram below summarizes the key elements of the experimental design employed in the randomized, controlled trial that comprises Part 2 of the Research Strategy. Part 2 of the Research Strategy is the subject of this manual of procedures. The chapters that follow provide details about each of these elements of the randomized, controlled trial.



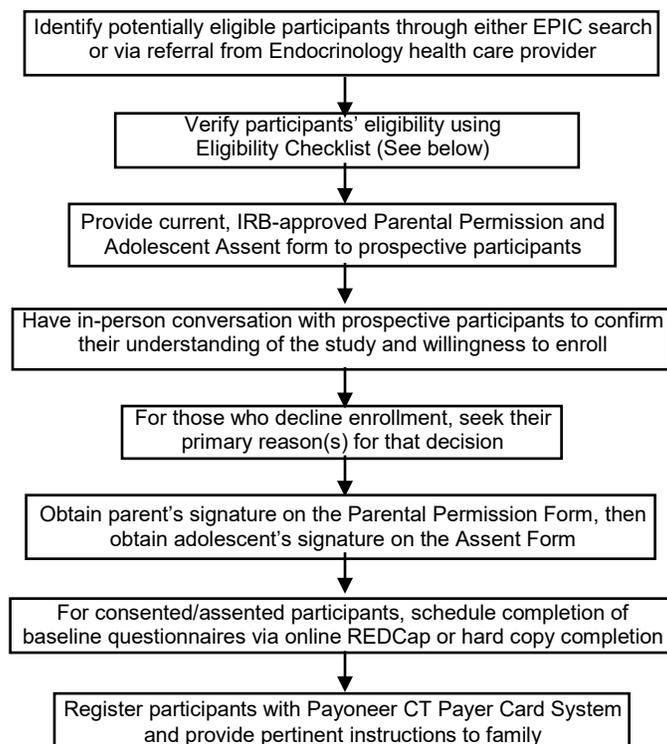
CHAPTER 2.

ELIGIBILITY, RECRUITMENT, PARENTAL PERMISSION AND ASSENT

2.1. Eligibility: The RCT would test the TC model with appropriate clinical candidates who could benefit from a relatively low intensity intervention but who may not need more intensive psychological services. We will enroll 150 Nemours T1D patients at Nemours Children’s Hospital (NCH) in Orlando, FL, or the Alfred I. du Pont Hospital for Children (AIDHC) in Wilmington, DE (~75/site), including ~21 African American and ~21 Hispanic youth (~28% minorities). The Facilities and Resources section confirms the feasibility of the sampling plan. Each parent/youth will sign IRB-approved Parental Permission and Assent Forms prior to participation. State laws require that participants in telehealth sessions must all be physically present in a state in which the participating HCPs are licensed and the team will ensure this. Youth eligibility criteria are: Age, ≥ 11 and < 17 yrs old; T1D for > 1 yr; Most recent HbA1C or mean HbA1C over the prior year 7.5-10.0%, inclusive; Able to complete questionnaires in English; No other medical obstacles to participation per the treating MD; No concurrent enrollment in other T1D studies, and no T1D clinic visits in the preceding 12 months in which two or more care providers saw the patient together. Parent eligibility criteria are: Biological parent/legal caregiver of an enrolled patient; At least weekly involvement in T1D care; Able to complete questionnaires in English; Plans to continue T1D care at Nemours for > 1 yr. Two parents of the same child may enroll, but they would jointly complete one set of questionnaires. HCPs (MDs, Advanced Practice Nurses, Dietitians, and Psychology Fellows) also contribute data and will provide informed consent. A racially and ethnically diverse Family Advisory Committee of 4-6 adolescent-parent dyads recruited from among enthusiastic members of the Parent and Adolescent Crowds will provide ongoing study guidance during monthly conference calls.

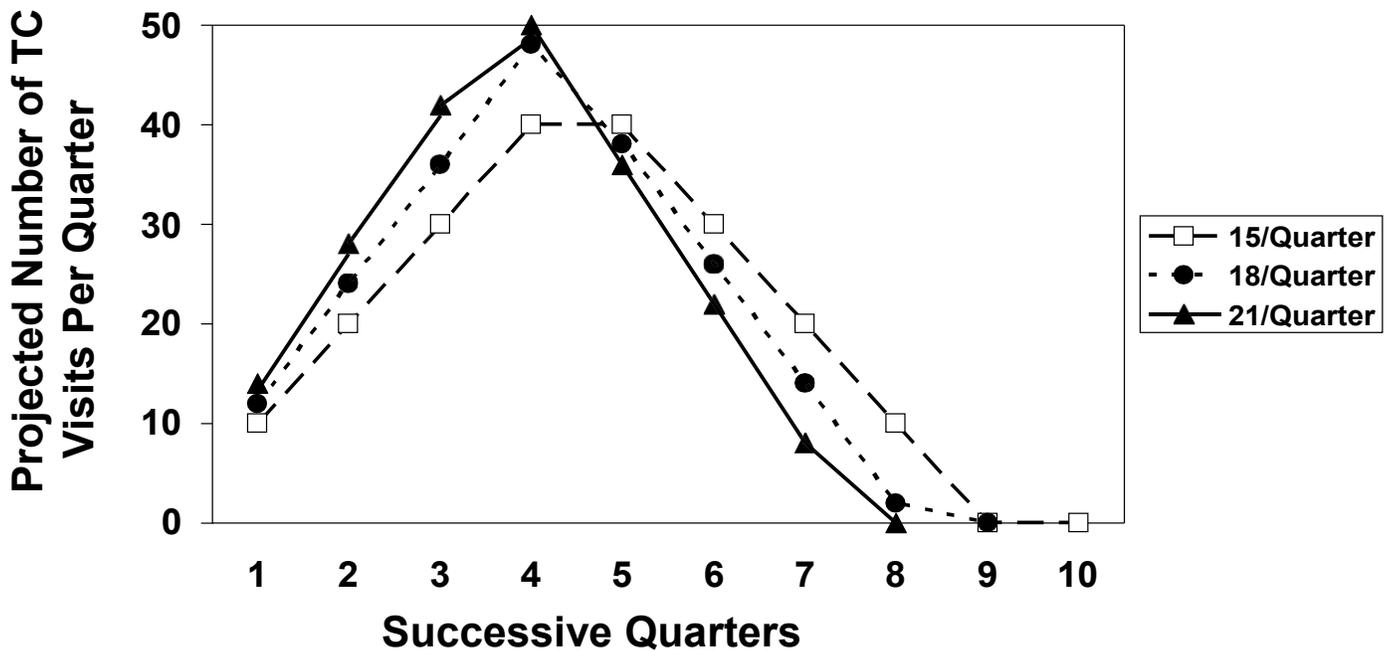
2.2. Parental Permission and Adolescent Assent Process: The objective of the Parental Permission and Assent process is to ensure that parents and adolescents who are considering enrollment do so from a position of being thoroughly informed about the study rationale, aims, procedures, risks and benefits so that they can make a completely voluntary decision about whether study participation is in their interests. The role of research staff in conducting this process is to help parents and adolescents make autonomous decisions about whether to enroll and, once enrolled, whether to continue participating. See **Chapter 6. Responsible Conduct of Research** for details about the Parental Permission and Assent Process for this project.

2.3. Recruitment Process and Rate:



Recruitment Rate: The figure and tables below summarize the projected accumulation of TC visits required for study participants based on several different rates of participant recruitment. The conclusion from this analysis is that a recruitment rate of 18 participants per quarter per site (6 per month) will meet the enrollment objective in just over 1 year and will require only one quarter in which the maximum of 50 TC visits will need to be scheduled. A slightly faster recruitment rate of 21 participants per quarter will result in earlier completion of the RCT, while a recruitment rate of 15 participants per quarter will decrease the clinical workload of the TC team members but at the expense of prolonging completion of the study

Projected Quarterly TC Visits as a Function of Several Enrollment Rates



Enrollment and randomization of 75 families per site will result in two-thirds of families being randomized to the two Transdisciplinary Care groups and the others to Usual Care. At each enrollment rate, the peak number of TC visits occurs at one year into recruitment. The peak value ranges from 38-50 depending on enrollment rate, with more rapid recruitment yielding a higher peak. The above projections ignore failed appointments and study dropouts, both of which would reduce the projected number of TC visits. At the highest projected number of quarterly TC visits (50 or about 16-17 visits per month), and an estimate of 2.5 hours per visit, total time for the nurse practitioner, dietitian and psychologist in delivering the TC model of care to study participants would be about 41 hours per month. At 3 hours per TC visit, this would increase to about 51 hours. The time and effort demands on these staff would be lower in the months preceding and following the peak of clinical activity. The figures underlying these estimates are shown in the tables on the next page.

Recruitment of 15 families/quarter; 10 to TC groups

Quarter	Cum # New Enrollments	# Needing TC F/U Visits	# Active For \geq 12 Mo	# Active Participants	Total TC Visits
1	10	0	0	10	10
2	20	10	0	20	20
3	30	20	0	30	30
4	40	30	0	40	40
5	50	40	10	50	40
6		50	20	40	30
7			30	30	20
8			40	20	10
9			50	10	0
10				0	0

Recruitment of 18 families/quarter; 12 to TC groups

Quarter	Cum # New Enrollments	# Needing TC F/U Visits	# Active For \geq 12 Mo	# Active Participants	Total TC Visits
1	12	0	0	12	12
2	24	0	0	24	24
3	36	0	0	36	36
4	48	0	0	48	48
5	50	12	12	38	38
6		24	24	26	26
7		36	36	14	14
8		48	48	2	2
9			50	0	0

Recruitment of 21 families per quarter: 14 to TC groups

Quarter	Cum # New Enrollments	# Needing TC F/U Visits	# Active For \geq 12 Mo	# Active Participants	Total TC Visits
1	14	0	0	14	14
2	28	0	0	28	28
3	42	0	0	42	42
4	50	0	0	50	50
5		14	14	36	36
6		28	28	22	22
7		42	42	8	8
8		50	50	0	0
9				0	0

Transdisciplinary Care Study
Recruitment Eligibility Checklist

Please review the following eligibility criteria and check all that apply. If any criterion is not checked, then the patient will be excluded from study participation.

Patient

- Age \geq 11 years but < 17 years at time of consent
- Plan to live at home for the rest of their participation in this study
- Have been diagnosed with T1D for at least 1 year
- Most recent HbA1C or average for the past year 7.5% to 10.0% inclusive
- Have had at least two T1D clinic visits in the prior year
- Have a parent or other legal caregiver who also agrees to be in the study or gives permission for the adolescent to be in the study
- Can speak and read English well enough to complete questionnaires
- Have made normal progress in school (Not retained for more than one grade level)
- No other medical obstacles to participation per the treating MD
- No concurrent enrollment in other T1D studies
- No T1D clinic visits in the preceding 12 months in which two or more care providers saw the patient together
- Live in a state that allows health professionals to legally provide health care services to them by telehealth when the health professional is in Florida or Delaware at the time of that service

Parent/Legal Guardian

- Is either a biological parent or legally appointed caregiver of an enrolled patient
- Has at least weekly involvement in T1D care
- Can speak and read English well enough to complete questionnaires
- Plan for the adolescent to keep receiving diabetes treatment at the medical facility where child receives diabetes care for their duration in the study
- Live in a state that allows health professionals to legally provide health care services to them by telehealth when the health professional is in Florida or Delaware at the time of that service

Study ID: _____

Date: _____

Transdisciplinary Care RCT
Enrollment/Baseline Visit Checklist

- Complete eligibility checklist with family
- Review consent with parent(s) and assent with adolescent; sign and date
- Give signed copy of consent and “Becoming a Research Volunteer” handout to the family
- Have parent complete the Contact Information sheet
- Give family REDCap handout and review it with them. Inform them they will receive an email with links to complete the baseline surveys and they should be completed as soon as possible.
- If the adolescent does not have his/her own email account, give them the handout about creating a new email account (each participant requires their own individual email account).
- If families prefer to complete the baseline forms on paper copy in clinic, they can do so instead of completing them online.

After visit:

- E-mail scanned consent, assent (signature pages only) eligibility form, and Contact Information sheet to Alex Taylor at NCC-Jacksonville
- Complete Consent Log
- Submit signed parental consent form (not assent) to be scanned into patient’s medical record
- Complete research encounter in EMR and close encounter
- Add new patient to REDCap system and send baseline surveys to the parent and adolescent
- Obtain A1c value from EMR/Endocrinology clinic and enter in REDCap
- Complete the patient’s visit information in the electronic Patient Database
- Note participant’s next endocrinology visit on your calendar and on the patient spreadsheet

After all baseline questionnaires have been completed:

- Inform Alex Taylor that all questionnaires have been completed and she will send you the family’s randomization
- Inform family of their group assignment
- For families randomized to either of the two Transdisciplinary Care Groups (**In-Person Group** or the **Telehealth Group**), schedule Family’s next appointment with the Nurse Practitioner, Registered Dietitian and Psychologist/Post-Doctoral Fellow

- For families randomized to either of the two Transdisciplinary Care Groups (**In-Person Group** or the **Telehealth Group**), inform Nurse Practitioner, Registered Dietitian and Psychologist/Post-Doctoral Fellow of patient's enrollment in the study, the group they were randomized to and of their next appointment date/time
- Alex will send Liz list of participants that need a CT Payer card mailed to them
- Liz will credit participants' CT Payer card with \$25 payment for completing the measures

Use of IRB-Approved Study Flyer

The IRB-approved protocol and the Initial Application for IRB Review do not stipulate any specific method(s) of distribution of the study flyer to prospective participants. Project staff are therefore free to distribute the flyer to potentially eligible patients in hard copy either in person or by mail, electronically via e-mail, text messages or posting on an internet site, or reproduced in other print media such as newspapers, newsletters or magazines. The flyer version with current IRB approval at any given time must always be used.

TC Study

Follow-Up Visit Checklist:

Visits in Months

3 6 9 12

	<input type="checkbox"/>		<input type="checkbox"/>	Confirm that questionnaires have been completed prior to visit and if not, have family complete at visit
	<input type="checkbox"/>		<input type="checkbox"/>	Liz will credit \$25 to each participant's CT Payer card that completes the Questionnaires
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Obtain A1c value from EMR/Endocrinology Clinic & enter in REDCap
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Download Devices: (Youth will receive \$5 per device credited to their CT Payer Card for downloading a glucose meter, insulin pump or continuous glucose monitor prior to each visit). Notify Alex each time this is done so she can credit their CT card.
			<input type="checkbox"/>	All 3 groups: At the end of the 12 month visit, give each of the HCPs a hard copy of the Physician Satisfaction Questionnaire (PSQ) and enter responses in REDCap
			<input type="checkbox"/>	<u>All 3 groups</u> : Give each of the HCPs a hard copy of the Team Decision Making Questionnaire (TDMQ) and enter responses in REDCap
	<input type="checkbox"/>		<input type="checkbox"/>	<u>TC Groups Only</u> : Mid and Post RCT Qualitative Interviews will be done with HCPs and adolescents/parents as respondents.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter the Visit Information and any hard copy questionnaires in REDCap
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete visit information in the electronic Patient Database
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete research encounter in EMR for the study visit and close encounter
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<u>TC Groups Only</u> : Schedule next appointment for family with the 3 HCPs and input date into Patient Database and write on personal calendar

BECOMING A RESEARCH VOLUNTEER: IT'S YOUR DECISION

What Is Research?

- Research is a study that is done to answer a question.
- Scientists do research because they don't know for sure what works best to help you.
- Some other words that describe research are clinical trial, protocol, survey, or experiment.
- Research is not the same as treatment.

Why Is Research Important?

Research has led to important discoveries that make our lives better. Some examples are:

- New drugs to treat cancer, diabetes, and other diseases
- Ultrasound, X-ray machines, and diagnostic tests
- Vaccines
- Ways to stop smoking
- Improved medical procedures

Points to Consider

- A research study may or may not help you personally.
- In the future, the results could help others who have a health problem.
- Taking part in research is voluntary.

Someday, you or a family member may want to take part in a research study. If this happens, the information here may help you make the right decision.

Questions to Ask

- What exactly will happen to me in the research?
- Will there be any unpleasant side effects?
- Will the research help me personally?
- What other options do I have?
- Can I leave the study at any time?
- Will it cost me anything personally?

Research discoveries can improve people's health.

Before you decide to become a research volunteer, get the facts:

- Know what you're getting into.
- Ask questions.
- Learn as much as you can.
- Know the pros and cons.

It's Your Decision

For more information call:

The Nemours Office of Human Subjects Protection:
904-697-4023
Toll Free: 1-800-SOS-KIDS
Email: NOHSP@nemours.org

Office for Human Research Protections
Toll-Free (866) 447-4777
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
www.hhs.gov/ohrp
Fax: (301) 402-0527
E-mail: ohrp@osophs.dhhs.gov

CHAPTER 3.

MEASUREMENT PROTOCOL

3.1. Measurement Schedule and Protocol:

Measures will be obtained at clinic visits at Baseline and ~quarterly for 1 year. Primary outcomes are change in HbA_{1C} and the Diabetes Self Management Profile Self-Report Form total score over 1 year. Other planned measures will be reviewed and refined by the Adolescent and Parent Crowds during RCT planning. To promote retention and minimize missing data, each participant will receive \$25 credited to a CT-Payer Card when all measures scheduled for a visit are completed. Online completion of questionnaires will be available for those with internet access using REDCap. Those who do not complete questionnaires online before visits can do so at visits via PC, tablet or hard copy or online during TC visits. Table 3 shows the measurement schedule, including estimated participation burden per measure. Respondents are indicated by A (Adolescent), P (Parent) or HCP (Health Care Provider). Participation burden has been minimized in several ways. Questionnaire completion is limited to study visits at 0, 6 and 12 months rather than every quarterly visit. Questionnaire completion time at the Baseline visit is 75-80 minutes for parents and adolescents and 65-70 minutes at 6 and 12 months. Online completion of questionnaires via REDCAP can minimize inconvenience by enabling participants to complete questionnaires at convenient times or over several distinct periods.

Table 3.1. Measurement schedule.

Measures	Burden (Min/Visit)	~Quarterly Clinic Visits				
		0	3	6	9	12
Demographic Information (P)	10	•				
HbA _{1C} ; Device downloads (A,P)	20	•	•	•	•	•
Health Care Use Survey (P; EMR)	5	•	•	•	•	•
Hilliard et al Quality of Life Scales (A, P)	15	•		•		•
Diabetes Self Management Profile-Self Report (A,P)	15	•		•		•
Problem Areas in Diabetes Scale (A,P)	15	•		•		•
Collaborative Parent Involvement Scale (A)	5	•		•		•
Family Centered Care Assessment Scale (A,P)	10	•		•		•
Readiness Assessment for Emerging Adults with Diabetes Diagnosed in Youth (A)	10	•		•		•
Diabetes Choices Scale (DCS) (A)	10	•		•		•
Team Decision Making Questionnaire (HCP)	10					•
Physician Satisfaction Questionnaire (HCP)	5					•

Demographic information: This form records child and parent age, gender, race, ethnicity, family composition, education, occupational category, socioeconomic status²⁸⁴ and certain details of the child’s medical history.

Glycohemoglobin (HbA_{1C}) will be measured using point of care devices at the respective clinics, at the NCH or AIDHC labs, or at insurer-mandated labs certified by the National Glycohemoglobin Standardization Program, to index recent glycemic control.²⁸⁵⁻²⁸⁶ TC-TH patients can do this at many Nemours Endocrinology or Urgent Care clinic sites in the Delaware Valley or Central Florida, or at a designated external lab as required by the patient’s insurance, so results will be available at visits. For those who cannot obtain an HbA_{1C} result in one of those ways, the procedure for collecting and processing dried blood spot samples detailed in the Appendix provides an alternative method that can be used if absolutely necessary.

See Appendix A1 for instructions for reporting Dried Blood Spot HbA_{1C} results to Nemours Health Information Management for scanning into each participant’s EMR.

Device Download Summary: Youth will receive \$5 credited to a CT Payer Card for downloading a glucose meter, insulin pump or continuous glucose monitor prior to each study visit (Adolescents bringing multiple glucose meters will be paid \$5 for each meter they provide). These data will quantify monitoring frequency/use, mean and SD of blood glucose, mean daily glycemic excursions²⁸⁷⁻²⁸⁹ and, for insulin pump users, mean daily

frequency of pre-meal bolus infusions. A device download summary of these measures will be prepared and entered by the research coordinator for each patient visit.

Health Care Use Survey: At or prior to each visit, parents will complete Section 1 of the Health Care Use Survey for tracking health care use, including hospital and ED admissions as well as primary care and urgent care visits.^{290,291} We will use EHR data to measure the interval between electronically recorded check-in (or login for TC-TH) and check-out times (logout for TC-TH). At the end of each visit, parents will also estimate time expended for each visit, including travel, using Section 2 of the Health Care Use Survey.

Diabetes Self Management Profile-Self Report Version (DSMP-SR): Among T1D adherence measures,²⁹²⁻³⁰² the 24 item DSMP-SR assesses self-care behaviors that typify current T1D care and it has a mean correlation of .48 with HbA_{1c}, α of .79 and parent-youth correlation of .63.²⁹⁷⁻³⁰⁰

Hilliard, et al. Quality of Life Scales (H-QOL): Marisa Hilliard is conducting validation studies of age-adapted revised versions of a Quality of Life scale³⁰⁴ that will be completed by adolescents and parents who are RCT participants. Internal consistency has been established in prior work and data collection has been completed to permit factor analyses and possible condensing of the measure to fewer items. We will utilize the condensed versions when they become available.

Physician Satisfaction Questionnaire (PSQ): The 20 item PSQ³⁰⁵ is completed by a health care provider who rates the quality of the patient-provider relationship ($\alpha = .84$); adequacy of obtained clinical information ($\alpha = .74$); efficient use of time ($\alpha = .74$); and absence of excessive patient demands ($\alpha = .65$). Total scale α was .82. HCPs will complete the PSQ after the final study visit for each patient and higher scores reflect greater HCP visit satisfaction.

Problem Areas in Diabetes Scale (PAID): (Youth and parent versions). Respondents rate their agreement with 26 statements related to their worry and burden about their diabetes.³⁰⁶⁻³⁰⁸ Items are rated on a 6-point scale from “not at all” to “serious problem”, and higher scores reflect less perceived burden/worry. Wasserman et al.³⁰⁹ recently validated condensed versions of both scales that we can consider using in the RCT.

Family Centered Care Assessment (FCCA): (Adolescent and Parent versions). Adolescents and parents will complete the respective forms of this 24-item scale that quantifies the extent to which a recent health care encounter fulfilled the core principles of family-centered care. The instrument was developed with extensive stakeholder involvement and its psychometric properties were verified in a sample of 790 adolescents and parents.³¹⁰⁻³¹¹

Collaborative Parent Involvement Scale (CPI): The 12-item CPI obtains youths' level of teamwork in T1D care with a specified adult.¹⁵⁷ Those living with two parents will complete the CPI separately about each. Higher total scores indicate that the youth perceives more T1D collaboration with that caregiver. Cronbach's α was .93 and .96 for youths' ratings of primary and secondary caregivers, respectively.

Diabetes Choices Questionnaire (DCQ): The DCQ is an adolescent self-report measure of the frequency at which they engage in each of 34 diabetes-specific risk-taking behaviors. Wasserman and colleagues have presented initial psychometric data and a larger-scale validation study has been completed and results are expected soon.

Transition Readiness Assessment for Emerging Adults with Diabetes Diagnosed in Youth (READDY): This is a scale on which adolescents and young adults with T1D report on their readiness for transition to adult care by assessing their current ability to exhibit each of 46 skills that are presumed to mediate a successful transition. The instrument is in development by Coroathers, et al. at Cincinnati Children's Hospital and Medical Center and appropriate validation data should be available prior to recruitment for the present RCT.

Team Decision-Making Questionnaire (TDMQ): This 19 item scale measures the depth of inter-professional collaboration within multi-HCP teams.³¹² The scale has strong α (.86) and temporal stability (.92). Principal

components analysis yielded four primary factors: Decision Making, Team Support, Learning, and Developing Quality Services. The TDMQ will be completed by all physicians, nurses, dietitians, and psychologists just after the final study visit for each enrolled adolescent.

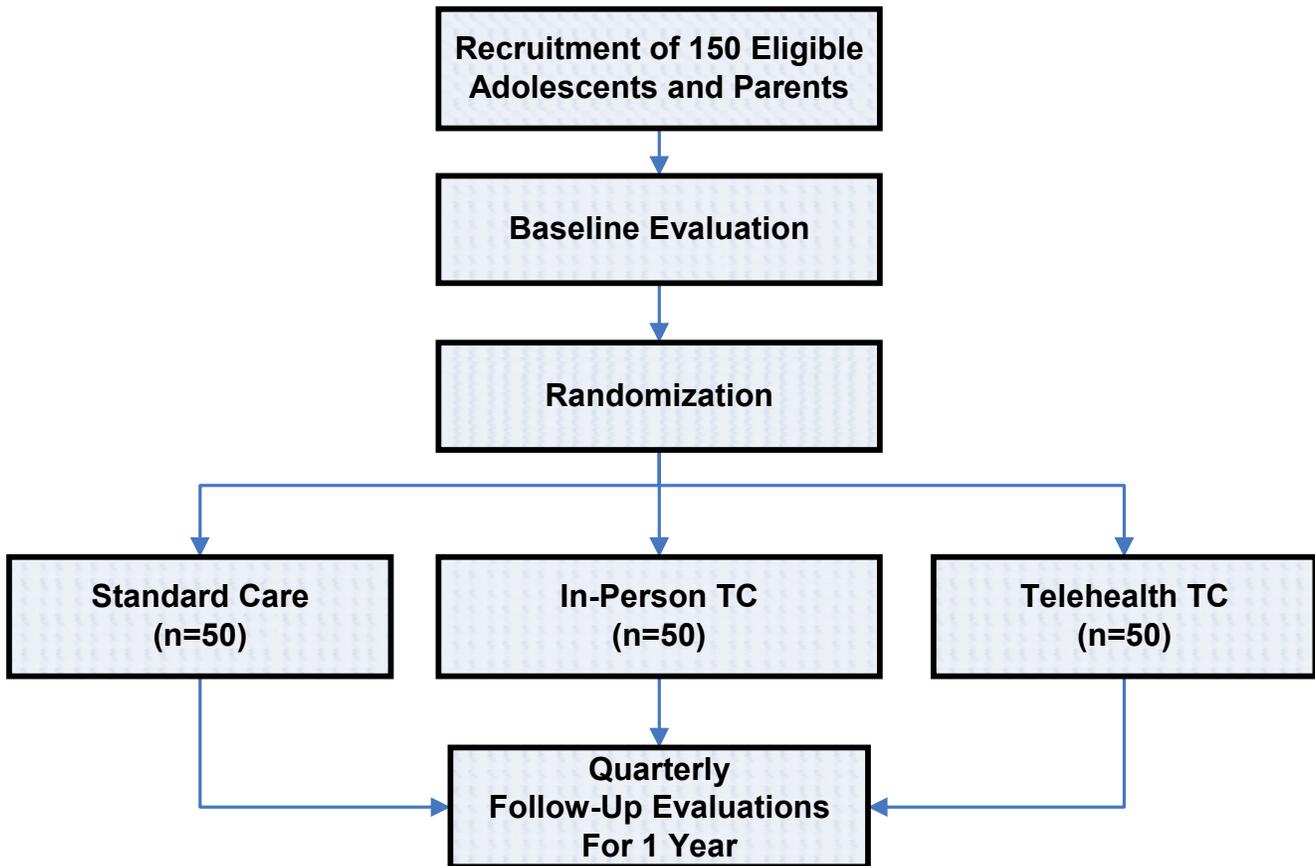
Mid- and Post-RCT Qualitative Interviews: These interviews (See Appendix) will obtain parent/adolescent views of the TC process, factors affecting its efficacy, advantages/disadvantages of the model, and suggested refinements. Qualitative interviews of representatives of third party payers will seek their views of the viability of the TC model, based on the RCT results and costs relative to UC. Audio recordings of interviews will be transcribed verbatim and coded by trained coders under the supervision of Dr. Aroian.

CHAPTER 4.

EXPERIMENTAL DESIGN, RANDOMIZATION, AND STUDY CONDITIONS

4.1. Experimental Design

The experimental design is a 3 (Treatments) X 5 (Measurements) between-group, randomized treatments design. The three treatment conditions include: Usual Care; Transdisciplinary Care-In Person; and Transdisciplinary Care-Telehealth. Measurements will occur at Baseline (0 months) and approximately quarterly thereafter (3, 6, 9 and 12 months after Baseline). An equal number of participants (n=50) will be randomized to each of the three treatment conditions. About 75 participants will be enrolled at each of the two sites in Orlando and Wilmington. The graphic below depicts the experimental design and randomization procedures schematically.



4.2. Randomization

The Jacksonville Research Coordinator will construct randomization lists that assign a given patient to either Usual Care ("1"), TC-IP ("2") or TC-TH ("3"). Using tables of random numbers, the Research Coordinator will construct separate randomization lists for the two performance sites (Orlando and Wilmington) and each list will be further stratified by Baseline HbA_{1c} ($\leq 8.7\%$ or $> 8.7\%$), ensuring that the two centers have similar numbers of participants in each study arm and that the mean Baseline HbA_{1c} is similar for the three treatment conditions. The lists will be constrained such that no list will have more than three consecutive assignments to the same treatment condition and each list will contain exactly 10 1's, 2's and 3's within a given sequence of 30 treatment assignments.

Research Coordinators in Wilmington and Orlando will notify the Jacksonville Research Coordinator(s) when an enrolled adolescent and parent have completed all Baseline data collection responsibilities. At that time, the Jacksonville Research Coordinator will consult the pertinent randomization list for that site and for the adolescent's Baseline HbA_{1c} result. The adolescent and parent will then be randomized to the treatment condition that appears next in the randomization list sequence. Once that assignment is made, the Research coordinator will delete that treatment condition entry from the list of random assignments, setting up the next eligible participant for randomization to the condition that is next on the list.

The researchers will periodically check to determine if these randomization procedures are yielding adequately similar groups in terms of racial and gender representation. If not, appropriate adjustments may be made to the stratification procedures.

4.3. Descriptions of each treatment condition

Usual Care (UC)

Patients randomized to UC will receive the same multidisciplinary care that they would have received had they not enrolled in the study. In the vast majority of instances, it is expected that UC patients will continue seeing the same health care providers in the same settings where they have recently received T1D care. While there are some differences in clinical practices, workflow procedures and available resources across the two sites, the fundamentals of the care process for UC patients will rest on these principles and practices:

Principles of Care:

- Avoidance of long-term complications of T1D and of sources of risk for their development.
- Heavy emphasis on education of patients and families to equip them to implement optimal T1D care in their daily lives, and reliance on shared decision making about treatment and monitoring options.
- Preservation or facilitation of optimal flexibility and quality of life and normal achievement of developmental milestones and physical growth.
- Maintenance of glycohemoglobin below 7.5% and avoidance of frequent or severe hypoglycemia
- Maintenance of blood glucose in the normal range for as great a proportion of time as is feasible.
- Focus on the family as the unit of care and promotion of healthy family teamwork around T1D care.
- Preparation of the adolescent for transition to adult care and for withdrawal of direct parental involvement in care.

Clinical Practices:

- Clinic visits with a pediatric endocrinologist or experienced advanced practice endocrine nurse at approximately 3 month intervals.
- Insulin replacement therapy as close as possible to physiologic through reliance on either continuous subcutaneous insulin infusion or basal-bolus multiple daily injection regimens, with use of conventional sliding-scale insulin regimens in very few patients who may lack the capacity to manage insulin regimens that require meticulous self-regulation skills.
- Frequent daily blood glucose monitoring through use of a conventional home glucose meter 4-6 times daily or use of a continuous glucose monitor, including analysis and application of the resulting data to both proactive and remedial adjustment of insulin, carbohydrate intake or physical activity.
- Nutritional management based on carbohydrate intake that satisfies the patient's appetite while also achieving the above metabolic and growth objectives satisfactorily.
- Regular physical activity to promote aerobic and anaerobic fitness in balance with the other goals of T1D therapy.
- Annual visits for ophthalmologic and renal examinations to evaluate onset or progression of long term complications of T1D.

- Negotiation and distribution of a diabetes management plan for extension of T1D care to the school setting.
- Screening for psychosocial impediments to optimal family management of T1D and referral when needed to social work, psychology, psychiatry or community agencies for appropriate supportive services.

Billing

Guarantors for UC patients participating in the study will be billed for UC visits just as they would be billed for the routine diabetes follow-up visits they have been experiencing recently.

Transdisciplinary Care: Elements in common to both arms

Patients randomized to the two Transdisciplinary Care arms of the study will receive T1D care embodying all of the UC principles and practices, while experiencing those services in the context of clinic visits that differ in important ways from typical UC visits, as described below. TC visits are expected to be approximately quarterly, as will be the case for UC participants' visits. TC visits will be characterized by blurring of boundaries among the professions, a commitment to principles of family-centered care, a strong emphasis on use of motivational interviewing techniques as a communication style, extensive reliance on the evidence base derived from pediatric psychology research, frequent use of evidence-based assessment and intervention methods validated in that research and clinical conversations focused on identification and resolution of problems impeding the parent and adolescent from reaching their T1D management goals and priorities. With the concurrence of all team members, TC professionals will be allowed to see TC adolescents and/or parents for supplementary clinical visits with these caveats: 1. The objective of the supplemental visit (patient education, more detailed assessment, is expected to be achievable in a single visit; 2. If the objective cannot be achieved in a single visit, the adolescent/parent will be referred for additional services to a qualified clinician who is not associated with this study; 3. The TC team member will carefully document the content and activities that comprise the supplemental TC visit in the adolescent's EHR; 4. Parents should be informed that the guarantor and/or the guarantor's health insurance will be billed for the supplemental TC visit and the parent must accept this circumstance before the supplemental TC visit is scheduled.

Billing

TC visits will be billed to the guarantor's insurance for that part of the visit consisting of the Advanced Practice Nurse's history, physical exam, review of systems, medication reconciliation, review of data downloaded from glucose meters, insulin pumps, continuous glucose monitors, etc., and planning/adjusting indicated treatment changes. These elements are part of standard care for T1D and do not constitute the research aspects of TC visits. The portion of TC visits that follow these routine care elements, consisting of agenda setting, problem solving discussion with the parent and adolescent, participation of the psychologist and dietitian in those discussions, negotiation of a problem solving plan and derivation of a collaborative After Visit Summary are considered to be integral to the research intervention and therefore not to be billed to the guarantor or the guarantor's health insurance.

Below is a sequential outline of a typical TC visit:

TC Visit Outline

1. NP starts by introducing the team and the rationale for TC visits and each person introduces him/herself.
 - a. "Thanks for coming in today!"
 - b. Each person introduces themselves
 - c. Always trying to help families the best way we can; having all of the professionals working together in one room can help us help you

- d. It may feel overwhelming to have all 3 of us here at the same time, but we want to make this a collaborative effort. We have expertise in our own areas, and you have expertise in your life and your T1D. So we want to hear from you. Give them more input into their visits and care
 - e. We know that these visits can be stressful and we want to find ways to make them more helpful
 - f. Although these visits will last longer (~2.5 hours), we hope that we can be more efficient as a team and be more effective in guiding you in your t1d management
2. Start agenda setting, using visuals, for family to help decide order of required elements and what other topics/issue to address
 - a. Proposed agenda – “This is the general flow of how we expect the visit will go. We will gather some background information, then we’ll talk about your concerns, and finally we’ll work together to create one plan that fits your T1D goals.”
 - i. History
 1. ER visits, changes in health
 2. Significant hypo, ketones
 3. Current doses
 4. Outline of typical day of eating
 5. Education
 6. Family
 7. Adolescent history (obtained privately and confidentially by psychologist)
 - a. Social/emotional
 - b. Risk behaviors
 - i. Substance use
 - ii. Sexual activity
 - iii. Harm to self or others
 - ii. *RD & APN meet during adolescent only hx to review HbA_{1c}, blood glucose meter or CGM data, pump bolus history, etc.*
 - iii. *Psychology reports to team about risk bx’s*
 - iv. *APN returns to exam room with caregiver and performs physical exam of adolescent*
 - v. Review of BG & A1c data
 - vi. Review of systems
 - b. Topics family would like to discuss (options provided as examples, but can add in other topics)
 - i. Visuals
 1. Areas that families tend to work on
 2. Whiteboard entries listing successes and areas for growth/refinement
 - c. Wrap-up, plan, scheduling
1. Write out agenda for the visit for everyone to follow along, perhaps with general time guidelines to help people stay on track, but with flexibility to use more time if needed for any one topic
 2. All work together to incorporate MI skills during required portions
 3. Depending on topic family chooses to focus on, one of the professionals will take the lead
 4. End of visit-After Visit Summary
 - a. Referrals
 - b. Problem-solving materials
 - c. Contact with team
 5. Scheduling
 6. Documentation

Transdisciplinary Care – In Person (TC-IP)

TC-IP visits will consist of clinical encounters involving all 3 TC team clinicians (APN, Dietitian, Psychologist) participating in the visit simultaneously with the parent and adolescent with T1D. Following the visit outline above, the TC team will assist the parent and adolescent in defining a visit agenda focusing on problems identified by the family as priorities. Providers will block the dates and times in which TC-IP visits may be scheduled using the template for Advanced Visits in EPIC, within the EPCI research module.

Transdisciplinary Care – Telehealth (TC-TH)

TC-TH visits will be conducted using the Vidyio platform, selected because it enables screen-sharing capabilities that are not currently feasible with other alternatives. Participants can be physically located anywhere that permits them to take part in the video conference. The default arrangement should be that the three TC team members are physically present in the same room during TC-Telehealth visits, although the Vidyio platform will enable participants to connect from up to four different locations if absolutely necessary.

For TC-TH visits to be productive, it will be necessary for TC-TH patients to have certain responsibilities completed in time to ensure that certain results and information are available to the TC team well in advance of the TC-TH encounter. About 2 weeks prior to each TC-TH encounter, the parent and adolescent will be prompted to obtain professional measurements of vital signs (blood pressure, heart rate, respiration rate, temperature), height and weight, and a blood sample for HbA_{1C} assay. The TC team, led by the Advanced Practice Nurse aided by the Research Coordinator for that site, will assist each adolescent in identifying a suitable location for obtaining these measurements, which may include any workable combination of the following:

- Coming to the primary Nemours clinic location (AIDHC, NCH, Nemours Orange Avenue Clinic) where they already receive T1D care for measurement of height, weight, and vital signs, and for blood sampling for a point-of-care HbA_{1C} assay.
- Coming to a conveniently located Nemours Urgent Care or Primary Care Clinic for a nursing visit to obtain these measures
- Arranging for a school nurse to measure vital signs, height and weight
- Having blood drawn for HbA_{1C} at a laboratory mandated by the patient's health insurance and reported to the Nemours care provider.
- As a last option for HbA_{1C} determination, adolescents may collect and submit dried blood spot samples to CoreMedica Labs using the procedures outlined in the Appendix. Such samples must be submitted 3 weeks prior to the scheduled Telehealth encounter.

Research Coordinators at each site will be responsible for ensuring that results of these various assessments are made available to the TC team members prior to each adolescent's scheduled Telehealth visit.

Vidyo User Quick User Guide for Parents and Adolescents

Supported Devices: Any IOS supported device, IPHONE, IPAD, Android Device, laptop or PC with camera. For mobile devices, 3G or 4G data connection **is not** recommended as it can affect the quality of the connection. **Please always use a WIFI connection.**

1. Please follow the link sent to you from your provider's office. If this is the first time you are connecting with your provider using Vidyo, you will be asked to download the mobile app for IOS and Android devices. For a laptop or PC, you will be prompted to run an install of the device driver. For any device, the install should take less than 30 seconds. Once downloaded, go back to the email /text with the link and select the link again. You will be asked to join and enter your name. Always click (Yes) to allow Vidyo access to microphone and camera. Please follow the below steps if you are having trouble connecting
 - a. Ensure you followed the link after downloading the software
 - b. Rebooting your device
 - c. Ensure your device's software is up to date
 - d. If you continue to experience problems, please call **a support team member (see below)**
2. During your visit and you are having problems with the following:
 - a. Camera- ensure your camera is initialized and any another program that uses your camera is not open and running. You can toggle through front camera and rear camera and mute camera with mobile devices
 - b. Audio- ensure your audio is turned on and internal microphone is not muted.
3. Please fill out our online Telemedicine Consent Form at:
<https://e-signature.nemours.org/#/add-identification/1>

Florida Support Team:

Collin McQueen- 407-462-9749

Sarah Hendy- 407-867-1280

John Ninah- 321-246-0376

Delaware Valley Support Team:

Email- dvtelehealth@nemours.org

Phone- 302-298-7700

Getting Started

1. To join a meeting, you need an iOS device with a WiFi/3G/4G connection and earbuds/headset.
2. First time users have to download the VidyoMobile application.



3. Select the **Guest Link** in your email or calendar.



4. The application will direct you to a browser. Select **Join Conference**.



5. First time users will need to accept the terms and conditions.
 - Enter or edit your display name and click **Join**.



Nemours CareConnect

In-Call Controls

Pinch and zoom on individual participants or presentations.

Best Practices

- ⇒ When you are too close to the camera, your head appears very large. To help mitigate this hold the device away and above you.
- ⇒ For the best positioning and hands free conferencing use a stand.
- ⇒ Ensure you are in a well lighted room for the most professional appearance.
- ⇒ Opt for a WIFI connection over 3G or 4G.

Access additional call settings:

- Tap names to view names listed under participant's.
- Tap call quality to view the quality of each participant.
- Tap the dial pad to dial an external end point.

Toggle the camera between rear facing, front facing, and privacy.

Mute and unmute the microphone and speakers.

Access docked participants and presentations.

Disconnect from the call.

The VIDYO logo is a registered trademark of Vidyo, Inc. in the U.S. Patent and Trademark Office and in other jurisdictions. VIDYO, the Vidyo cube icon, the Vidyo Partner Logos and names of Vidyo Inc.'s products and offerings are trademarks or registered trademarks of Vidyo, Inc., in the United States and in other jurisdictions. Other trademarks reference herein are the property of their respective owners.

Vidyo Clinical Quick User Guide for Health Care Providers

Supported Devices: Any IOS supported device, IPHONE, IPAD, Android Device, laptop or PC with camera. For mobile devices, 3G or 4G data connection **is not** recommended as it can affect the quality of the connection. **Please always use a WIFI connection.**

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 - a. Ensure you followed the link after downloading the software
 - b. Rebooting your device
 - c. Ensure your device's software is up to date
 - d. If you continue to experience problems, please call **a support team member (see below)**
2. During your visit and you are having problems with the following:
 - a. Camera- ensure your camera is initialized and any another program that uses your camera is not open and running. You can toggle through front camera and rear camera and mute camera with mobile devices
 - b. Audio- ensure your audio is turned on and internal microphone is not muted.

Florida VidyoAccount:

User- orlendoresearch

Password- nemours

Florida Telehealth Support Team:

Collin McQueen- 407-462-9749

Sarah Hendy- 407-867-1280

John Ninah- 321-246-0376

Delaware Valley Vidyo Account:

User- deendoresearch

Password- nemours

Delaware Valley Telehealth Support Team:

Email- dvtelehealth@nemours.org

Epic Pool- DV Telehealth

Phone- 302-298-7700

Getting Started

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CHAPTER 5.

HYPOTHESES AND STATISTICAL ANALYSES

Analytic Plans Primary endpoints are change in HbA_{1c} and DSMP-SR total score (treatment adherence) over 1 year. Secondary endpoints are: measures of glycemic variability at each visit; and questionnaires obtained quarterly. The Full Analysis Set will include those who provide data at ≥ 1 follow-up visit. The Completer Analysis set will include those who provide data at all follow-ups. Efficacy analyses will be done on both sets.³¹³⁻³¹⁵ We will use multiple imputation for treatment of missing data.³¹³⁻³¹⁵ Obtained data will be summarized in graphs and tables. Categorical variables will be summarized by frequencies and percentages; continuous variables by mean, median, standard deviation (or SEM), minimum and maximum. Data will be summarized by group (UC, TC-IP and TC-TH) and measurement points.^{316,317} Model assumptions will be checked before analyses, and appropriate transformations or non-parametric methods will be used when indicated. For summarization of normally distributed data, group means and SEM will be presented. In case of substantial deviation from normality, boxplots will be presented. Exploratory subgroup analyses (e.g. race, ethnicity, gender, SES) will be conducted as needed.^{318,319} Most tests will be performed against a two-sided alternative at the $\alpha = 0.05$ significance level and a 95% confidence interval and/or a p-value will be provided for inferential purposes. Data from both clinics will be pooled for analyses.^{316,317} All analyses will be done using the most recent version of SAS, SPSS, R or M-Plus.³¹⁵⁻³²² Demographic variables (age, gender, race, ethnicity, family structure, marital status, SES) and baseline values of primary and secondary end points, and questionnaire results will be summarized by group. If the normality assumption holds, one way ANOVA of continuous baseline variables and a Fisher exact test/chi-square test/CMH test for categorical variables will be used to compare the TC-IP, TC-TH and UC groups at baseline. The statistician will select analytic methods based on data distributions and any imbalanced baseline scores.³²³ Linear mixed effects modeling (continuous outcomes) or generalized linear mixed modeling (categorical outcomes) is planned for the hypotheses below.³¹⁵⁻³²² Treatment group and demographic characteristics will be fixed effects in these models, while site, physician, and within-subject effects will be random effects. If initial outcome analyses reveal no statistically significant differences between the two TC groups on the dependent measure of interest, the TC-IP and TC-TH groups will be pooled for subsequent analyses. We will use Holmbeck's methods³²⁴ to evaluate baseline demographic variables and questionnaire scores as moderators of TC-UC effects on primary outcomes and to evaluate mediation of effects on primary endpoints. Candidate mediators are variables that are obtained serially concurrent with the primary endpoints at ≥ 3 visits.

Sample Size and Statistical Power: A sample of 150 patients (50/group), with 80% retention at 1 year yields 89.2% power to detect clinically meaningful group differences in mean HbA_{1c} of 0.5% (~0.7 SD) versus the alternative of equal means using an F test with $p = .05$. Limiting recruitment to those with HbA_{1c} = 7.5-10.0% reduces the SD from 1.5% for the general adolescent T1D population to 0.7%, boosting effective statistical power for the RCT. The predicted 12-month means are 8.1% (TC-IP and TC-TH) and 8.6% (UC). This sample size also achieves power of 86.7% to detect clinically meaningful mean differences in DSMP-SR total scores of 7.0 points (~0.7 SD) at 1 year. The estimated mean values are 63.0, 63.0 (TC-IP and TC-TH) and 56.0 (UC). This preliminary trial will yield rich data that could be used to guide the sampling plan for a future, more ambitious, multi-center trial.³²⁵⁻³²⁷ These hypotheses will be tested:

Hypothesis 1: Compared with UC patients, those randomized to TC-IP and TC-TH will have significantly more favorable primary (HbA_{1c} and DSMP-SR scores) and secondary (frequency of severe hypoglycemia and level of glycemic variability) outcomes at each quarterly follow-up visit.

Hypothesis 2: Compared with UC patients, those randomized to TC-IP and TC-TH will demonstrate more favorable scores on the MY-Q, PAID, and CPI at follow-up measurements.

Hypothesis 3: Significantly higher scores will be obtained on the TDMQ and PSQ completed by HCPs concluding care of TC-IP and TC-TH patients compared to scores provided by HCPs concluding UC care.

Hypothesis 4: Effects of TC-IP and TC-TH on HbA_{1c} and DSMP-SR scores will be moderated by demographic variables (youth age, family SES, # of adult caregivers in the home) and by baseline scores on the MY-Q, PAID, and CPI. More benefit from TC will accrue to youth who are younger, from two-parent families with higher SES, and with more favorable scores on the MY-Q, PAID and CPI.

Hypothesis 5: Effects of TC-IP and TC-TH on HbA_{1c} and DSMP-SR scores will be mediated by changes in scores on the MY-Q, PAID, and CPI. More benefit from TC will accrue to youth with favorable changes in MY-Q, PAID and CPI scores during the 12 months of the study.

Hypothesis 6: TC-TH adolescents will keep significantly more appointments than either TC-IP or UC youths.

Limitations: Aspects of this application could have been done differently: 1.) Randomization at the level of patients/families was selected over randomizing sites to TC-IP, TC-TH or UC in a Cluster RCT design. A Cluster RCT could reduce the potential for contamination, but it introduces problems in that differences between Nemours sites could obscure detection of treatment effects. We opted for randomization of patients/families to treatments with concomitant efforts to minimize possible contamination. Since this funding mechanism seeks to develop preliminary data to support a larger multi-site RCT in the future, empirical evaluation of our success in detecting, preventing and managing possible contamination effects would be an important feature of a future application of that type. 2.) The structure of the RCT as a 3-arm trial (UC vs TC-IP vs TC-TH) introduces added complexity and expense and may decrease the sample size available for each study arm. Since telehealth delivery of subspecialty care for chronic conditions may be the wave of the future, it is prudent to capitalize on the availability of the DP3 mechanism to provide initial data on if and how telehealth delivery of the proposed TC intervention may be superior to conventional face to face delivery of that same care. 3.) The enrolled sample represents a period of marked developmental change. We have not planned specific adaptations to the TC model, but a key role of the Psychology Post-Doctoral Fellow will be assurance that negotiated interventions are developmentally appropriate for each adolescent.

CHAPTER 6.

RESPONSIBLE CONDUCT OF RESEARCH

6.1. Human Subjects Protection

Nemours Office of Human Subjects Protection operates Nemours IRB 1 and Nemours IRB 2. The program is accredited by the Association for Accreditation of Human Research Protections Programs, and it is one of the few pediatric programs to have achieved this high level of recognition. The detailed policies and procedures developed and promulgated by Nemours Office of Human Subjects Protection have guided and will continue to guide every element of the design, planning and implementation of the current research, assuring that those who volunteer for this research will be treated with appropriate respect, beneficence and justice. The procedures for protection of the rights and well-being of participants are described below for the RCT.

6.2. Data and Safety Monitoring Plan

The risks associated with the current RCT are considered to be negligible and so our assessment is that an external and independent data and safety monitoring board is unnecessary. Instead, the typical safety monitoring functions for this study will be accomplished by an internal Data Safety Committee (DSC) with members consisting of Dr. Wysocki, Dr. Benson and Dr. Price, with statistical consultation provided by Dr. Andre Williams. The DSC will additionally draw upon the perspectives of a Family Advisory Council and it will have the following charges:

- Ensure that all activities comprising this research are conducted in strict accord with the ethical principles of the American Psychological Association pertinent to the responsible conduct of research.
- Ensure that all research staff working on this project are in continuous compliance with Nemours requirements for training in human subjects protection and the responsible conduct of research.
- Serve as the liaison between the research team and Nemours Delaware IRB, Nemours Clinical Research Review Committee and Nemours Committee on Research Integrity.
- Receive and investigate reports of unanticipated problems submitted by project staff as required by Nemours Policies and Procedures governing human subjects protection.
- Receive and address complaints from participants in the study as outlined in the Nemours Office of Human Subjects Protection policy and procedure regarding this issue.
- Advise the research team regarding possible amendments to the research protocol in the interests of more effective protection of study participants' privacy, confidentiality and overall well-being.
- Meet at least quarterly once recruitment of participants begins and send copies of its periodic reports to the Family Advisory Council and Nemours IRB.

6.4. Participants and Eligibility Criteria

Participants will be 150 adolescent patients who receive care for T1D at participating Nemours operating entities in Florida or Delaware as described elsewhere in this document.

6.5. Sources of Research Material

Sources of research material include HbA_{1c} tests, scores on the Diabetes Self Management Profile-Self Report version (primary outcomes) as well as downloaded data from glucose meters, insulin pumps and continuous glucose monitors, questionnaires completed by youth and parents each 6 months and EMR data extracted regarding each T1D care visit during the study.

6.6. Methods of Recruitment

Participants will be recruited from among eligible patients treated for type 1 diabetes mellitus at Nemours locations in central Florida or the Delaware Valley. Endocrinologists will be asked to identify patients from their clinics who are good candidates for participation in this research. Prospective participants will then

receive a copy of the study flyer, either in person in the clinic or by mail or e-mail. This initial contact will be followed with a telephone call to the parents to determine eligibility and interest in study participation. Parents/caregivers and youth will sign IRB-approved consent/assent documents.

6.7. Assessment of Research-Related Risks

Even though this is a randomized trial of an intervention, we believe that this study poses no greater than minimal risk for either adolescents or parents. The primary foreseeable study risks to youth and parents are those associated with threats to privacy and confidentiality related to the measurement protocol. UC participants will have the same medical care for T1D they would experience if not enrolled in the study. TC-IP and TC-TH participants are very unlikely to experience additional risks beyond those encountered by the UC participants.

6.8. Assessment of Research-Related Benefits

TC-IP and TC-TH participants could experience better treatment adherence, glycemic control, self-efficacy and quality of life after the decision. UC participants are unlikely to derive any direct benefits from study participation.

6.9. Safeguards to Protect Against Risks

Substantial efforts are planned to protect each participant's privacy and confidentiality. All data files containing the clinical outcomes and questionnaire responses will be stored without any HIPAA-defined identifiers. All participants will be identified by a unique study ID number. A separate password-protected list will link participants to their ID numbers. With these safeguards in place designed to minimize the risks to participating clinicians, we believe that this protocol entails minimal risks to them. Access to the list linking code numbers to individual participants will be password-protected and will be limited to Dr. Wysocki and the research specialists on his Jacksonville team. The list will not be provided to any other Nemours staff or to any non-Nemours researcher or consultant.

6.10. Informed Consent and Parental Permission Process

Those who are eligible and interested will have a face to face informed consent conversation with a qualified research coordinator or research specialist. Signatures of parents will be obtained on an IRB-approved Parental Permission and Informed Consent Form and of youths on an IRB-approved assent form before they are scheduled for any research procedures, including data collection or SMDM intervention procedures. Research staff obtaining consent will be trained to use the "Teach-Back" method of verifying parents' comprehension of these key elements of the Parental Permission and Informed Consent form: What is the Purpose of the Study?; Who Can Be in the Study?; How Long Will Participation in the Study Last?; What Are the Research Procedures?; What Are the Possible Risks of being in the Study? What are the Possible Benefits of Being in the Study? Is Being in the Study Voluntary?; Will We Be Paid for Being in the Study?; and What Information About Me or My Child Will Be Used or Disclosed?. Each of these sections will be reviewed and the participant will be asked to describe the content of that section in his/her own words. The research staff member will correct instances of erroneous or absent knowledge and ensure comprehension before proceeding to the next section of the consent document. A similar but condensed procedure will be used with adolescents in reviewing the key points of the Adolescent Assent Form.

6.11. Protection of Confidentiality

As a covered entity under HIPAA, Nemours operations are all fully compliant with applicable federal and state laws and regulations regarding the protection of patients' confidentiality and the security of stored confidential data. All staff members who will interact with study participants or their research data will be trained in the HIPAA research regulations and in general human subjects protection by completing Nemours-approved online curricula on this topic. Data collection, scoring and data entry will be organized to place a priority on protecting the confidentiality and privacy of study participants. Data recording instruments, questionnaires, etc., will all be labeled with a unique study ID number rather than participants' names or other HIPAA-defined identifiers. Signed parental permission forms will be stored separately from other study data and documents since these forms will identify the participants. Raw data will be stored, without personal identifiers attached, in locked file cabinets in private offices. Data will be entered into password-protected computer files on the Nemours local area network, access to which is also password-protected.

6.16. Family Advisory Council

Five parents and their adolescents with T1D will serve as members of a Family Advisory Council. They will be selected to reflect diverse representation in terms of Nemours sites, socioeconomic status, race/ethnicity, gender and degree of active participation in the qualitative research phase. Each FAC dyad will be paid \$500 annually to compensate them for expenses they incur due to their FAC participation.

The FAC will be convened in monthly meetings using video or telephone conferencing facilities that are in place at all Nemours operating entities. Each meeting will be audio-recorded and minutes will be taken and distributed to all members. The FAC will be considered advisory to the research team, in that their recommendations will be given very serious consideration, but final decisions regarding study design, implementation or interpretation will rest with Dr. Wysocki and the Co-Investigators. The initial charge of the FAC will consist of review of, and commentary on, the study protocol, procedure manual, and human subjects protection plan. Since an external and independent Data and Safety Monitoring Board is unnecessary for this research since it poses minimal risk to participants, the FAC (with participation by Dr. Wysocki, Dr. Hossain and one of the endocrinologists) will provide study oversight regarding the recruitment experience, and the occurrence of any data quality issues, threats to privacy or confidentiality, other unanticipated problems, participant complaints or other such issues.

6.22. Resource Sharing

Once IRB-approved, this study will be registered on www.clinicaltrials.gov, ensuring that information about the study will be available to interested parties and so that they will understand when archived data will be made available. Publications resulting from this study will also be shared on the pertinent website in accord with NIH policies and procedures regarding internet sharing of publications resulting from NIH-supported investigations. The intervention manual will be made available to appropriately qualified diabetes programs and health care professionals. The current research will include data from 150 adolescents with type 1 diabetes and their parents recruited through several Nemours diabetes clinics. The final dataset will include: self-reported demographic and behavioral data from the participants obtained periodically during the study. Even though the final dataset will be stripped of HIPAA-defined identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. The dataset will be redacted to protect subjects' identities. This project has specified research questions that address both the long-term effects of the intervention and longitudinal changes in specific variables. Datasets will be made available through a data enclave immediately following acceptance for publication of papers addressing all research questions specified in the protocol only when those data are not to be used to address subsequent specified research questions. The data will be kept for at least 3 years after the publication of the last article based on the proposed research questions.

CHAPTER 7.

PUBLICATION POLICY

Purpose

The purpose of this policy statement is to ensure the scientific integrity, fairness, accuracy, timeliness, and readiness of dissemination efforts from research supported by this grant. The policy rests on management of these activities by a Publications Committee co-chaired by Dr. Wysocki and Dr. Alderfer and with 3 additional rotating members serving staggered terms consisting of other doctoral members of the research team. The general goals of this policy are to:

1. Ensure that the Publication Committee members approve all information that is intended to be disseminated from the study;
2. Establish priorities for dissemination of study findings;
3. Foster timely dissemination of study findings;
4. Stimulate dissemination efforts on the part of all members of the study group, (defined as all investigators and co-investigators who ultimately participate in the study);
5. Establish procedures to ensure a fair and appropriate acknowledgment of the contributions made by study investigators and any others who work with the study group members to accomplish the goals of this study;
6. Permit the largest possible use of the data produced under the study by encouraging publications and presentations in multiple arenas, including but not limited to descriptive studies, implementation studies, and inferential studies, for practitioners, policy makers, and researchers;
7. Provide equal access to, and responsibility for the development of publications and presentations involving findings from the study through a dissemination plan;
8. Appropriately acknowledge funding support from NIH/NIDDK;
9. Maintain an archive of all publications and presentations developed for the study;
10. Accomplish the above goals of information dissemination with minimal delays;
11. Provide a mechanism for the prevention and resolution of disputes regarding such issues as inclusion as an author, order of authorship, and differences of opinion regarding the analysis or interpretation of data.

Policies governing publications and presentations are subject to review and modification as necessary to accomplish the goals of the study. Any member of the research team may suggest additions or modifications to these policies. For the purposes of this policy, publications and presentations will include journal submissions, books, book chapters, monographs, dissertations, theses, abstracts, overheads and slides that report procedures or data resulting from the research completed under this grant. The term “publications” when used in this document refers to any and all of these types of academic products.

Publication Policy Guidelines

This policy defines two major categories of publications, Primary and Secondary publications. Guidelines for these vehicles are summarized separately below.

(1) **Primary:** Manuscripts reporting findings of analyses that address the specific aims and associated primary hypotheses of the study as delineated in the research protocol.

(2) **Secondary:** Manuscripts reporting findings of analyses that address other specified secondary objectives; and manuscripts reporting findings of analyses of data from subsets of data or of objectives identified in addition to those contained in the protocol. Examples might include psychometric studies of project measures or analyses of longitudinal or cross-sectional associations between questionnaires and diabetes outcomes.

Topics for Primary manuscripts will be identified collaboratively by the Publications Committee and that committee will convene writing groups to prepare manuscripts on each of the topics that will be considered

Primary Publications. Any member of the research team can propose a Secondary Publication by submitting to the Publication Committee a proposal including the following information:

- Primary objectives of the publication or hypotheses to be tested
- Measures or variables to be analyzed and reported
- Statistical analysis plan
- Proposed writing group and order of authorship
- Potential journal(s) or other outlets for the submission
- Time frame for preparation and submission deadline, if any

The Publications Committee has responsibility for final approval/disapproval of proposals for manuscripts as well as for the final product. Topics for Secondary Publications can be identified or proposed by any member of the research team, and will also be brought to the Publications Committee for discussion and approval. The Publications Committee will inform the entire research team when it identifies a given paper as a Primary Publication or a Secondary Publication and that notification will include a proposed title, authors with proposed order of authorship, outline of the content of the publication and potential journal(s) or other outlets for the publication.

Authorship: Listed authors for all manuscripts will include the members of the writing group for that paper. After the list of authors' names will appear the following comment: "writing for the Nemours Transdisciplinary Care Research Group" and all team members' names will be listed in the notes or in an appendix accompanying the article. Secondary manuscript authors can be any individuals with an interest in participating in manuscript preparation around the selected topics and whose role meets the journal's or association's requirements for inclusion as a co-author. Writing groups have the responsibility for submitting a proposal to the Publications Committee and for creating the final manuscripts. Authorship decisions will be the responsibility of the writing group: the first author will be designated as chairperson and will have overall responsibility for manuscript completion, and serve as liaison for the purpose of manuscript review. Decisions about authorship order should be made prior to initiation of work on the manuscript.

Inclusion as an author and order of authorship will be guided by the principles published by the American Psychological Association in the current editions of its *Publication Manual of the American Psychological Association* and its *Ethical Principles of Psychologists and Code of Conduct*. Where authorship guidelines stipulated by the journal or professional association in question exceed the APA standards, the former will be followed.

"Authorship is reserved for people who make a primary contribution to and hold primary responsibility for the data, concepts and interpretation of results for a published work. Authorship encompasses not only those who do the actual writing but also make substantial scientific contributions to a study.....To prevent misunderstanding and to preserve professional relationships, it is best to establish as early as possible in a research project who will be listed as an author, what the order of authorship will be and who will receive an alternate form of recognition".

Internal Manuscript Review: The writing committee for an approved paper should submit the finished manuscript to the Publications Committee for review, final edits and approval before submission. When the Publications Committee agrees that the manuscript is scientifically accurate, the chairperson of the writing group will be notified. For Primary Publications, copies of each final manuscript will be made available concurrently to all members of the research group for their review and input; however final approval/disapproval is the responsibility of the Publications Committee.

Documents submitted for formal review should be in final form as required by the journal to which they are being submitted. These documents should be complete, including title, list of authors, abstract, and references. The target journal should be indicated on the submission. Once cleared, the chairperson of the writing group will notify the authors and submission may proceed. The submission and results of the review process will be logged into a spreadsheet created and maintained for this purpose by the Publications Committee and accessible via a shared network directory by all members of the research team.

Revisions and resubmissions of manuscripts: Upon receiving editorial correspondence requiring changes in a submitted manuscript, the first author of the paper will have the primary responsibility for formulating and distributing the proposed changes to the writing committee. First authors are encouraged to prepare a draft letter responding to each of the reviewers' criticisms and a "tracked changes" version of the revised manuscript showing those changes. The writing committee will be given 14 days to provide comments to the first author about these documents. Failure to respond by that deadline will be interpreted as approval of the draft documents by that member of the writing committee. Once the first author compiles and incorporates the final changes in both documents, the completed response letter and revised manuscript will be sent to the Publications Committee for final approval. The Publications Committee members will be allowed 3 days to provide any additional comments. Lack of response will again be interpreted as approval of the submitted documents. Submission of the paper and accompanying letter should occur after notification of Publications Committee approval.

Receipt of Published Materials: After publication of an article, chapter, abstract, etc., the lead author is expected to save the accepted paper to a designated shared directory folder.

Presentations: Material for all presentations of study results or procedures must be reviewed by the Publications Committee. These include presentations given to scientific, professional, or public groups. Particular attention is drawn to presentation of material when proceedings of the meeting or workshop are likely to be published or publicized.

Dissertations or theses: Proposals for dissertations or theses based on this research must be submitted under the sponsorship of a member of the research team. It is expected that at least one investigator from this group will be a member of the candidate's dissertation committee. All other aspects of the review process with regard to the prospectus will be the same as for participating sites. The dissertation or thesis proposal must consist of addressing a research question that is initiated by the graduate student and that does not overlap with a publication proposed by a member of the research team. Review of the draft dissertation will not be a responsibility of the Publications Committee.

Prevention and resolution of disputes: An important function of these policies and procedures is to ensure that the dissemination of project findings is orderly, fair, and consistent with published principles of research ethics and scientific integrity. When this process functions as expected, disputes about publication issues will generally be either prevented or resolved prior to the preparation of manuscripts, presentations and other such products. Nonetheless, situations may arise in which there are genuine and legitimate disagreements around such issues as inclusion as an author, order of authorship, or interpretation of scientific data. In all such circumstances the study group will be guided by the Ethical Principles of the American Psychological Association which encourage attempted resolution at the level of the affected individuals as a first step. Should that prove unsatisfactory to any of the involved parties, the matter should be presented to the Publications Committee for further review, arbitration and resolution. The Publications Committee may elect to seek confidential external consultation for guidance in this process such as internally from the Committee on Research Integrity or externally from the Ethics Office of the American Psychological Association or other appropriate professional body.

Acknowledgment of NIH/NIDDK Grant support: The following acknowledgment shall be used in all publications and presentations:

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(Principal Investigator, Tim Wysocki, Ph.D.). The title of the grant is “Transdisciplinary Versus Usual Care for Type 1 Diabetes in Adolescence”.

In addition, an Appendix or Author Note for each publication should include a full listing of each member of the Nemours Transdisciplinary Care Research Group, including name, degree and institutional affiliation.

Archival Data Set: Upon completion of the research (defined as publication of the Primary Publications), a completely de-identified data set will be stored and made available for public access using a reputable public Data Archive service. No HIPAA-defined identifiers will be included in the archived data set. Notification of the availability of this archival data set will appear in footnotes to all publications and presentations that follow the publication of the Primary Publications, including instructions for applying to access the data set, and the requirements for negotiation of a Data Use Agreement and the conditions of data use.

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APPENDICES

A1. Procedure for collection and processing of dried blood spot samples and for reporting the results to Health Information Management for scanning and uploading to patients' electronic medical records.

A.2. Measures, questionnaires, qualitative interview scripts

A3. Instructions for REDCap administration of study questionnaires

1. Before You Begin

Check the contents of your kit for the following:

- 1 DBS Blood Card (Collection Device)
- 2 Lancets (one extra if needed)
- 1 Alcohol Swab
- 1 Adhesive Bandage
- 1 Gauze Pad
- 1 Return Mailing Envelope

Please call us immediately if your kit is missing any items.

Please do your child's sample the Sunday after you receive the kit in the mail and place back in the mail no later than the Monday after (within 24 hours).

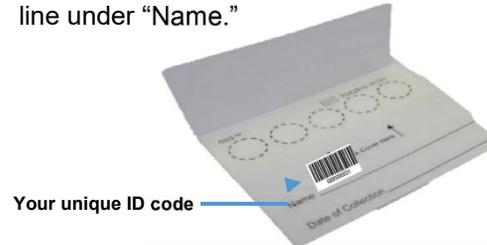
4. Prepare for Collection

1. Stimulate blood flow to the selected finger by letting your child's hand hang at your child's side for 15-20 seconds.
2. Shake your child's hand back and



2. Identify Your Sample

1. Retrieve Blood Card (Collection Device).
2. Your child's Blood Card has been labeled with a unique ID code next to where it says "Name."
3. Please DO NOT place your child's name or your name anywhere on the card.
4. Please write the date of collection on the line under "Name."



5. Lance Finger

Note: Only use the side of the fingertip as the puncture site. Do **NOT** use the center of the fingertip. Please use the lancet provided with the kit. Do **NOT** use your own lancet.

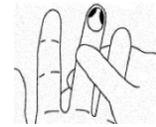
1. Remove the lancet cap, place palm up and position lancet on finger.
2. Place finger firmly against hard surface and press down on Lancet to puncture site.
3. Wipe off the first blood drop with the gauze pad.



Keep the gauze pad until you are done.

3. Prepare for Collection

1. Lay Blood Card on flat surface with printed circles facing up.
2. Rinse your child's hands in warm water.
3. Select your child's ring or middle fingertip.
4. Clean with alcohol swab.

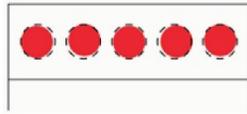


6. Apply Blood Drops

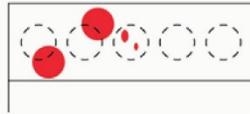
1. Blood should begin to flow freely from your child's finger.
2. Allow a large drop to form (larger than a typical blood sugar check). If a blood drop does not form, wipe your child's finger with gauze again and gently squeeze finger from palm to fingertip.
3. Allow one large blood drop to fall in the middle of each circle. FIVE (5) large blood drops are required to fall in the center of the circle.
4. One drop per circle. Do NOT place more than ONE drop per circle.
5. **If blood flow stops, repeat step 2 above as needed to generate blood.**



7. Proper Collection Technique



CORRECT



INCORRECT

1. After applying 5 drops, allow Blood Card to dry for 30 minutes.
2. After use, the Blood Card containing your child's blood sample can be stored at room temperature (65°- 72° F) before being mailed. Do NOT put the Blood Card in the refrigerator or leave in your car.
3. Sample must be shipped within 24 hours of collection

Within 24 hours of collection:

1. Verify that the Barcode Label and Date of Collection are on the Blood Card. The Laboratory will NOT be able to process your child's sample without the Barcode Label and Date of Collection on the Blood Card.
2. Close the top flap of the Blood Card over the blood samples.
3. Place in the return mailing envelope.
4. Seal the return mailing envelope and drop in any Blue USPS Mail Box.

Important Blood Collection Information

Improper collection of blood specimens may affect laboratory results. Carefully read and follow the collection instructions. Persons with hemophilia or anti-coagulation therapy should consult a licensed physician or healthcare professional before using this kit.



CoreMedica
Laboratories Inc

200 NE Missouri Road • Lee's Summit MO 64086 • www.coremedicalabs.com

INSTRUCTIONS

Blood Spot Collection Using 5 Spot DBS Card

LABORATORY TESTING AT YOUR FINGERTIPS

**PLEASE READ ALL INSTRUCTIONS BEFORE
HANDLING COLLECTION DEVICE**

QUESTIONS?

(877) 449-7942

Blood Spot A1c Results: Reporting to Nemours HIM

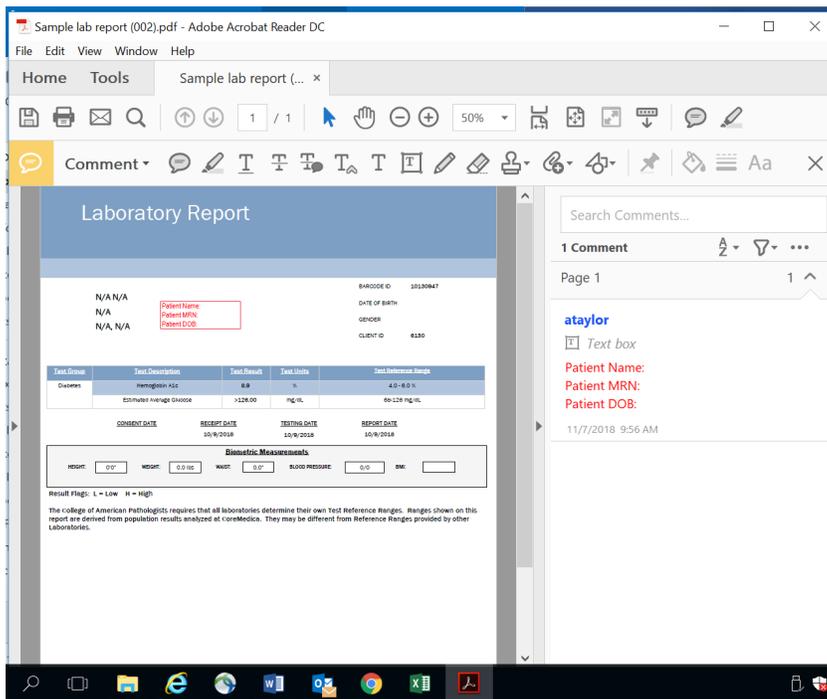
Some participants in the TC-Telehealth group may opt to have their glycosylated hemoglobin tests done by obtaining a dried blood spot sample and mailing it to CoreMedica Lab. These participants will need to be supplied with a Blood Spot collection kit. The card containing the dried blood sample is labeled only with a bar code (we do not provide patients' names, medical record numbers or other identifiers to CoreMedica) so the research coordinators will need to keep track of the bar codes and linking patient identifiers.

The HbA1c results are made available to us online from CoreMedica. Once the results are uploaded onto their Results Portal, they email the research coordinators a notification so the results can be accessed. Using the bar code number, the research coordinators can then re-identify the patient and record the HbA1c test result in our study database.

The A1c results will also need to be reported to Nemours HIM so that they can be entered into the Patient's EPIC charts (Lab Results).

Steps for reporting the TC-TH participants' HbA1c results to Nemours HIM:

1. In the CoreMedica Secure Results Portal, go to the '6145-Transdisciplinary Study' folder and open the most recent file
2. The test results, receipt date, testing date and report date as well as the Barcode ID # will appear on the page; the patient identifiers will need to be added to the file prior to saving the file to Nemours HIM share folder
3. To insert the Patient Identifiers to the file:
 - Select Tools
 - Select Comment
 - Select Text Box (box with T in it)
 - Add a Text Box to the top of the page and Insert Patient Identifiers (Patient's Name, MRN, and DOB)



4. Go to File, choose 'SAVE AS', label the file and save it to the HIM share folder '**00_CoreMedica Lab Studies_Research**' (no need to notify HIM that a new file has been saved to the HIM share folder; they have abstractors assigned to work these share folders daily; results should always be entered w/n 24hrs).

Demographic Information Form

Person completing this form:

Name: _____ Age in Years: _____

Country of Birth: _____

Your spouse or partner who lives in the home (if not applicable, leave blank):

Name: _____ Age in Years: _____

Country of Birth: _____

Relationship to child with type 1 diabetes:

	You	Your spouse/partner
Mother	<input type="checkbox"/>	<input type="checkbox"/>
Father	<input type="checkbox"/>	<input type="checkbox"/>
Step-Mother	<input type="checkbox"/>	<input type="checkbox"/>
Step-Father	<input type="checkbox"/>	<input type="checkbox"/>
Grandparent	<input type="checkbox"/>	<input type="checkbox"/>
Adoptive Mother	<input type="checkbox"/>	<input type="checkbox"/>
Adoptive Father	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

	Child with T1D	You	Your spouse/partner
Gender			
Male			
Female			
Ethnicity			
Hispanic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Hispanic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Race (check all that apply)			
Caucasian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
African-American	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Asian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Native Hawaiian/ Pacific Islander	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Native American	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other/ Prefer Not to Say	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EDUCATION: (Select one for each caregiver):	You	Your spouse/partner
Received M.A., M.S., Ph.D., M.D., etc.	<input type="checkbox"/>	<input type="checkbox"/>
Received bachelor's degree from a college or university	<input type="checkbox"/>	<input type="checkbox"/>
At least one year of college or other specialized training	<input type="checkbox"/>	<input type="checkbox"/>
Received high school diploma or GED	<input type="checkbox"/>	<input type="checkbox"/>
Completed 10 th or 11 th grade	<input type="checkbox"/>	<input type="checkbox"/>
Completed 7 th , 8 th , or 9 th grade	<input type="checkbox"/>	<input type="checkbox"/>
Completed less than 7 th grade	<input type="checkbox"/>	<input type="checkbox"/>
OCCUPATION: (Select one for each caregiver)	You	Your spouse/partner
Administrative, executive, managerial, and professional specialty occupations; Business owner w/ 25 or more employees	<input type="checkbox"/>	<input type="checkbox"/>
Administrative support; mid-level executive or manager; business owner w/ 10 to 24 employees	<input type="checkbox"/>	<input type="checkbox"/>
Lower-level manager, allied health professional, computer professional, teacher, business owner w/ 4 to 9 employees	<input type="checkbox"/>	<input type="checkbox"/>
Technician, business owner w/ 3 or fewer employees	<input type="checkbox"/>	<input type="checkbox"/>
Clerical worker; retail sales worker; public safety worker	<input type="checkbox"/>	<input type="checkbox"/>
Skilled production, craft, and technical repair	<input type="checkbox"/>	<input type="checkbox"/>
Transportation and material moving; Service occupations	<input type="checkbox"/>	<input type="checkbox"/>
Manual labor, assistant to craftsman or technician	<input type="checkbox"/>	<input type="checkbox"/>
Unemployed; On public assistance	<input type="checkbox"/>	<input type="checkbox"/>

HOUSEHOLD ANNUAL INCOME (US Dollars):

- | | |
|---|---|
| <input type="checkbox"/> Less than 10,000 | <input type="checkbox"/> 50,000 to 74,999 |
| <input type="checkbox"/> 10,000 to 14,999 | <input type="checkbox"/> 75,000 to 99,999 |
| <input type="checkbox"/> 15,000 to 24,999 | <input type="checkbox"/> 100,000 to 149,999 |
| <input type="checkbox"/> 25,000 to 34,999 | <input type="checkbox"/> 150,000 to 199,999 |
| <input type="checkbox"/> 35,000 to 49,999 | <input type="checkbox"/> 200,000 or more |

Please list all other people who live with your child.

Name	Gender	Age	Relationship to Child
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Primary Language Spoken At Home: _____

Please provide your email address to be contacted about the study:

Please provide your phone number to be contacted about the study:

Information about your child with T1D:

Child's Name: _____ Child's Date of Birth: _____
(Month) (Day) (Year)

Country of Birth: _____

Date diagnosed with diabetes: _____
(Month) (Day) (Year)

Type of insulin delivery (choose one):

- Conventional (NPH, mixed insulin, or sliding scale)
- Multiple daily injections (basal-bolus injections using carbohydrate counting and insulin to carb ratios)
- Insulin pump

Does your child have a continuous glucose monitor? YES or NO

Last Hemoglobin A1c : _____ % Date of last A1c: _____

Please report how often your diabetes clinic visits in the past year included seeing each of the following types of health professionals:

	0	1	2	3	4 or more
Physician	<input type="checkbox"/>				
Nurse Practitioner/Advanced Practice Nurse	<input type="checkbox"/>				
Physician's Assistant	<input type="checkbox"/>				
Diabetes Nurse Educator/CDE	<input type="checkbox"/>				
Dietitian	<input type="checkbox"/>				
Social Worker	<input type="checkbox"/>				
Psychologist	<input type="checkbox"/>				
Psychiatrist	<input type="checkbox"/>				

Number of years receiving T1D care at current practice: _____

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The MIND Youth Questionnaire

Maartje de Wit

VU University medical center

Department of Medical Psychology

8S7-0352

PO box 7057

1007 MB Amsterdam

Netherlands

T: +31 204448224

F: +31 2044448230

E: m.dewit@vumc.nl

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3 **Assessing Diabetes related Quality of Life of Youth with Type 1 Diabetes in**
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6 **Routine Clinical Care: the MIND Youth Questionnaire (MY-Q)**
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10 Authors: Maartje de Wit¹; Per W interdijk ²; Henk-Jan Aanstoot²; Barbara Anderson ³;
11
12 Thomas Danne⁴; Larry Deeb⁵; Karin Lange⁶; Anja Ostergren Nielsen⁷; Soren Skovlund⁸;
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14 Mark Peyrot⁹; Frank Snoek¹ on behalf of the DAWN Youth Advisory Board.
15
16

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18
19 1. Department of Medical Psychology & EMGO+ Institute for Health and Care Research, VU
20 University Medical Center Amsterdam, 1081 BT Amsterdam, The Netherlands
21
22 2. Diabeter, Center for Pediatric and Adolescent Diabetes Care and Research, 3011 TG
23 Rotterdam, the Netherlands
24
25 3. Baylor College of Medicine, Department of Pediatrics, Psychology Section, Houston, Texas,
26 77030, USA
27
28 4. Diabetes Centre for Children and Adolescents, Kinderkrankenhaus auf der Bult, 30173
29 Hannover, Germany
30
31 5. Department of Medical Psychology, Medizinische Hochschule, 30625 Hannover, Germany
32
33 6. The Pediatric Endocrine Office, Tallahassee, Florida 32308, USA
34
35 7. Monocyte Biology, Biopharmaceutical Research Unit, Novo Nordisk A/S, 2760 Malov,
36 Denmark
37
38 8. Global Patient Research, Advocacy and Support, Novo Alie, DK-2880 Bagsvaerd, Novo
39 Nordisk A/S
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41 9. Department of Sociology, Loyola University Maryland, Baltimore, Maryland, 21210, USA
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ABSTRACT

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AIM: It is recommended to assess health-related quality of life (HRQoL) in teenagers with diabetes periodically as part of ongoing medical care. In this study, we describe the development and psychometric evaluation of the Monitoring Individual Needs in Diabetes (MIND) Youth-Questionnaire (MY-Q), a multi-dimensional self-report HRQoL questionnaire designed for use in pediatric diabetes care.

DESIGN AND METHODS: Expert meetings were organized to define characteristics and domains of interest of the MY-Q. Existing questionnaires were reviewed, topics selected and new items were added, resulting in the 36-item MY-Q. To test face validity 22 teenagers were interviewed. In addition, 84 teenagers with type 1 diabetes (age 10-18 years) completed the MY-Q and the PedsQL generic and diabetes modules to examine psychometric properties. Recent HbA_{1c} values were obtained by chart audit.

RESULTS: The MY-Q consists of seven subscales (Social impact, Parents, Control, Responsibility, Worries, Satisfaction and Body) as well as General HRQoL and Emotional well-being. Cronbach's alpha for the total scale was 0.80. Concurrent validity was confirmed by strong correlations between the MY-Q total and PedsQL generic and diabetes module scores ($r=0.58$ and $r=0.71$, $p<.001$). Higher HbA_{1c} was associated with lower Control ($r=-0.35$, $p=.001$), Worries ($r=-0.24$, $p=.029$) and Body ($r=-0.26$, $p=.019$) scores. Younger age was associated with higher Control ($r=-0.26$, $p=.020$) and Body ($r=-0.23$, $p=.038$) scores and lower Responsibility ($r=0.25$, $p=.027$) scores.

CONCLUSION: The MY-Q is the first HRQoL questionnaire designed for use in clinical care. It has acceptable measurement properties and seems suitable for implementation in routine care of teenagers with diabetes.

Key words: Type 1 diabetes, adolescents, health related quality of life, questionnaire, validation

INTRODUCTION

It is increasingly recognized that Health related Quality of Life (HRQoL) of teenagers with diabetes should not only receive attention in research, but in clinical care as well.

The International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines recommend:

"Assessment of developmental progress in all domains of QoL (i.e., physical, intellectual, academic, emotional, and social development) should be conducted on a routine basis" (1).

Indeed it has been shown that a structured HRQoL assessment followed by respectfully discussing the psychosocial issues is highly appreciated by teenage patients and effective in improving psychological outcomes and satisfaction with care (2,3).

Routine assessment of HRQoL provides an opportunity to screen for common psychological problems in youth with diabetes, in particular depressive symptoms and problematic eating (4, 5). Using a stepped care approach, routine periodic assessment and discussion of the patient's psychosocial needs may identify specific psychosocial problems that warrant professional evaluation and possible intervention.

A key foundation for securing comprehensive psychosocial care is the use of effective psychosocial evaluation methods. In the context of the Diabetes Attitudes Wishes and Needs (DAWN) Youth program, the DAWN MIND (Monitoring Individual Needs in Diabetes) Youth (DM-Y) program was initiated and supported by the International Diabetes Federation (IDF) and ISPAD (6). DM-Y aims to promote and simplify psychosocial assessments as integral part of routine pediatric diabetes care and evaluate the impact on medical and psychosocial outcomes.

As a first step in the DM-Y initiative, a critical review of existing HRQoL measures for youth with diabetes was performed, with a focus on validity and clinical utility (6). It was concluded that none of the existing instruments fulfilled all criteria set for use in routine pediatric care, either because they were found too lengthy or did not cover all relevant domains

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3 (especially family functioning, depressive symptoms and problematic eating). Therefore, we set
4
5 out to develop a new multi-dimensional questionnaire, building on existing measures, specifically
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7 designed for use in routine pediatric diabetes care. Our aim was to cover all relevant domains
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9 without overburdening the patient. This study reports on the development and validation of the
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11 MIND Youth Questionnaire (MY-Q) in Dutch teenagers with type 1 diabetes.
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METHODS

Development of the MY-a

Criteria

An international multi-disciplinary group of psychologists, pediatricians, pediatric endocrinologists and nurses working with teenagers with diabetes as well as young people with type 1 diabetes worked to further specify which aspects of living with diabetes should be included in a HRQoL instrument and to identify criteria for effective clinical use.

There was consensus that the MY-Q questionnaire should be:

- 1) Actionable (clear scoring algorithm, assessing clinically relevant / modifiable factors);
- 2) Comprehensive (topic should cover areas of life affected and majority of patients should feel assessment is not lacking a critical area);
- 3) Acceptable (high face validity, patient/clinical acceptability);
- 4) Brief (maximum administration time of 15 minutes);
- 5) Psychometrically reliable (with minimal item redundancy)

Discussions among the international group resulted in a list of several potentially relevant domains, including: General QoL, Diabetes-specific QoL, Family functioning, Diabetes-distress, Fear of hypoglycemia, Peer support, Depressive symptoms, Problematic eating behavior, Self-management and Self efficacy.

Selection of items

Based on the outcomes of the expert meetings, candidate items for the MY-Q were identified from a variety of sources, including a review of previously published studies (7-9).

The short form of the freely available Diabetes Quality of Life for Youth (DOOL-Youth-SF) measure (7) formed the basis for the MY-Q. To address the domains School and Friends, we examined the PedsQL (10). For the domain of Family functioning we checked the Diabetes Family Conflict Scale (DFCS) (11). To assess (mis)Management of diabetes, we examined the

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4 Confidence In Diabetes Self-care-Youth (CIDS-Youth) (12) and the Mismanagement
5
6 questionnaire (13). Analyses of DFCS, CIDS, Mismanagement and PedsQL questionnaire data
7
8 showed which topics were the most informative within their particular domain (8, 9). For items
9
10 with high inter-item correlations (>0.70), we retained one item to avoid redundancy. To assess
11
12 Problematic eating, two items of the Eating Disorders Examination-Questionnaire (EDE-Q) were
13
14 added (14). As HRQoL questionnaires are not designed to cover Emotional well-being and
15
16 depressive symptoms, we added the WHO-Five Well-being Index (WHO-5) (15, 16). Lower
17
18 scores on this questionnaire indicate the need for further depression screening (17).
19
20 Members of the DAWN Youth Advisory Board made suggestions for additional items on the
21
22 domains of Responsibility, Parental support and Treatment satisfaction. Response options for
23
24 the final item selection were made uniform (except for the WHO-5). The DAWN Youth Advisory
25
26 Board approved the final selection of items.
27

28 29 **Final questionnaire**

30
31 The MY-Q consists of 36 items, covering the domains of General QoL, the teenagers' social
32
33 life (friends, family, school), diabetes management (worries, treatment barriers, self efficacy and
34
35 satisfaction, problematic eating) and emotional well-being. Most questions use a Likert scale,
36
37 pertaining to frequency or intensity.
38

39
40 *General QoL:* The MY-Q starts with a general QoL item that asks how teenagers rate their
41
42 overall life on a 10 point ladder (1=worst life possible till 10=best life possible). The raw scores
43
44 are transformed to 1-100.
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47 *Total MY-Q:* This question is then followed by 27 items on generic and diabetes-related well-
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49 being, scored on a 5 point Likert scale (1=all the time through 5=never / 1=never through 5=11-
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51 14 days). Positively worded items are reversed, so that higher scores represent better QoL.
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53 Items scores are recoded (1=0, 2=25, 3=50, 4=75, 5=100) and the total score computed as a
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3 mean of the items, resulting in scores between 0 and 100. Several subscales were derived from
4
5 the 27 items by explorative factor analysis; these are described in the results.
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7

8 *Emotional well-being:* Screening of emotional well-being is done by means of the WHO-5,
9 which consist of five positively worded items, scored on a six-point Likert scale. Raw scores are
10 converted to 0= worst thinkable well-being - 100=best thinkable well-being. Within this range, a
11 score <50 suggests poor emotional well-being and a sign for further testing (17).
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15 *Treatment barriers:* To assess treatment barriers, teenagers are asked with one question to
16 check which aspects of their treatment they find hardest to fit in their life. Response options
17 include: pricking my finger, injecting insulin, carbohydrate counting, deciding what to eat or drink,
18 responding to low blood sugars, changing infusion set, controlling high blood sugars, something
19 else and nothing.
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26 *Open-end questions:* Two open-end questions conclude the questionnaire, asking about life
27 events in the past 6 months and any topic(s) the teenager would like to discuss with the health
28 care team.
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32 **Facilitating discussion: flags**

33 To facilitate interpretation and the discussion of HRQoL outcomes, we formulated criteria to
34 indicate when the respondent reports a low score on a specific domain. A flag is generated when
35 a teenager ticks one of the two worst options of the Likert scale of any item within the domain.
36 For the questions on frequency of eating binges and insulin omission, a flag is generated if the
37 teenager reports eating binges four or more days and/or omitted insulin one or more days. If the
38 WHO-5 score is <50, a flag is generated to indicate elevated depressive symptoms (17).
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50 **Evaluation of psychometric properties**

51 **Patients and procedure**

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3 For the validation of the MY-Q, teenagers in the age range 10 until 18 years were recruited
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5 from two pediatric outpatient clinics in the Netherlands (VU University medical center and
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7 Diabeter) by sending out emails. Treating physicians approached eligible patients and parents
8
9 and provided information on the study. Inclusion criteria were type 1 diabetes and Dutch
10
11 language understanding. Interested teenagers signed informed consent and completed the
12
13 questionnaire online. At the same time, an additional 22 teenagers were invited to participate in
14
15 a semi-structured interview while completing the MY-Q to assess face validity. The study
16
17 procedure was approved by the medical ethics committee of the VU University medical center.
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19

20 **Additional measures**

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22 To examine concurrent validity, we asked the teenagers to complete the *Pediatric Quality of*
23
24 *Life Inventory* (PedsQL) (10) in addition to the MY-Q. The PedsQL evaluates youth perceptions
25
26 of their HRQoL. Both the generic and diabetes specific module of the PedsQL were
27
28 administered. The generic module consists of 23 items (encompassing physical and
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30 psychosocial subscales) and the diabetes module of 28, both scored on a 5-point Likert scale.
31
32 Several *demographic and diabetes related variables* (gender, age, diabetes duration, treatment
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34 regimen and most recent HbA1c value) were collected from the participants' medical charts.
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37 **Statistical analyses**

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39 To study the factor structure of the items, excluding the general QoL question, the WHO-5
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41 and the treatment barriers question, an exploratory factor analysis (EFA), using principal
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43 component analysis with promax rotation was conducted. Internal consistency (Cronbach's
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45 alpha), item-total and inter-item correlations were calculated to assess the reliability of the
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47 subscales. Floor and ceiling effects were examined on item and subscale levels, by calculating
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49 the percentage of patients receiving the lowest or highest score. Moderate effects have been
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51 described when 22% to 25% of respondents are at the floor or ceiling of a scale (18) and
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53 excessive when more than 50% of respondents report the minimum or maximum score (19).
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3 Concurrent validity was assessed by calculating Pearson or Spearman correlation coefficients
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5 between the MY-Q, WHO-5 and PedsQL questionnaires. Construct validity was assessed by
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7 associations of the MY-Q measures with age, gender and clinical variables using Pearson or
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9 Spearman correlation coefficients or analysis of variance (ANOVA). A p-value<0.05 was
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11 considered significant.
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RESULTS

Face validity

Twenty-two teenagers were interviewed while completing the questionnaire. The MY-Q was generally considered easy to understand, with exception of four questions. We slightly changed the wording afterwards. Nineteen of the respondents thought it was a good idea to assess their HRQoL as integral part of their consultations with their diabetes team; three had no opinion. One teenager would have wanted more questions about sleeping over; the remaining teenagers reported that the questionnaire did not miss important topics. We also asked whether there were questions, they would rather not complete. Two teenagers were reluctant to complete questions about their family, as the results were to be discussed while the family member was present. One teenager preferred not to answer the open-end questions about life events and topics to be discussed with the team. It took teenagers on average 11 minutes (range 4-15 minutes) to complete the questionnaire. Only one teenager thought this was a bit too long.

Psychometric properties

Forty boys and 44 girls with type 1 diabetes and a mean age of 14.4 ± 2.2 years (range 10-18 year) completed the questionnaires online. Mean diabetes duration was 6.4 ± 4.0 years and mean HbA1c level was $8.1 \pm 1.4\%$. The majority (86.7%) was on an intensive treatment regimen (77.1% used an insulin pump).

Reliability

The Cronbach's alpha for the total questionnaire was 0.80. Principal component analysis suggested a seven-factor structure. The explained variance was 58%. To enhance clinical utility of the questionnaire, we decided to split one of the factors in two subscales: Parents and Control. In addition, the items in the last subscale were divided over subscales that made more sense conceptually, as they did not seem to represent one underlying construct. The item

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3 "paying attention in class/at work" was placed into the Social impact scale (alpha decreased from
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5 0.69 to 0.68); the item "feel like a burden to my family" was put in the Parent scale (alpha
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7 decreased from 0.68 to 0.64), and the item "happy with the way I look" was placed into the Body
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9 scale (alpha increased from 0.32 to 0.38). The item "relying on teachers/colleagues to take care
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11 of diabetes" loaded on the Worries subscale. However, exclusion of this item resulted in a higher
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13 alpha (0.64 vs. 0.55) so the item was moved to the Social impact scale where it fit better
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15 conceptually. The item "not enough help and support from parents" did not demonstrate a
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17 significant loading on any of the factors. Placing this item in the 'Parents' subscale did not alter
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19 the internal reliability of the scale.
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23 The internal consistencies for the final subscales are described in Table 1. The reliability was
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25 above 0.60 for all subscales except Responsibility and Body. Responsibility was not expected to
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27 have high inter-item agreement because in general we expect a negative correlation between
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29 having too much responsibility and too little responsibility (the modest positive inter-item
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31 correlation is a result of the fact that most respondents have neither too much nor too little
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33 responsibility). The low reliability of the Body subscale could be explained by the skewed
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35 distribution of the items (very few problems are reported, see Table 1).
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39 Item-total correlations ranged from 0.11 to 0.54. Low item-total correlations were found for
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41 the items: "rely on teacher(s) / colleagues", "too little responsibility for diabetes care" and "trying
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43 to control weight or shape". Inter-item correlation within subscales ranged from .00 to 0.59
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45 (median 0.15), indicating low redundancy.
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47 Descriptives

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49 Table 1 displays the frequencies of the given answers on the individual items. In this sample,
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51 23% of the teenagers reported satisfactory HRQoL with no flags. Another 23% scored low on
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53 one item; 47% reported low scores on 2 to 5 items and 7% reported low scores on 6 to 10
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3 questions. Twenty-four percent of the teenagers reported suboptimal emotional well-being
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5 (WH0-5 score <50).
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8 Table 2 shows the mean scores and the percent with minimum and maximum scores for the
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10 MY-Q total score and subscales. We found no floor effects on the total score or on any of the
11
12 subscales. The Worries and Satisfaction scales showed moderate ceiling effects.
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14 Teenagers were asked to indicate three aspects of their treatment that they found hardest to
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16 fit into their daily activities (Treatment barriers). The three aspects most frequently endorsed
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18 were: "Controlling high blood sugars"(56%), "changing infusion set"(45%) and "pricking my
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20 finger(28.6%)". The remaining aspects were: "carbohydrate counting"(22.6%), "injecting
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22 insulin"(19%), "deciding what to eat or drink"(16.7%) and "responding to low blood
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24 sugars"(14.3%). "Nothing" was ticked by 7.1% of the teenagers and 26.2% ticked "something
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26 else... ". Examples are: unexplainable values; going to the clinic; controlling blood sugar values
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28 when sick; check regularly; not eating too much; school; remembering to check blood sugars
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30 and/or change infusion set and/or to bolus.
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33 34 **Validity** 35

36 Associations of the MY-Q total and subscale scores with the PedsQL measures, HbA1c and
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38 age are described in Table 3. The strong associations between higher total scores of the MY-Q
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40 and higher PedsQL generic ($r=0.58$, $p<.001$) and diabetes ($r=0.71$, $p<.001$) scores support
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42 concurrent validity of the MY-Q. The MY-Q total score correlated moderately with the WH0-5
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44 ($r=0.42$, $p<.001$) and the single General QoI question ($r=0.55$, $p<.001$).
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46 Correlations among MY-Q subscales ranged from 0.06 (Worries and Treatment satisfaction) to
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48 0.45 (Parents and Control), with a median of 0.22. The low to moderate correlations indicate that
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50 the subscales assess different constructs.
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53 Construct validity was examined by comparing MY-Q subscales with areas likely to be
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55 related. As expected, higher HbA1c was associated with lower Control ($r=-0.35$, $p=.001$),
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3 Worries ($r=-0.24$, $p=.029$) and lower Body ($r=-0.26$, $p=.019$) scores. Younger age was associated
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5 higher scores on the Control ($r=-0.26$, $p=.020$) and Body ($r=-0.23$, $p=.038$) subscales and with
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7 lower scores on the Responsibility scale ($r=0.25$, $p=.027$). Girls reported more problems on the
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9 Body subscale (76.49 vs. 83.50, Cohen's $d = 0.52$, $p=.021$) than boys. Girls also reported more
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11 Worries than boys did (72.92 vs. 85.26, Cohen's $d = 0.63$, $p=.006$).
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14 We found no differences between treatment regimens on total or subscales scores.
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DISCUSSION

The MIND Youth Questionnaire (MY-Q) is the first validated HRQoL measure for teenagers with diabetes, specifically designed for routine clinical use, in compliance with international recommendations (1). The questionnaire was developed under the auspices of the international DAWN Youth initiative, with input from a multidisciplinary group of experts and young patients living with type 1 diabetes. Results from this study in Dutch teenagers with type 1 diabetes provide evidence for the psychometric validity of the MY-Q and patient acceptance. Strengths of the instrument include its brevity, while encompassing multiple relevant domains and providing actionable outcomes. Importantly, the MY-Q combines the evaluation of perceived HRQoL with screening items for likely depression and problematic eating, conditions warranting special attention in this age-group. In line with previous findings, a quarter of the teenagers in our study reported poor well-being, indicating a need for further testing for clinical depression (17). Previous research showed that half of the teenagers rarely or never talk with their health care team about their feelings and only a quarter of those with elevated depressive symptoms receive psychological care (20). By including a depression screener in the MY-Q, patients' emotional well-being can be discussed in the context of overall HRQoL and specific areas of concern, such as family conflicts, school performance and treatment burden. With regard to eating problems, most patients do not spontaneously admit to having an eating disorder and it is commonly detected first by health care professionals (21). The MY-Q may help to lower the threshold for reporting problems with eating, prompting a discussion with a pediatrician or nurse educator. If indicated and agreed upon, a referral can then be initiated for a more extensive clinical assessment of eating problems (22).

Overall, the validity and reliability of the MY-Q were found to be sound. Teenagers found the questionnaire acceptable and appreciated that their HRQoL was taken into account. The factor analysis revealed six clinically meaningful constructs and to enhance clinical utility, we split one

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3 factor in two subscales (Parents and Control). The Responsibility and Body subscales showed
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5 low reliability. We did not expect a high inter-item agreement because in general, having too
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7 much responsibility and too little responsibility should correlate negatively. Indeed, teenagers
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9 who reported a low score on one item, reported a high score on the other. However, most
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11 respondents reported neither too much nor too little responsibility, so the Cronbach's alpha for
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13 this subscale was low. The low reliability of the Body subscale could be explained by the fact
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15 that very few problems are reported. However, the screening possibilities of the individual items
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17 justify the inclusion. For clinical use, a flag on either of these two subscales warrants closer
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19 examination of the individual items.
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23 Indeed, low scores on a single item are meaningful in themselves, irrespective of whether
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25 scores on other items are in a desirable range. Each item is designed to assess an important
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27 aspect of living with diabetes. QoI interventions can be targeted specifically to the areas of risk,
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29 making it easier for health care professions who are not psychosocial specialists to provide
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31 meaningful assistance to their own patients or to refer to another provider with a targeted
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33 request for intervention.
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36 Additional research is necessary to examine test-retest reliability and the sensitivity to
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38 change of the MY-Q in longitudinal studies and trials. Further research is also warranted to
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40 examine the measurement properties of the MY-Q across countries and languages and in more
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42 ethnically and racially diverse samples of adolescents. Acceptance and readability could be
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44 sensitive to educational level and cultural differences and therefore deserve special attention.
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47 Regular monitoring of HRQoI provides an opportunity to track changes over time and
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49 examine the impact of treatment (alterations) on an individual and group level. Thereby providing
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51 a unique source of new data to explore associations of psychosocial and clinical outcomes over
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53 time. Over three-quarters of the teenagers scored low on one or more questions. This suggests
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55 that the questionnaire is sensitive enough to detect possible issues at an early stage. However,
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3 the use of HRQoL outcomes in routine care requires training of the health care professionals. A
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5 questionnaire is one important part of the assessment, but communication skills are also vital to
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7 achieve positive health care outcomes (23). Therefore, in addition to the MY-Q, a 1-day training
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9 program and a user manual have been developed to facilitate implementation of HRQoL
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11 assessment and discussion in routine pediatric diabetes care. We have also developed a web-
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13 based program to generate a report for each administration of the MY-Q, including flags where
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15 the score is indicative of low HRQoL. More information about these programs can be obtained
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17 from the first author.
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21 The role of parents should receive extra attention in this context. In our interviews, some
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23 teenagers indicated they preferred not to complete questions on family because of the concern
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25 about having to discuss their responses with the parents present. It should therefore always be
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27 made clear to teenagers that they can discuss the outcomes with their health care team alone if
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29 so wished and that it is up to them if and how parents will be involved. However, in the
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31 management of diabetes in teenagers, the role of the family is very important. Therefore, sharing
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33 a summary of the discussion with parents should be encouraged. It is evident that cultural and
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35 individual differences in this regard need to be carefully considered and respected in each case.
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38 In adults with diabetes, the international DAWN MIND study demonstrated the feasibility of
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40 implementing a computer-assisted assessment and discussion of well-being in routine care (24).
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42 Currently, an implementation study is ongoing in 13 pediatric diabetes clinics throughout the
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44 Netherlands with the MY-Q included in the annual review. This study will provide further
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46 evidence regarding the feasibility of the routine use of the MY-Q in clinical practice. At present,
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48 the MY-Q seems suitable to assess the psychosocial needs and barriers to effective self-
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50 management of young people with diabetes and their families in a structured way.
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Table 1: Frequencies of answers on items, flags and Cronbach's alpha's.

Items	Frequencies (%)						Reliability
	<i>All the time</i>	<i>Often</i>	<i>Some times</i>	<i>Seldom</i>	<i>Never</i>	Flag•	Cronbach's alpha
Social impact							0.68
diabetes Intetieres with sports	1.2	11.0	34.1	24.4	29.3	12.2	
diabetes interrupts leisure time activities	1.2	6.1	50	34.1	8.5	7.3	
doing activities without parents	2.4	6.1	30.5	15.9	45.1	8.5	
diabetes limits friendships and relationships	0	10.7	31	33.3	25	10.7	
getting along with people my age•	53.6	41.7	2.4	1.2	1.2	2.4	
other people of my age bully me	0	2.4	9.5	20.2	67.9	2.4	
diabetes interferes with family activities	0	3.6	26.5	28.9	41.0	3.6	
pay attention in class / at work	1.2	15.5	45.2	28.6	9.5	16.7	
rely on teacher(s) /colleagues•	32.1	23.8	27.4	11.9	4.8	16.7	
Parents							0.64
parents worry too much about your diabetes	4.8	21.7	45.8	18.1	9.6	26.5	
parents act like diabetes is their disease	6.0	10.8	19.3	24.1	39.8	16.8	
argue with parents about checking blood sugars / giving injections	1.2	14.6	29.3	35.4	19.5	15.8	
argue with parents about meals and snacks	2.4	8.5	22.0	24.4	42.7	10.9	

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parents do not give enough help and support	0	2.4	4.8	13.3	79.5	2.4	
feel like a burden to members of your family	1.2	3.6	21.7	16.9	56.6	4.8	
Control							0.76
feel in control of diabetes*	13.6	48.1	29.6	6.2	2.5	8.7	
happy with the blood sugar control'	11,1	32.1	38.3	13,6	4.9	18.5	
Responsibility							0.36
too much responsibility for diabetes care	4.1	6.0	19	19	32.1	10.1	
too little responsibility for diabetes care	1.2	1.2	6,0	23.8	52.4	2.4	
Worries							0.64
Worry about hypo's	1.2	2.5	18.5	33.3	44.4	3,7	
Worry about complications	2.5	4.9	13.6	34.6	44.4	7.4	
Satisfaction							0.79
happy with health care team'	65.4	28.4	6.2	0	0	0	
happy with medical treatment regimen*	42	54,3	2.5	1.2	0	1.2	
Body							0.38
happy with the way I look'	28.4	38,3	27.2	4.9	1.2	6.1	
trying to control weight or shape	1.2	13.6	19.8	16.0	49.4	14,8	
	<i>never</i>	<i>1-3 days</i>	<i>4-7 days</i>	<i>8-10 days</i>	<i>11-14 days</i>		
eating binges	35,8	40,7	14.8	4.9	3,7	23.4	

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omitted insulin	96.3	0	2.5	1.2	0	3.7	
Mood							
WHO-5 questionnaire	N/A					24	0.78

- reverse scored items, 'Flag algorithm: one of the two worst option on the Likert scale is ticked and/or *eating binges* 4 days and/or *omitted insulin* 1 day and/or WHO-5 score < 50.

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Table 2: Descriptives

	Mean	Std. Deviation	Minimum	Maximum	% floor/ ceiling
General QoI	75.24	14,1	10	100	1.2 / 6.0
MYQ total	74.26	9.4	48.15	89.81	0 / 0
Social impact	73.62	12.2	37.50	100	0 / 1.2
Parents	68.05	17.1	25.00	100	0 / 3.7
Responsibility	74.70	19.9	25.00	100	0 / 24.4
Control	62.03	21.2	.00	100	2.5 / 2.5
Worries	78.85	20.41	.00	100	1.2/27.2
Treatment satisfaction	87.04	13.6	37.50	100	0 / 39.5
Body	79.86	13.8	37.50	100	0 / 9.9
WHO-5	60.69	17.6	0	96	1.2 / 0

Higher scores indicate better HRQoL

Table 3: correlations

	MY-Q									
	General Qol	Total	Social impact	Parents	Responsibility	Control	Worries	Treatment satisfaction	Body	WHO-5
Age	-.42**	-.19	-.08	-.10	.25*	-.26*	-.19	-.11	-.23*	-.24*
HbA1c	-.26*	-.26*	-.07	-.22	-.04	-.35**	-.24*	.02	-.26*	.06
General Qol	1.0	.55**	.40**	.38**	-.08	.62**	.17	.22*	.36**	.58**
WHO-5	.58**	.42**	.35**	.33**	-.04	.32**	.13	.04	.31**	1.0
PedsQL										
Total generic	.53**	.58**	.57**	.33**	.07	.28*	.40**	.08	.36**	.54**
Physical	.43**	.33**	.37**	.20	.03	.13	.23*	.01	.30**	.46**
Psychosocial	.52**	.64**	.60**	.37**	.09	.32**	.43**	.11	.34**	.53**
Emotional	.54**	.59**	.54**	.32**	.11	.30**	.40**	.13	.36**	.56**
Social	.31**	.48**	.55**	.20	.10	.15	.35**	.08	.28*	.32**
School	.30**	.45**	.37**	.48**	.06	.26*	.13	-.00	.21	.37**
Total diabetes	.56**	.71**	.51**	.53**	.09	.55**	.38**	.10	.49**	.49**
Symptoms	.49**	.50**	.41**	.31**	.11	.41**	.30**	.02	.33**	.53**
Barriers	.49**	.64**	.46**	.55**	-.02	.61**	.20	.17	.39**	.38**
Adherence	.49**	.55**	.40**	.45**	-.01	.42**	.33**	.11	.36**	.42**
Communication	.34**	.45**	.34**	.35**	.23*	.27*	.28*	.18	.24*	.29*

Significance level: *p<0.05, **p<0.01

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Table 1: Frequencies of answers on items, flags and Cronbach's alpha's.

Items	Frequencies (%)						Reliability
	<i>All the time</i>	<i>Often</i>	<i>Some times</i>	<i>Seldom</i>	<i>Never</i>	Flag•	Cronbach's alpha
Social impact							0.68
diabetes intetieres with sports	1.2	11.0	34.1	24.4	29.3	12.2	
diabetes interrupts leisure time activities	1.2	6.1	50	34.1	8.5	7.3	
doing activities without parents	2.4	6.1	30.5	15.9	45.1	8.5	
diabetes limits friendships and relationships	0	10.7	31	33.3	25	10.7	
getting along with people my age'	53.6	41.7	2.4	1.2	1.2	2.4	
other people of my age bully me	0	2.4	9.5	20.2	67.9	2.4	
diabetes interferes with famHy activities	0	3.6	26.5	28.9	41.0	3.6	
pay attention in class / at work	1.2	15.5	45.2	28.6	9.5	16.7	
rely on teacher(s) /colleagues•	32.1	23.8	27.4	11.9	4.8	16.7	
Parents							0.64
parents worry too much about your diabetes	4.8	21.7	45.8	18.1	9.6	26.5	
parents act like diabetes is their disease	6.0	10.8	19.3	24.1	39.8	16.8	
argue with parents about checking blood sugars/ giving injections	1.2	14.6	29.3	35.4	19.5	15.8	
argue with parents about meals and snacks	2.4	8.5	22.0	24.4	42.7	10.9	
parents do not give enough help and	0	2.4	4.8	13.3	79.5	2.4	

A47

Pediatric Diabetes

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support							
feel like a burden to members of your family	1.2	3.6	21.7	16.9	56.6	4.8	
Control							0.76
feel in control of diabetes..	13.6	48.1	29.6	6.2	2.5	8.7	
happy with the blood sugar control•	11.1	32.1	38.3	13.6	4.9	18.5	
Responsibility							0.36
too much responsibility for diabetes care	4.1	6.0	19	19	32.1	10.1	
toolittle responsibility for diabetes care	1,2	1.2	6.0	23.8	52.4	2.4	
Worries							0.64
Worry about hypo's	1.2	2,5	18.5	33.3	44.4	3.7	
Worry about complications	2.5	4.9	13,6	34.6	44.4	7.4	
Satisfaction							0.79
happy with health care team*	65.4	28.4	6.2	0	0	0	
happy with medical treatment regimen*	42	54.3	2.5	1.2	0	1.2	
Body							0.38
happy with the way I look•	28.4	38.3	27,2	4,9	1.2	6.1	
trying to control weight or shape	1.2	13.6	19.8	16.0	49.4	14.8	
	<i>never</i>	<i>1-3 days</i>	<i>4-7 days</i>	<i>8-10 days</i>	<i>1H4days</i>		
eating• binges	35.8	40.7	14.8	4.9	3.7	23.4	
omitted insulin	96.3	0	2.5	1.2	0	3.7	
Mood							

A48

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[WHO-5 questionnaire	NIA		24	0.78
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'reverse scored items,'"Flag algorithm: one of the two worst option on the Liker! scale is ticked
and/or *eating binges* 4 days and/or *omitted insulin* 1 day and/or WHO-5 score<50.

A49

Table 2: Descriptives

	Mean	Std. Deviation	Minimum	Maximum	%floor/ceiling
General Qol	75.24	14,1	10	100	1.2 / 6.0
MYQ total	74.26	9.4	48.15	89.81	<i>DID</i>
Social impact	73.62	12.2	37.50	100	0 / 1.2
Parents	68.05	17.1	25.00	100	0 / 3.7
Responsibility	74.70	19.9	25.00	100	0 / 24.4
Control	62.03	21.2	.00	100	2.5 / 2.5
Worries	78.85	20.41	.00	100	1.2 / 27.2
Treatment satisfaction	87.04	13.6	37.50	100	0 / 39.5
Body	79.86	13.8	37.50	100	0 / 9.9
WHO-5	60.69	17.6	0	96	1.210

Higher scores indicate better HRQoL

A50

Table 3: correlations

	MY-Q									
	General Qol	Total	Social impact	Parents	Responsibility	Control	Worries	Treatment satisfaction	Body	WHO-5
Age	-.42**	-.19	-.08	-.10	.25*	-.26*	-.19	-.11	-.23*	-.24*
HbA1c	-.26*	-.26*	-.07	-.22	-.04	-.35**	-.24*	.02	-.26*	.06
General Qol	1.0	.55**	.40**	.38**	-.08	.62**	.17	.22*	.36**	.58**
WHO-5	.58**	.42**	.35**	.33**	-.04	.32**	.13	.04	.31**	1.0
PedsQL										
Total generic	.53**	.58**	.57**	.33**	.07	.28*	.40**	.08	.36**	.54**
Physical	.43**	.33**	.37**	.20	.03	.13	.23*	.01	.30**	.46**
Psychosocial	.52**	.64**	.60**	.37**	.09	.32**	.43**	.11	.34**	.53**
Emotional	.54**	.59**	.54**	.32**	.11	.30**	.40**	.13	.36**	.56**
Social	.311<*	.48**	.55**	.20	.10	.15	.35**	.08	.28*	.32**
School	.30**	.45**	.37**	.48**	.06	.26*	.13	-.00	.21	.37**
Total diabetes	.56**	.71**	.51**	.53**	.09	.55**	.38**	.10	.49**	.49**
Symptoms	.49**	.50***	.41**	.31**	.11	.41**	.30**	.02	.33**	.53**
Barriers	.49**	.64**	.46**	.55**	-.02	.61**	.20	.17	.39**	.38**
Adherence	.49**	.55**	.40**	.45**	-.01	.42**	.33**	.11	.36**	.42**
Communication	.34**	.45**	.34**	.35**	.23*	.27*	.28*	.18	.24*	.29*

Significance level: *p<0.05, **p<0.01

Diabetes Self Management Profile Scoring Guide

Diabetes Self Management Profile – Self Report form (DSMP-SR) This 24-item self-report questionnaire was derived from a previously validated structured interview. It yields subscale scores for five domains of diabetes adherence (Exercise, Diet, Hypoglycemia, Glucose Testing and Insulin) and parents and .71 for youths. Parent-youth scores correlated 0.59. a total adherence score. Items are rated on Likert response scales, with higher scores indicating better diabetes-related adherence. Cronbach's alpha coefficient was .76 for the total score and inter-rater agreement was .94. The correlation between total scores of parents and adolescents was .72. Correlations with HbA_{1C} reported by several research groups were consistently significant (range -.25 to -.60). Based on administration of the self-report version to 36 parents and youths in another ongoing study, internal consistency was .83 for

Administration: Administer the parent form to parents and the youth form to kids 11 and up. Ensure that they do not interact about their responses either by separating them or by staying with them while they complete it. Emphasize that many/most kids and parents struggle with doing everything exactly as expected of them and that we really want their most accurate and true answers.

Scoring: Each response option yields a specified numerical score per the DSMP Scoring Sheet. Enter the score for each item, total the individual item scores. Possible range is 0 to 86. Higher total scores indicate better overall treatment adherence and more meticulous diabetes management.

Data Entry: Enter the numerical score for each item of the scale and the total score separately for parents and adolescents. If one or more item scores is missing, subtract the maximum number of points for each missing item from 86. Then divide that quantity by 86, yielding a value between 0 and 1. Divide the total score for that participant by this value, which will provide a total score adjusted for any missing items.

Question by Question Scoring of the DSMP-SR

1. In the past 3 months, how often have you gotten exercise such as running, skateboarding, bike riding, swimming, skating, or playing any sports for at least 20 minutes?

- More than three times per week 4
- 2 – 3 times per week 3
- Once a month..... 1
- Less than once per month 0

2. In the past 3 months, if you got more exercise than usual, or planned to get more exercise than usual, what did you usually do about the meal plan or insulin?

- Exercises so consistently that adjustments are unnecessary 4
- Always eats more or gives less insulin..... 4
- Frequently eats more or gives less insulin (2-3 times per week) 3
- Sometimes eats more or gives less insulin (once a week) 2
- Occasionally eats more or gives less insulin (few times a month) 1
- Eats less than usual or gives more insulin or does not adjust eating or insulin 0

3. In the past 3 months, if you got less exercise than usual, or if you planned to get less exercise, what did you usually do about the meal plan or insulin?

- Exercises so consistently that adjustments are unnecessary 4
- Always eats less or gives more insulin 4
- Frequently eats less or gives more insulin (2-3 times per week) 3
- Sometimes eats less or gives more insulin (once a week) 2
- Occasionally eats less or gives more insulin (few times a month) 1
- Eats more than usual or gives less insulin or does not adjust eating or insulin 0

4. Do you keep something handy in case your sugar gets too low? For example, when you are at school or at a ball game, or in the car and your sugar gets too low, do you have something handy to eat?

- Yes..... 1
- No 0

5. If you think you are having a low blood sugar, how often do you check your blood sugar before treating?

Has not had a low blood sugar in past 3 months.....	4
Always checks before treating a low blood sugar.....	4
Usually checks before treating a low blood sugar (more than half the time)	3
Sometimes checks before treating a low blood sugar (about half the time)	2
Rarely checks before treating a low blood sugar..... (less than half the time)	1
Never checks before treating a low blood sugar.....	0

6. People take care of low blood sugars in many different ways. What did you usually do to treat your low blood sugars in the past 3 months?

Has not had a low blood sugar in the past 3 months.....	4
Careful to quickly take the right amount of carbs and check blood sugar after 10 minutes.....	4
Takes the right amount of carbs but does not check blood sugar afterwards	3
Takes some carbs without thinking about how much	2
Keeps taking carbs until feel better	1
Waits until there's a better time to treat low blood sugar	0

7. Do you usually wear or carry any kind of diabetic identification, like a card or bracelet?

Wears a necklace, bracelet or charm.....	2
Carries an ID card in wallet or purse.....	1
Doesn't wear or carry diabetic ID	0

8. In the past 3 months, did you usually count carbs, measure or weigh food, or use exchanges to figure out how much to eat?

Uses carb counting (or exchange list) as a guide and either measures food or read labels.....	3
Uses carb counting (or exchange list) as a guide, but knows meal plan well enough so that they can eat the right amounts without measuring or reading labels.....	2

Eats about the same amounts of food each meal, but doesn't use carb counting, measuring or an exchange list 1

Eats the amount they are hungry for and doesn't follow any set patterns of types or amounts of foods 0

9. In the past 3 months, how often have you eaten "fast foods" or "junk foods" such as sweets, cookies, cakes, ice cream, chips, pizza, french fries, hot dogs, or others?

Occasionally (few times a month or less) 4

Sometimes (once a week) 3

Frequently (2-3 times per week) 2

Almost always (4 or more times per week) 1

Every day 0

10. In the past 3 months, how often have you eaten more than what was on your meal plan (more than total amount of carbs or calories recommended at meals)?

Never or hardly ever (1-2 times in the last 3 months) 4

Seldom (once a month) 3

Occasionally (few times each month) 2

Frequently (2-3 times per week) 1

Almost daily (4 or more times per week) 0

11. In the past 3 months, before you ate more than usual, did you make any insulin changes?

Gives MORE insulin when eats more 1

Gives LESS insulin when eats more 0

Does not adjust insulin 0

12. In the past 3 months, how often have you eaten less than what was planned?

Never or hardly ever (1-2 times in the last 3 months) 4

Seldom (once a month) 3

Occasionally (few times each month) 2

Frequently (2-3 times per week) 1

Almost daily (4 or more times per week).....0

13. Before you eat less than usual, do you make any insulin changes? What do you do?

Gives LESS insulin when eats less 1

Gives MORE insulin when eats less 0

Does not adjust insulin 0

14. In the past 3 months, how often have you checked your blood sugar?

6 or more times daily 4

4 or 5 times daily 3

2 or 3 times daily 2

At least once daily 1

Less than once daily 0

Does not check..... 0

15. In the past 3 months, how often did you do a blood sugar check within 30 minutes before a meal?

Always checks blood sugar within 30 minutes before every meal 4

Usually checks within 30 minutes before meals (more than half the time)..... 3

Sometimes checks within 30 minutes before meals (about half the time)..... 2

Checks within 30 minutes before meals less than half the time 1

Never checks within 30 minutes before meals 0

16. In the past 3 months, how often did you do a blood sugar check within 2-3 hours after a meal?

Checks blood sugar within 2-3 hours after a meal 4 or more times per week 4

Checks 2-3 hours after a meal 3 times per week 3

Checks within 2-3 hours after a meal 2 times per week 2

Checks within 2-3 hours after a meal once a week 1

Never checks within 2-3 hours after meals 0

17. In the past 3 months, how often did you do a blood sugar check within 2-3 hours after heavy exercise?

Always checks blood sugar within 2-3 hours after exercise 4

Checks 2-3 hours after exercise more than half the time 3

Checks 2-3 hours after exercise about half the time	2
Checks 2-3 hours after exercise less than half the time	1
Never checks 2-3 hours after exercise	0

18. In the past three months, how often have you changed either the insulin dose, diet or exercise when the blood sugars were running high?

Made a change every time it was needed	4
Made a change when needed more than half the time	3
Made a change when needed about half the time	2
Made a change when needed less than half the time	1
Never made a change when needed	0

19. In the past 3 months, if you had two blood sugar results above 240 in a row, how often did you do a ketone test?

Did not have two blood sugars in a row above 240	4
Always checks after 2 consecutive blood sugar results above 240	3
Usually checks after 2 consecutive blood sugar results above 240	2
Occasionally checks after 2 consecutive blood sugar results above 240	1
Never checks after 2 consecutive blood sugar results above 240	0

20. When you've been sick, how often did you do a ketone test?

Always checks several times a day when sick	4
Always checks once a day when sick	3
Usually checks once a day when sick	2
Occasionally checks when sick	1
Never checks when sick	0

21. In the last three months, how often have you bolused or taken an insulin shot more than 30 minutes late?

Never, always take insulin on time	4
Has been late once a month or less	3
Has been late once a week or less	2
Has been late more than once a week	0

22. In the past 3 months, how often have you bolused or taken MORE insulin than you should have?

- Always took the prescribed amount OR never took more 4
- Took more than prescribed amount 1 - 3 times..... 3
- Took more than prescribed amount 4 - 6 times..... 2
- Took more than prescribed amount 7 - 10 times..... 1
- Took more than prescribed amount more than 10 times 0

23. In the past 3 months, how often have you bolused or taken LESS insulin than you should have?

- Always took the prescribed amount OR never took less 4
- Took less than prescribed amount 1 - 3 times 3
- Took less than prescribed amount 4 - 6 times 2
- Took less than prescribed amount 7 - 10 times 1
- Took less than prescribed amount more than 10 times 0

24. In the last three months, how often have you missed a bolus or shot because you forgot or were too busy, or failed to give your basal insulin because your pump was not working or inserted?

- Never forgot, always take insulin 4
- Forgot once a month or less (1-3 times in the last month)..... 3
- Forgot once a week or less (2-4 times in the last month) 2
- Forgot more than once a week (more than 10 times in the last month) 0

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Hot Topic

Diabetes-specific emotional distress among adolescents: feasibility, reliability, and validity of the problem areas in diabetes-teen version

Weissberg-Benchell J, Antisdel-Lomaglio J. Diabetes-specific emotional distress among adolescents: feasibility, reliability, and validity of the problem areas in diabetes-teen version. *Pediatric Diabetes* 2011; 12: 341-344.

Jill Weissberg-Benchell and Jeanne Antisdel-Lomaglio

Child and Adolescent Psychiatry, Feinberg School of Medicine, Northwestern University, Children's Memorial Hospital, Chicago, IL, USA

Key words: adolescents - emotional distress - measure development

Corresponding author:
Jill Weissberg-Benchell,
Child and Adolescent Psychiatry,
Feinberg School of Medicine,
Children's Memorial Hospital,
Northwestern University,
2300 Children's Plaza,
P. O. Box 10, Chicago,
IL 60614, USA.
Tel: 773-880-4818;
fax: 773-880-8110;
e-mail:
JWBenchell@childrensmemorial.org

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Adolescents with diabetes may face a variety of psychosocial challenges, leading to diabetes-specific emotional distress. Adolescents with diabetes are at increased risk for anxiety and depressive symptoms (1,2), poor coping and problem-solving skills (3,4), poor regimen adherence (5,6), and family conflict (7). In the absence of a psychometrically sound measure of diabetes-specific emotional distress, attempts to assess adolescents' adjustment have previously used general measures of psychological distress (8), and diabetes-specific measures of family support (9,10), treatment adherence (11), and quality of life (12,13). In the adult literature, the Problem Area in Diabetes (PAID; see references 14-16) has proven a useful tool in assessing diabetes-specific emotional distress.

The aim of this study was to adapt the PAID for use with adolescents with type 1 diabetes. A psychometrically sound measure of diabetes-specific emotional distress for adolescents can facilitate identification of high risk individuals and aid in developing treatment interventions around specific problem areas to ultimately promote better health and well-being among adolescents with diabetes.

Experimental design and methods

Survey development

Established methods for adapting adult measures for children (8,17) were used. The original 20 items from the PAID (15) and 33 items from the PAID-2 were

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retained (Polansky, 1999, personal communication). An additional 31 items relevant to adolescents were derived through interview with 10 pediatric diabetes clinicians. Poorly worded or redundant items were deleted, resulting in a 61-item measure: problem areas in diabetes-teen version (PAID-T). Consistent with the original measure, the PAID-T is scored using a 6-point Likert scale (1 = Not A Problem, 6 = Serious Problem). A total distress score is computed by summing responses. Higher scores mean the adolescent is experiencing more emotional distress.

Participants

Participants were recruited from two major hospitals and a large diabetes private practice group at their regularly scheduled endocrine appointment. Inclusion criteria were diabetes duration >1 yr, able to read and speak English, and no other major medical or psychiatric diagnoses. The sample consisted of 130 adolescents, mean age of 15.5 ± 1.7 yr, age range 11-19yr. Mean HbA1c was 9.1 ± 1.9 (range 5.3-14.1). The sample was predominantly male (54%), Caucasian (77%), affluent (31% earned between \$50 and \$100 000, 30% earned >\$101 000), intact (70% lived with both parents), and educated with 44% of both parents at least graduating from college.

Procedures

Adolescents completed the PAID-T, either the Children's Depression Inventory (8) or the Beck Depression Inventory (18), The State Anxiety Inventory for Children (19), Diabetes Family Behavior Checklist (10), and Adolescent Quality of Life Scale (12). Hemoglobin A1c was gathered via parent report of their child's most recent value.

Results

Item analysis

Individual items were deleted if: item-to-total correlations <0.5 ($n = 17$), communalities <0.5 ($n = 1$), or >50% of respondents responded 'never' ($n = 17$). Cronbach's alpha (α) for the resulting 26 item measure was strong ($\alpha = 0.96$). These 26 items were then subjected to a Principal Components Analysis using varimax rotation. All items loaded highly (>0.5) and positively on the first principal component, accounting for 46% of the variance, confirming the presence of a large general factor underpinning all items and supporting the summation of the 26 individual items into a total distress score (Appendix).

Construct validity. The PAID-T showed strong positive correlations with measures of depression

(BDI $r = 0.61$, $p < 0.0001$; CDI $r = 0.76$, $p < 0.0001$), quality of life total scale score ($r = 0.29$, $p < 0.07$), and the diabetes worry subscale of the quality of life measure ($r = 0.69$, $p < 0.0001$) and negative correlations with measures of anxiety ($r = -0.18$, $p < 0.04$), the satisfaction subscale of the quality of life measure ($r = -0.67$, $p < 0.0001$), diabetes family behavior ($r = -0.33$, $p < 0.01$), and warm/caring interactions ($r = -0.37$, $p < 0.003$).

Adolescents reporting higher levels of diabetes-specific emotional distress also exhibited higher HbA1c ($r = 0.26$, $p < 0.006$). Girls ($M = 70.11 \pm 27.3$) reported higher levels of distress than boys ($M = 60.68 \pm 24.1$) ($t = -2.1$, $p < 0.04$).

Diabetes-specific emotional distress. Adolescents reported a fair degree of diabetes-specific emotional distress with a mean score of 65.0 ± 25.9 (range 27-136). Over half (54%) reported at least one serious concern with an average of 3.3 ± 4.8 serious concerns reported (range 0-20). The most common concerns were worrying about weight (24%), worrying about complications (24%), feeling upset when diabetes management was 'off track' (23%), feeling that friends/family act like 'diabetes police' (21%), and feeling that friends/family do not understand how difficult living with diabetes can be (19%).

Discussion

This study provides initial psychometric data on the newly adapted measure of diabetes-specific emotional distress for adolescents (PAID-T). Results suggest that it is face-valid, internally consistent, and correlates with measures of depression, anxiety, diabetes quality of life, and diabetes family behaviors. The moderate correlation between the PAID-T and measures of depression is consistent with previous research (20), which found similar correlations between the adult version of the PAID and a depression questionnaire. Moreover, this group found that although 11.4% of adults with diabetes meet criteria for a depressive disorder using diagnostic interviews, 31% have elevated depressive symptoms on the self-report depression questionnaire. These authors suggest that the association between the PAID and the depression questionnaire may indicate that questionnaires of depression are more reflective of emotional distress than actual depression.

There are several important limitations which need to be considered in the interpretation of the results. The sample was largely Caucasian, educated, and economically comfortable. It will be important to obtain additional data from a more diverse sample of families with diabetes. For example, families in less advantageous circumstances with respect to economic

and educational achievement may experience greater levels of diabetes-specific emotional distress than the sample reported in this study. The clinical utility of this measure will be made stronger by developing a parent report version of this measure, and our research team has begun developing such a measure.

The PAID-T is brief and easy to administer, and therefore may be used as a routine screening tool at clinic visits to identify potential problem areas and sources of distress for adolescents. Responses could be quickly viewed by the clinician and discussed directly during the clinic appointment. The PAID-T could also be used to guide clinical decisions when introducing more technologically sophisticated treatment regimens, as it is currently unclear whether these treatments impact diabetes-specific emotional distress. Clinicians may use PAID-T scores to track their patient's level of distress at predictable diabetes and developmental milestones, such as changes in treatment protocols, obtaining a driver's license, and going to college. This would ultimately lead to more timely interventions and potentially reduce the psychosocial impact of diabetes upon the lives of adolescents.

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Appendix j

Identifying Your Problem Areas in Diabetes: Teen Version (PAID-T)

Name: _____

Age; _ Sex: M_ F _

How old were you when your diabetes was diagnosed? _

Today's date _____

DIRECTIONS: Living with diabetes can sometimes be difficult. In day-to-day life, there may be many problems and hassles with your diabetes. The problems may range from minor hassles to major life difficulties. Listed below are a variety of possible problem areas which people with diabetes may have. Think about how much each of the items below may

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have upset or bothered you **DURING THE PAST MONTH** and circle the appropriate number.

the item is merely true for you. If you feel that an item is not a bother or a problem for you, you would circle "1". If it very bothersome to you, you would circle "6".

Please note that we are asking you how much each item may be bothering you in your life, **NOT** whether

	Not A Problem		Moderate Problem		Serious Problem	
1. Feeling sad when I think about having and living with diabetes.	1	2	3	4	5	6
2. Not knowing if the mood or feelings I am having are related to my blood sugar levels.	1	2	3	4	5	6
3. Feeling overwhelmed by my diabetes regimen.	1	2	3	4	5	6
4. Feeling angry when I think about having and living with diabetes.	1	2	3	4	5	6
5. Feeling constantly concerned about food and eating.	1	2	3	4	5	6
6. Worrying about the future and the possibility of serious complications.	1	2	3	4	5	6
7. Feeling upset when my diabetes management is "off track."	1	2	3	4	5	6
8. Feeling "burned-out" by the constant effort to manage diabetes.	1	2	3	4	5	6
9. Feeling that I am not checking my blood sugars often enough.	1	2	3	4	5	6
10. Feeling unclear about exactly what or how much I should be doing to take care of my diabetes properly.	1	2	3	4	5	6
11. Not feeling motivated to keep up with my daily diabetes tasks.	1	2	3	4	5	6
12. Feeling discouraged or defeated when I see high blood sugar results on my meter.	1	2	3	4	5	6
13. Feeling that my friends or family act like "diabetes police" (e.g. nag about eating properly, checking blood sugars, not trying hard enough).	1	2	3	4	5	6
14. Feeling like my parents don't trust me to care for my diabetes.	1	2	3	4	5	6
15. Feeling I must be perfect in my diabetes management.	1	2	3	4	5	6
16. Missing or skipping blood sugar checks.	1	2	3	4	5	6
17. Feeling that my blood sugars are often swinging wildly, no matter how hard I try.	1	2	3	4	5	6
18. Feeling that I am often failing with my diabetes regimen.	1	2	3	4	5	6
19. Feeling like my parents blame me for blood sugar numbers they don't like.	1	2	3	4	5	6
20. Feeling that my friends or family don't understand how difficult living with diabetes can be.	1	2	3	4	5	6
21. Feeling that I can't control my eating.	1	2	3	4	5	6
22. Worrying about my weight.	1	2	3	4	5	6
23. Worrying that diabetes gets in the way of having fun and being with my friends.	1	2	3	4	5	6
24. Fitting my diabetes regimen into my day when I'm away from home (e.g. school, work, etc.).	1	2	3	4	5	6
25. Worrying about getting low during a sports activity.	1	2	3	4	5	6
26. Feeling like my parents worry about complications too much.	1	2	3	4	5	6



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Re-examining a measure of diabetes-related burden in parents of young people with Type 1 diabetes: the Problem Areas in Diabetes Survey – Parent Revised version (PAID-PR)

J. T. Markowitz¹, L. K. Volkening¹, D. A. Butler¹, J. Antisdel-Lomaglio², B. J. Anderson³, and L. M. B. Laffel¹

¹Pediatric, Adolescent, & Young Adult Section, Joslin Diabetes Center, Boston, MA

²Department of Child and Adolescent Psychiatry, Children's Memorial Hospital, Chicago, IL

³Sections of Psychology and Endocrinology, Baylor College of Medicine, Texas Children's Hospital, Houston, TX, USA

Abstract

Aims—In a pediatric patients, the burden of diabetes lies within the family. In the current era of intensive insulin therapy, perceived parental burden may affect the family's efforts at effective diabetes management. The aims of this study were to re-examine and revise a measure of perceived parental burden associated with caring for a child with diabetes in the current era.

Methods—A geographically diverse population of young people ($N = 376$) with Type 1 diabetes and their parents included participants in the Juvenile Diabetes Research Foundation continuous glucose monitoring study and patients from the Joslin Diabetes Center. Participants provided data on demographics, diabetes management, diabetes-specific family conflict, and quality of life at baseline and after 6 months of follow-up.

Results—Young people were 12.9 ± 2.7 years old with diabetes duration of 6.3 ± 3.5 years. Mean HbA_{1C} was $8.0 \pm 1.2\%$ (64 mmol/mol), 58% received insulin pump therapy, and young people monitored blood glucose 5.2 ± 2.3 times/day. Factor analysis yielded two factors, 'Immediate Burden' and 'Theoretical Burden'. The Problem Areas in Diabetes Survey – Parent Revised version (PAID-PR) demonstrated excellent internal consistency (Cronbach's $\alpha = 0.87$; factor 1 $\alpha = 0.78$; factor 2 $\alpha = 0.83$). Greater parental burden was associated with more frequent blood glucose monitoring, higher HbA_{1C} levels, greater diabetes-specific family conflict, and lower quality of life. Test-retest analysis was acceptable ($r = 0.62$).

Conclusions—The PAID-PR demonstrated excellent internal consistency, good test-retest reliability, and associations with diabetes-specific family conflict and quality of life. This brief measure may have both clinical and research utility in the management of young people with Type 1 diabetes.

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Correspondence to: Lori M.B. Laffel, Joslin Diabetes Center, Pediatric, Adolescent, & Young Adult Section, One Joslin Place, Boston, MA 02215, USA. lori.laffel@joslin.harvard.edu..

Competing interests

Nothing to declare

Supporting Information

Additional Supporting Information may be found in the online version of this article.

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Keywords

adolescence; Type 1 diabetes

Introduction

The Problem Areas in Diabetes Survey (PAID) assesses diabetes-related burden in adults [1]. It has excellent psychometrics (Cronbach's $\alpha = 0.95$) and correlates with a number of emotional and diabetes-related variables [1]. In paediatrics, the burden of care lies with the patient and parent/guardian. For young patients, the burden lies with parents. Parental stress and burden in parents of children with Type 1 diabetes is common [2]. Parental burdens include daily diabetes-related tasks, financial burdens, managing blood glucose fluctuations, and, often, guilt and fear about future medical complications [3,4].

Family involvement is associated with increased adherence and improved glycaemic control [5,6]. If parents feel overly burdened, they may prematurely transfer responsibility for diabetes management to their child, which may lead to worsening control. Also, parental burden may promote diabetes-specific family conflict, which has an impact on glycaemic control [7]. Thus, parental burden is an important construct that may be amenable to intervention [4,5,7,8].

The Problem Areas in Diabetes – Parent version (PAID-P) assesses perceived parental burden associated with caring for a child with diabetes [9]. The original PAID-P had one general factor, excellent internal consistency (Cronbach's $\alpha = 0.92$) and validity in a conventionally treated sample of young people with Type 1 diabetes [9]. The aims of the current study were to re-examine and revise the PAID-P in parents of young people with Type 1 diabetes in the modern era of intensive insulin therapy.

Patients and methods

Participants were 376 young people with Type 1 diabetes (ages 8–18 years) and their parents. We combined data from a publicly-available dataset of nine centres (Juvenile Diabetes Research Foundation, JDRF [10], $n = 223$ and from the Joslin Diabetes Center, $n = 153$). Inclusion criteria were: Type 1 diabetes for ≥ 9 months, no major psychiatric/medical disorder, and fluency in English/Spanish.

Institutional Review Boards of participating institutions approved study procedures. Written informed consent/assent was obtained. Data were collected on age, duration of diabetes, height/weight, frequency of blood glucose monitoring, glycaemic control, diabetes-specific family conflict, quality of life, parent education and race/ethnicity.

Measures

Problem Areas in Diabetes – Parent Version (PAID-P [9])—Parents completed the 20-item PAID-P to assess perceived parental burden associated with caring for a child with diabetes.

Revised Diabetes Family Conflict Scale (DFCS-R [11], Joslin only)—Parents completed the 19-item DFCS-R to assess diabetes-specific family conflict.

Paediatric Quality of Life Inventory-Generic Scales and Diabetes Module (PedsQL [12,13])—Parents completed the 23-item PedsQL generic scales to measure parental perceptions of child's quality of life, including psychosocial and physical subscales.

Joslin participants completed the total scale while JDRF participants completed only the psychosocial subscale and 14 items of the diabetes module.

Glycaemic control—Haemoglobin A_{1C} was measured by automated, high-performance liquid chromatography (reference range 4.0–6.0%, Tosoh 2.2; Tosoh Corporation, South San Francisco, CA, USA) at the Joslin Diabetes Center and the University of Minnesota Laboratories.

Statistical analysis

Analyses were performed using SAS (v9.2 for Windows; SAS Institute Inc., Cary, NC). Data are presented as mean \pm SD or per cent. Statistics included Pearson/Spearman correlations for concurrent validity and test–retest reliability. For factor analysis, principal components analysis and Promax rotation were used. Internal consistency was assessed using Cronbach’s α . A P-value of < 0.05 indicated significance.

Results

Participant characteristics

The total sample included 376 young people with Type 1 diabetes and their parents (Table 1). The two samples were similar in age, zBMI (age- and sex-adjusted BMI), duration of Type 1 diabetes, gender, and race/ethnicity; only frequency of blood glucose monitoring and HbA_{1C} differed. The distributions and mean scores of the PAID-P were nearly identical between samples; therefore, datasets were combined.

PAID-P factor analysis

Results of the Kaiser–Meyer–Olkin test [overall measures of sampling adequacy (MSA) = 0.85] and individual MSA statistics indicated the combined sample size was sufficient and the data acceptable for factor analysis on the 20-item PAID-P [14]. Factors were extracted using principal components analysis. Promax rotation was used because of the inherent relationship between many of the items. Factor analysis resulted in two factors (nine items in each) and two eliminated items with factor loadings < 0.40 with low face validity. One item with factor loading of 0.38 was retained for its construct value. Factor 1 represents the ‘Concrete Burden’ (see Appendix S1) of having a child with Type 1 diabetes and includes items focused on present, concrete burdens. Factor 2 represents ‘Unpredictable Burden’ (see Appendix S1) and includes items focused on negative emotions and worry about the future. The two factors were correlated ($r = 0.54$, $P < 0.0001$).

Psychometrics and concurrent validity

The 18-item Problem Areas in Diabetes Survey – Parent Revised version (PAID-PR) revised demonstrated excellent internal consistency (Cronbach’s $\alpha = 0.87$), with good internal consistency within the two factors (factor 1: $\alpha = 0.78$; factor 2: $\alpha = 0.83$). Higher PAID-PR scores, indicating greater perceived parental burden, were correlated with more frequent blood glucose monitoring and higher HbA_{1C}.

Greater parental burden was associated with greater diabetes-specific family conflict. The PAID-PR was negatively correlated with parent-proxy report of quality of life. There were no associations between parental burden and child age, gender, zBMI (age- and sex-adjusted BMI) or duration of Type 1 diabetes (Table 1).

We then assessed diabetes characteristics and survey responses by factor (Table 2). The association between frequency of blood glucose monitoring and parental burden was explained by factor 2, while the association between HbA_{1C} and burden was explained by

factor 1. Parent report of diabetes-specific family conflict and parent-proxy report of quality of life were significantly correlated with factors 1 and 2. Significantly greater burden was reported by parents of pump users than by parents of non-pump users on factor 2 ($P = 0.008$).

Test-retest analysis

Baseline and 6-month assessments of the PAID-PR in control participants ($n = 97$) from the JDRF study demonstrated acceptable test-retest reliability ($r = 0.62$; $P < 0.0001$).

Discussion

The 18-item, two-factor, PAID-PR demonstrated excellent overall internal consistency, high factor internal consistency, and acceptable test-retest reliability. Factor analysis yielded two factors: 'Concrete Burden' and 'Unpredictable Burden' of having a child with Type 1 diabetes. Concrete burden focused on concrete, daily parental burdens; unpredictable burden included parental worries about the future and negative emotions experienced by parents.

Concurrent validity was measured with correlations between the PAID-PR and multiple constructs incurring parental burden, including blood glucose monitoring, HbA_{1C}, diabetes-specific family conflict, and parent-proxy report of quality of life. For example, blood glucose monitoring, as a recurring management task, can be a constant reminder of the permanence of diabetes. Haemoglobin A_{1C}, as a measure of glycaemic control, can create worries for parents regarding the child's overall health. Diabetes-specific family conflict and parent perception of child's quality of life can also create parental burdens related to diabetes.

Although frequency of blood glucose monitoring and HbA_{1C} were significantly correlated with one another ($r = -0.34$, $P < 0.0001$), HbA_{1C} was weakly correlated with 'Concrete Burden' and blood glucose monitoring was weakly correlated with 'Unpredictable Burden'. For parents of young people with Type 1 diabetes, HbA_{1C} may represent a more unpredictable and immediate burden, as it reflects current glycaemic control. Blood glucose monitoring may represent a theoretical burden, as parents worry if their children will consistently check blood glucose levels when away from home and as they grow-up. Notably, parents of young people with diabetes have reported negative affect around blood glucose monitoring [15].

Parent report of diabetes-specific family conflict and parent-proxy report of quality of life were moderately correlated with both 'Concrete Burden' and 'Unpredictable Burden'; greater conflict and lower child quality of life were associated with higher parental burden. While diabetes management tasks can add physical and time burdens to families, conflict and quality of life can add emotional burdens to parents.

In this contemporary cohort of paediatric patients with Type 1 diabetes from multiple sites treated with modern insulin therapy, parents provided responses regarding parental distress, diabetes-specific family conflict, and child quality of life. These three constructs are potentially modifiable factors. Approaches to Type 1 diabetes treatment aim to optimize glycaemia, minimize diabetes-specific family conflict and preserve quality of life. Family teamwork around diabetes management has been shown to improve adherence and glycaemic control, prevent increases in diabetes-specific family conflict and maintain quality of life; thus, teamwork is often targeted in the design and implementation of interventions [6,7,16,17]. In research, use of the PAID-PR can help assess efficacy of intervention trials. In clinical practice, it can be used as a screening tool to identify parents in need of greater support.

There are a number of limitations of this investigation. First, surveys were not completed by all participants; some measures were completed by only half and test-retest reliability was assessed in less than one-third. Although we had a large and varied study population, parents were highly educated, which may limit generalizability. However, a comparison between parents with a college degree/graduate education and those with less than a 4-year degree showed no difference in scores on the PAID-PR. The data were cross-sectional, limiting our ability to assess causation. Our study was also unable to assess construct validity of the PAID-PR; future studies should address this. Although we found significant correlations between the PAID-PR and other measures, the correlations were weak or moderate and may be attributed to the large sample size. In addition, this study focused solely on measuring parents' perceptions of burden. Future research should examine burden from the child/adolescent's perspective. Use of the new teen PAID measure [18] may yield insight to this query.

Although the two samples comprising the study population differed in diabetes management characteristics, there were no significant differences in PAID-PR scores. The variability in diabetes management characteristics and the diversity of our population strongly support the generalizability of our findings. Parents/guardians were able to complete the PAID-PR in less than 10 min, providing a brief, valid, and reliable measure of perceived burden related to having a child with diabetes. This tool may be useful in both clinical and research environments.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Participant characteristics and survey responses

	All (N = 376)	JDRF (n = 223)	Joslin (n = 153)
Age (years)	12.9 ± 2.7	12.9 ± 3.0	12.9 ± 2.3
Gender of youth (% female)	54%	52%	56%
Relationship to youth (% mothers)	80%	81%	78%
Racial/ethnic minority (%)	9%	8%	10%
zBMI (SDS)	0.7 ± 0.8	0.7 ± 0.8	0.8 ± 0.7
Diabetes duration (years)	6.3 ± 3.5	6.3 ± 3.4	6.3 ± 3.5
Regimen (% pump treated)	58%	82%	23%*
Frequency of blood glucose monitoring (times/day)	5.2 ± 2.3	6.3 ± 2.4	3.8 ± 1.2*
HbA _{1c} (%), (mmol/mol)	8.0 ± 1.2% (64 mmol/mol)	7.6 ± 0.9% (60 mmol/mol)	8.4 ± 1.4%* (68 mmol/mol)
College/graduate degree (parents)	65%	73%	54%
Junior college/technical degree/some college (parents)	20%	14%	28%
Parent report surveys			
PAID-P	44.6 ± 15.0	45.1 ± 15.0	43.8 ± 15.1
PAID-PR	46.8 ± 16.7	47.8 ± 16.6	45.4 ± 16.8
Family conflict (diabetes-specific)	NA	NA	24.2 ± 3.7
Psychosocial quality of life	77.9 ± 13.5	76.9 ± 12.7	79.4 ± 14.4
Physical quality of life	NA	NA	84.1 ± 15.4
Diabetes-specific quality of life	NA	75.8 ± 13.2	NA

JDRF (Juvenile Diabetes Research Foundation) sample vs. Joslin sample; zBMI, age- and sex-adjusted BMI; PAID-P, Problem Areas in Diabetes-Parent version; PAID-PR, Problem Areas in Diabetes - Parent Revised version; SDS, standard deviation score.

* $P \leq 0.01$.

Table 2

Correlations with 18-item PAID-PR

	PAID-PR		Factor 1		Factor 2	
	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>
Age (years)	-0.04	0.46	-0.07	0.20	-0.01	0.93
zBMI (SDS)	-0.07	0.15	-0.09	0.08	-0.04	0.41
Diabetes duration (years)	0.005	0.92	0.06	0.23	-0.04	0.45
Frequency of blood glucose monitoring (times per day)	0.17	0.001	0.07	0.18	0.23	0.0001
HbA _{1c}	0.09	0.10	0.16	0.003	0.001	0.99
Parent report surveys						
Family conflict (diabetes-specific)	0.47	< 0.0001	0.39	< 0.0001	0.42	< 0.0001
Psychosocial quality of life	-0.48	< 0.0001	-0.43	< 0.0001	-0.42	< 0.0001
Physical quality of life	-0.37	< 0.0001	-0.31	< 0.0001	-0.35	< 0.0001
Diabetes-specific quality of life	-0.52	< 0.0001	-0.50	< 0.0001	-0.44	< 0.0001

zBMI, age- and sex-adjusted BMI; Problem Areas in Diabetes - Parent Revised version; SDS, standard deviation score.

Family ID#: _____

Clinic site#: _____

Date: _____

Visit: Visit 1 Visit 4 Visit 5 Visit 6 Visit 7Participant: Child Only**Collaborative Parent Involvement Scale**

My answers to the next set of questions are about my:

- Mother
 Stepmother
 Father
 Stepfather
 Other, please say who: _____

I have a <u>parent/guardian</u> who...	<u>Almost Never</u>	<u>Sometimes</u>	<u>Often</u>	<u>Almost Always</u>	<u>Always</u>
1. Knows how I am doing with my diabetes care.	①	②	③	④	⑤
2. Helps me plan my diabetes care to fit my schedule.	①	②	③	④	⑤
3. Knows when I need a little extra help with my diabetes.	①	②	③	④	⑤
4. Helps me figure out how to change my insulin or eating to fit the amount I exercise.	①	②	③	④	⑤
5. Knows how much insulin I take.	①	②	③	④	⑤
6. Helps me out when I am too tired or stressed to take care of my diabetes on my own.	①	②	③	④	⑤
7. Knows what things are hard for me in taking care of my diabetes.	①	②	③	④	⑤
8. Helps me learn how to take care of troubles I have with my diabetes.	①	②	③	④	⑤
9. Knows when to let me do more to take care of myself and my diabetes.	①	②	③	④	⑤
10. Helps me plan how to spend time with my friends and still take good care of my diabetes.	①	②	③	④	⑤
11. Knows how my insulin is adjusted when my blood sugar is high.	①	②	③	④	⑤
12. Talks with me about how to adjust (change) my insulin, eating, and exercise.	①	②	③	④	⑤
13. Helps me with my diabetes when I need it.	①	②	③	④	⑤
14. Knows what my blood sugar levels are.	①	②	③	④	⑤
15. Helps me take care of any problems I am having at school with taking care of my diabetes.	①	②	③	④	⑤
16. Knows how I am taking care of my diabetes when I am with friends.	<input type="checkbox"/> <input type="checkbox"/> ①	②	③	④	⑤

Family-Centered Care Assessment

For Adolescents

FCCA-A

This is a survey to measure the quality of family-centered care that your diabetes health care providers give you. There are no right or wrong answers. Please answer every question. The survey uses the words “health care providers” throughout to mean the team of health professionals who help you manage your diabetes. .

5/2014

*For more information or to request permission to use the FCCA, go to <http://www.fv-ncfpp.org/activities/fcca/> or email fcc@familyvoices.org.
The National Center for Family-Professional Partnerships (www.fv-ncfpp.org) is a project of Family Voices to help families of children and youth with special health care needs partner with professionals to improve care. (Maternal and Child Health Bureau #U40MC00149B0)*

1. My health care provider talks with me using words I understand.	Almost Never Rarely Sometimes Usually Almost Always
2. My health care provider supports me in the role that I <u>want to take</u> in making decisions about my child's health care.	Almost Never Rarely Sometimes Usually Almost Always
3. My health care provider and my family <u>decide together</u> on goals for my treatment. (For example, less pain, improved health, better school attendance, more involvement in our community.)	Almost Never Rarely Sometimes Usually Almost Always
4. I feel <u>comfortable</u> letting my health care provider know when I disagree with recommendations for my health care.	Almost Never Rarely Sometimes Usually Almost Always
5. When we are making decisions about my health care, my health care provider and I talk about how the health care decisions for me will affect my whole family.	Almost Never Rarely Sometimes Usually Almost Always
6. My health care provider works with me to plan for my health care when there are <u>big changes in my life</u> . (For example, when I move to a new school, or graduate.)	Almost Never Rarely Sometimes Usually Almost Always
7. My health care provider talks with me about promoting my overall health and well-being. (For example, healthy weight, physical activity).	Almost Never Rarely Sometimes Usually Almost Always
8. My health care provider has a way to help me understand medical tests and treatments before he or she does them. (For example, shows a video about MRIs, uses a model to show what surgery will do, provides a book or workbook about how to test blood sugar.)	Almost Never Rarely Sometimes Usually Almost Always
9. My health care provider offers ways that health care/treatment can be provided where I usually spend time. (For example, school, community program, after-school activities)	Almost Never Rarely Sometimes Usually Almost Always
10. My health care provider has a way to consider my schedule before making appointments.	Almost Never Rarely Sometimes Usually Almost Always
11. My health care provider asks me <u>what is working well in my health care</u> . (For example, medications, treatments, services from other providers.)	Almost Never Rarely Sometimes Usually Almost Always
12. My health care provider recognizes <u>my strengths in caring for myself</u> . (For example, well organized, lots of help from friends, willing to try new things, willing to keep trying when something doesn't work right away.)	Almost Never Rarely Sometimes Usually Almost Always
13. When we have trouble completing my daily care and treatments (for example, taking medications, asthma treatments, physical therapy exercises, special meal schedule, or blood sugar testing), my health care provider works with me to change my treatment plan so that it works better.	Almost Never Rarely Sometimes Usually Almost Always
14. My health care provider asks me about <u>health or emotional stresses I have</u> in caring for myself.	Almost Never Rarely Sometimes Usually Almost Always

<p>15. My health care provider asks about issues that affect the <u>well-being of my whole family</u>. (For example, financial hardships, housing problems, trouble getting food, living in an unsafe neighborhood, depression, substance abuse, or domestic violence.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>16. When my family is making decisions about my health care, my health care provider and I talk about if I would like other community members to be part of making decisions about my health care. (For example, elders, religious leaders.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>17. My health care provider asks about <u>my family's beliefs and practices</u> when we are developing diagnostic and treatment plans. (For example, customs and beliefs about food, religious rituals related to health, modesty concerns such as gender of the health care provider.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>18. My health care provider asks if we want to integrate traditional or alternative healing into my overall care. (For example, herbal treatments, acupuncture, spiritual practices.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>19. When my family or I need community services (for example, special education, recreation, after-school programs, family support services, respite care), my health care provider has a way to help me make the <u>first contact</u> with the community services.</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>20. My health care provider has a way to <u>connect me with other youth</u> who share similar life situations for support. (For example, youth with my same diagnosis, youth in transition to adulthood.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>21. My health care provider gives me information to help people outside my family understand my needs. (For example, at school, places of worship, community activities, work.)</p>	<p>Almost Never Rarely Sometimes Usually Almost Always</p>
<p>22. My health care provider has a way to make sure that my parents know about and understand ways to help pay for things that insurance doesn't cover. (For example, discount cards, government programs.)</p>	<p>Strongly disagree Disagree Neutral Agree Strongly agree</p>
<p>23. In relation to my medical records, my health care provider has a way to help my family understand what is in my medical record. (For example, provides explanation of medical terms and answers questions about what is written.)</p>	<p>Strongly disagree Disagree Neutral Agree Strongly agree</p>
<p>24. My health care provider talks with me about what <u>I hope</u> for my future.</p>	<p>Strongly disagree Disagree Neutral Agree Strongly agree</p>

DSQ (Survey 4 of 6)

This questionnaire asks about a number of different things that young people with diabetes sometimes do. They are included to provide us with greater understanding and knowledge about these behaviors and the best way to help young people manage their diabetes. There are no right or wrong answers.

- Please complete this questionnaire on your own.
- If the first part of a statement does not apply to you, please indicate "N/A"
- Example 1: "Engaged in physical activity without wearing a diabetes ID?"
- Indicate N/A if you haven't engaged in physical activity.
- Example 2: "Felt your blood sugar might be low, and did not treat it?"
- Indicate N/A if you haven't felt your blood sugar might be low.
- You do not have to answer any questions that you prefer not to answer.
- Answers do not have to be exact, please take your best guess.
- Try to answer as TRUTHFULLY as possible.

All of your answers are kept strictly PRIVATE and CONFIDENTIAL, the content of this survey will NEVER be shared with your parents OR your medical team.

OVER THE LAST YEAR, HOW OFTEN HAVE YOU...?

1. Gussed the number of carbs in a snack/meal you were eating when the nutrition information was right there?
 - Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
2. Decided not to wear a diabetes ID?
 - Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

3. Engaged in physical activity without wearing a diabetes ID?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
4. Engaged in physical activity without first checking your blood sugar?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
5. Participated in an organized sport or activity without telling the coach you have diabetes?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
6. Ate without first checking your blood sugar?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
7. Felt your blood sugar might be low, and did not treat it?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
8. Had high blood sugars, and did not check ketones?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
9. Felt nauseous and/or vomited and did not check ketones?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

10. Gone without checking your blood sugar for at least 24 hours?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
11. Told someone you checked your blood sugar when you really had not?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
12. Entered made-up blood sugar numbers in your log book?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
13. Reported a made-up blood sugar number to someone?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
14. Taken insulin without checking your blood sugar first?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
15. Ate without taking short acting insulin to cover carbs (except when blood glucose (BG) is low)?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer
16. Taken less insulin than you knew you needed?
- Daily
 Weekly
 Monthly
 Every Few Months
 Once/Twice a Year
 Never
 N/A
 Prefer not to answer

17. Taken more insulin than you knew you needed?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
18. Waited until you were out of insulin before telling your parents or getting more from the pharmacy?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
19. Waited until your glucagon had expired before telling parents or getting more from the pharmacy?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
20. Gone without taking insulin for at least 24 hours?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
21. Told your parents you had taken insulin when you really had not?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
22. Told your doctor you had taken insulin when you really had not?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
23. Driven a car without first checking your blood sugar?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

24. Driven a car without fast-acting carbs within reach?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
25. Drank alcohol without eating extra carbs?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
26. Drank alcohol when no one around knew you had diabetes?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
27. Drank alcohol without wearing a diabetes ID?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
28. Gone to sleep after drinking alcohol with no plan for checking blood sugars during the night?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
29. Gotten drunk to the point where you could not take care of your diabetes?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
30. Used drugs (for example: pills that were not prescribed to you, marijuana, etc.) when no one around knew you had diabetes?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

31. Had sex without first checking your blood sugar?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

FOR INSULIN PUMP USERS ONLY:

32. Taken your pump off for longer than 3 hours, without a plan to use shots in the meantime?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
33. Dismissed/ignored a pump alarm?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer
34. Taken your pump off before an activity and did not reconnect it right afterwards?
- Daily
 - Weekly
 - Monthly
 - Every Few Months
 - Once/Twice a Year
 - Never
 - N/A
 - Prefer not to answer

Measuring the quality of transdisciplinary teams

BEATA BATOROWICZ¹ & TRACY A. SHEPHERD²

¹*University of Western Ontario, and* ²*Speech Language Pathologist, Thames Valley Children's Centre, Ontario, Canada*

Abstract

The Team Decision Making Questionnaire (TDMQ) demonstrated internal consistency, stability over time, and construct validity. Internal consistencies were excellent and Cronbach's Alphas ($M = 102$) for the 4 components ranged from 0.83 to 0.91. The internal consistency for the total instrument was 0.96. Test re-test reliability ($N/22$) measured with Intraclass Correlation Coefficient was good. Transdisciplinary teamwork is widely practiced in health care. However, specific measures to evaluate transdisciplinary team decision-making are not described in the literature. The purpose of this study was to develop and psychometrically test a scale to measure the quality of transdisciplinary teamwork. A multi-method approach using focus groups, field testing, and quantitative instrument development procedures was used to develop and evaluate TDMQ. Principal component analysis (PCA) with a varimax rotation ($N = 102$) revealed a four-component solution resulting in a 19-item measure consisting of 4 subscales including Decision Making, Team Support, Learning, and Developing Quality Services. This study's findings support the use of the TDMQ for measuring the benefits of transdisciplinary teamwork. The four subscales of the measure provide insight into the nature of such benefits. To validate the TDMQ research is required with a greater number of health care professionals and in other clinical fields.

Keywords: *Transdisciplinary teams, teamwork, decision-making, health care, measurement tool*

Introduction

In health care practice, teamwork is an essential part of service delivery (Gibbon, 1999; Molyneux, 2001; Reilly, 2001; Thylefors, Persson, & Hellstrom, 2005). Literature defines and describes three different types of teamwork practiced in health care, including multidisciplinary, interdisciplinary, and transdisciplinary. These teams can be described on a continuum with multidisciplinary and transdisciplinary being on the opposite ends of the spectrum with respect to intensity of collaboration among team members from various disciplines (Reilly, 2001; Thylefors et al., 2005).

Team members of multidisciplinary teams complete independent assessments, set goals, measure outcomes and share their results with the larger team (Reilly, 2001; Thylefors et al., 2005). On the interdisciplinary team treatment plans and outcomes are established based on the input from all team members. In addition, the interdisciplinary model team members

Correspondence: Tracy A. Shepherd, Thames Valley Children's Centre, 779 Base Line Road East, London, Ontario, N6C 5Y6, Canada. Tel: p1 519 685 8680, ext. 53700. E-mail: tracy.shepherd@tvcc.on.ca

collaborate to make decisions but they do not branch out of their specific role on the team (Beukelman & Mirenda, 2005).

In the transdisciplinary model, team members share information among each other so that the boundaries of each discipline begin to be removed and professionals gain skills in other practice areas (Beukelman & Mirenda, 2005; Locke & Mirenda, 1992; Reilly, 2001; Thylefors et al., 2005). On transdisciplinary teams assessments are performed in the close collaboration of all team members as equals (Beukelman & Mirenda, 2005). Decisions are made in collaboration with colleagues similarly to interdisciplinary teams. However, typically there is a team meeting to establish the goals and intervention plans following assessment. Discussions are rich due to knowledge gained from working with other professionals (Beukelman & Mirenda, 2005).

The literature has defined many aspects of teamwork including communication and collaboration (Lowe & O'Hara, 2000; Malone & Koblewski, 1999; Malone & McPherson 2004; Molyneux, 2001) as well as decision-making (Larkin & Callaghan, 2005; Cook et al. 2001). Communication involves time and energy to enhance collaboration in the treatment planning process and effective communication results in better plans for clients (Malone & Koblewski, 1999). In addition, regular meetings and shared goal planning have an impact on the communication of the team and should be incorporated when establishing a team service delivery system (Lowe & O'Hara, 2000).

Cook et al. (2001) identified two kinds of team decision making the first related to client care and the second to the improved functioning of the team especially noted in the area of problem solving. Thylefors, Persson and Hellstrom (2005) found that teams in which people work more closely together (i.e., transdisciplinary teams) reported better climate and efficacy. When nurses' perceptions were examined, the transdisciplinary model of patient care provided the highest level of satisfaction compared to other models of service delivery (Hibbert et al., 1994).

Lowe and O'Hara (2000) examined the change in service delivery models from unidisciplinary to multidisciplinary. Participants of the study reported improvements in the areas of effectiveness, efficiency and quality of the service delivery. Transdisciplinary teams require further investigation to better understand their functioning and establish their effectiveness. The previously discussed studies are related to teams of professionals working together and studied their perceptions.

There are multiple tools available to measure team processes of health care professionals such as personal participation or socio-emotional behaviours (Roelofsen et al., 2001; Malone, 1996; Natvig & Malone, 1992); however, there is no published tool to measure the benefits or effectiveness of decision making on transdisciplinary health care professional teams and the quality of those teams. Larkin and Callaghan (2005) urged researchers to further investigate effectiveness of teams of professionals working together.

As a first step, it was important to examine perceptions of professionals who work on transdisciplinary team and participate in decision-making. The purpose of this study was to develop a measurement tool that evaluated advantages and disadvantages of a transdisciplinary team model and quality of the teamwork process. The transdisciplinary Team Decision Making (TDM) model practiced in Ontario, Canada in the clinical area of Augmentative and Alternative Communication (AAC) was used to develop the Team Decision Making Questionnaire (TDMQ). Items were based on a review of the literature and focus groups with key informants. Then professionals practicing AAC in Ontario completed the TDMQ. Furthermore, testing was conducted to examine the psychometric properties of the TDMQ (i.e., content validity and reliability). This study received ethics

approval from the Research Ethics Board at the University of Western Ontario. Informed consent was obtained from all the participants.

Methods

Stage 1: Qualitative aspect – identification of possible items

Participants

Study investigators contacted managers from all 21 AAC centres in Ontario, Canada, by phone or e-mail to solicit key informants to participate in focus groups. Focus groups were held in two geographic locations in Ontario to ensure representation from across the province and from various AAC centres.

Data collection procedures

The study investigators conducted and facilitated two 2-hour focus groups with 8 and 9 participants. The goal of those focus groups was to discuss the advantages and disadvantages of Team Decision Making (TDM). Initially, the participants were asked to write three key words describing TDM. Participants also completed two written tasks identifying advantages and disadvantages, as well as potential areas for improvement. During the discussion, seven main open-ended questions were asked to elicit participants' perceptions. Participants were also asked to write down their response to the question, "If you could change one thing about the TDM process, what would it be?" and then to share it with the group. Focus groups were audio taped.

Data analysis

Audiotapes were transcribed verbatim and analyzed by 2 independent reviewers to identify unique items. In addition, written materials gathered during the focus groups were reviewed in the same manner to identify unique items related to benefits of TDM and potential areas for improvement. Subsequently, all items identified by reviewers and written and transcribed materials were grouped into common themes that captured the breadth of the information.

Stage 2: Quantitative aspect – constructs and reliability of instrument

Participants

There are 21 AAC centres in Ontario. All clinical staff practicing within these centres were invited to participate. At the time, there were 193 individuals registered in Ontario.

Inclusion criteria. This study included speech language pathologists (SLPs), occupational therapists (OTs), communicative disorders assistants (CDAs), educators, computer technicians, and clinic managers practicing in AAC centres in Ontario, Canada. All AAC centre managers were asked to identify which clinical staff (including themselves) always, occasionally, or never participated in Team Decision Making (TDM). Those who were identified as having always or occasionally participated in TDM were included in this study.

Exclusion criteria. Individuals were excluded if they never participated in TDM or were on leave exceeding 3 months (e.g., parental leave) at the time of the study.

A research assistant forwarded a letter of information to the managers of the 21 AAC centres. The purpose of this letter was to: (a) verify the staff list because this list is updated only periodically, and (b) identify personnel who participated in TDM because this varies among centres in Ontario as noted during focus groups. This letter included: (a) a description of the study and, (b) a list of staff for the manager to confirm who participated. Managers who had not responded within 2 weeks from sending the information received a follow-up call from the research assistant. There were 189 participants identified who met the inclusion criteria.

Data collection procedures

The 189 participants identified in the above procedure received a letter of information, consent form, TDMQ and a stamped addressed return envelope. To examine test-retest reliability, a random sample of 25% of the participants was selected using a random number generator formula in Microsoft Excel. This retest, which took place 2 weeks after initial completion, measured the consistency of TDMQ over time. This amount of time is sufficient when measuring attitudes (Spector, 1992; Streiner & Norman, 1989).

Data analysis

Using standard test construction procedures, investigators analyzed responses to identify the key components of the questionnaire. To examine construct validity of the TDMQ, a PCA with a varimax rotation was performed using SPSS software Version 12. To reduce the number of items, investigators determined a cut-off point of 0.6 with a minimum difference among components of 0.1. Reliability of the TDMQ was examined through establishing test-retest reliability and internal consistency. Interclass correlation coefficient (ICC) was calculated to determine test-retest reliability (Portney & Watkins, 2000; Spector, 1992). Internal consistency or homogeneity indicates how individual items reflect a common underlying construct and was analyzed using Cronbach's Coefficient Alpha (Portney & Watkins, 2000; Spector, 1992). Cronbach's Alpha was calculated for each domain of the TDMQ.

Results

Qualitative data

Eighteen clinical staff from six AAC centres in Ontario, Canada volunteered to participate in the focus group. Each focus group was 2 hours long. Each group included participants representing various professional backgrounds; 8 SLPs, 5 OTs, and 4 clinical support staff (such as computer technicians or CDAs). The years of professional experience of the participants ranged from 1 to 18 years, and participants worked on teams consisting of 2 to 40 people.

Six themes emerged from the preliminary analysis of focus group discussions and written information. Domains included: (a) clinical learning specific to AAC, (b) applying funding policy, (c) obtaining and providing peer support, (d) serving AAC clients, (e) clinical decision making, and (f) specific procedures. On the basis of the initial analysis of the focus group discussions, a draft of the Team Decision Making Questionnaire (TDMQ) was constructed which included 26 items. The questions were scored on a

7-point rating scale ranging from 1 (*not at all*) to 7 (*to a vast extent*). Investigators randomized the order of 26 questions using a random number generator formula in Microsoft Excel.

Subsequently, the investigators piloted the tool with five experts in the field of AAC, including SLPs and OTs who had participated in TDM in the recent past. Feedback indicated that the tool captured the breadth of the construct and addressed specific and distinct key areas of relevance. In addition, the experts indicated that the tool was clear, the format was good and the length of time to complete the tool was appropriate (approximately 15 minutes). Suggestions provided were in relation to improving clarity and included five instances of changing the wording of questions and a suggestion to split one question into two, resulting in 27 questions. The investigators incorporated all these changes. The focus groups and pilot testing ensured content validity.

Quantitative data

Out of 189 eligible participants, 102 responded, yielding a 54% response rate. PCA revealed four components with eigenvalue of 1 or more. They accounted for 72.8% of total variance. The components were named as follows: Decision Making (24.5% of total variance), Team Support (21.6%), Learning (13.4%), and Developing Quality Services (13.3%). The final tool consisted of 19 questions grouped into four subscales. There were seven questions in the decision making subscale, five in team support, three in learning, and four in developing quality services. The TDMQ can be found in the Appendix.

Internal consistency (*N* 102) for each subscale was calculated and was found to be very good ranging from 0.83 to 0.91. The internal consistency for the total instrument was 0.96. Table I contains Cronbach’s Alpha scores for subscales and the entire tool.

For the re-test, out of 25 participants randomly selected, 22 responded, yielding a response rate of 88%. Although the sample size for re-test is not large the people who participated in focus groups were representative of all professionals practicing in AAC in Ontario. Internal consistency reliabilities for the 4 subscales were excellent. Average test- retest reliability estimates (Intraclass Correlation Coefficients/ICC) were statistically significant for the subscales: Decision Making (ICC 0.77), Team Support (ICC 0.94), and Developing Quality Services (ICC 0.74). For Learning, low test-retest reliability was found (ICC 0.52); however, investigators decided to retain this subscale because learning was discussed extensively during focus groups. Table I contains ICC scores for each subscale.

Table I. Psychometric properties of Team Decision Making Questionnaire.

Subscales of TDMQ	Interclass Correlation Coefficient	Cronbach’s Coefficient Alpha
Decision Making	0.77	0.90
Team Support	0.94	0.91
Learning	0.52	0.83
Developing Quality Services	0.74	0.88
Total instrument		0.96

Discussion and practice implications

The transdisciplinary team model of service delivery is currently implemented in the health care systems of various countries. Therefore, service providers are challenged to develop evidence in support of transdisciplinary team decision-making. This study provides some groundwork to aid in evaluating the quality of teamwork processes.

The qualitative analysis in this study indicated that there were multiple key domains in relation to the concept of teams working together to make decisions. This assertion was supported by the quantitative analysis, where six domains were collapsed into four components underlying this construct. Therefore, the results of this study contribute to the understanding of the underlying dimensions of team decision-making. These findings suggest that the focus is broader than simply the act of decision-making itself; it includes components such as learning, support, and providing quality services. This applies to transdisciplinary teams that are working together and are making final decisions collectively.

Results of this study provide preliminary evidence for the reliability and validity of the 19-item TDMQ and indicate that the TDMQ shows promise of practical utility. A major strength of the TDMQ is its unique contribution in relation to evaluating current practices. Also, it has an easy to administer format and only takes 15 minutes to complete.

This tool has some limitations: (a) it relies on the self-report of participants, and (b) it has only been tested with a small sample size given the 19-item instrument. However, 21 out of 22 distinct centres from across a large and most populated province in Canada participated. Further work is needed to confirm re-test reliability, because a small sample size for re-test was used in this study. However, the focus groups and the sample both included representation of all professions practicing in AAC. In addition, no work has been done on re-test reliability on the items themselves. It is suggested that future work considers whether similar constructs will hold true for different participants. In order to further validate the TDMQ, research is required with a greater number of health care professionals and in other clinical fields.

There are potential applications of the TDMQ in research and practice. Although this tool has been developed in one area of specialized practice it could be implemented in other clinical areas where various professionals work together and make clinical decisions. TDMQ was developed with a variety of professionals with varying areas of responsibility in decision-making. This tool might enable professionals and administrators to better understand complex processes involved in working together on teams. Health care providers in primary settings may use the TDMQ to gather information about the advantages and disadvantages of decision making within teams: high scores might indicate better team functioning; low scores might be a starting point for managers/team leaders to further explore the working processes of their teams. The TDMQ, in conjunction with a tool that measures team dynamics (e.g., Team Processes Tool by Roelofsen et al., 2001), has the potential not only to determine the advantages and limitations of specific transdisciplinary teams, but also to identify the underlining issues and help promote healthy teams.

In addition, the TDMQ could be used by clinicians on transdisciplinary teams to monitor clinical recommendations, examine one's own practice, ensure compliance with standards of practice and policies and procedures, improve team decision making processes, develop and identify clinical goals, identify professional development needs of the team, identify individual professional development needs, and/or ensure consistency of practice.

The questionnaire could identify key strengths and weaknesses for a given team and reflect changes in service provision over time. For example, if team scores lower on team support than on decision making, then the team might focus their efforts specifically on improving team support (e.g., obtaining clinical advice). A manager could use the tool to examine differences in perceptions across teams and help determine areas of need for team development.

It should be noted that decisions, which address client's needs and priorities, should be an integral part in the process within client-centred practice. This study only considered professionals working together. There is an urgent need to develop another measurement tool to account for the views of families and clients.

The TDMQ is currently being used in a study to evaluate clinical staff's perceptions of decisions making on AAC transdisciplinary teams in Ontario. In addition, this study will examine the relationships between these perceptions and the following variables: professional background, years of practice, size of the team, range of experience of the team, and team processes (Batorowicz & Shepherd, in preparation). Future investigation to establish the effectiveness of the team decision-making is needed. Also, research is needed to determine the characteristics of a team capable of making the best decisions.

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Appendix

Team Decision Making Questionnaire (TDMQ)

When completing this questionnaire please consider your overall experience with Team Decision Making (TDM). Please read each question and circle the appropriate answer.

To what extent does the Team Decision Making Process help <u>you</u> to ...	To a vast extent	To a very great extent	To a great extent	To a moderate extent	To a small extent	To a very small extent	Not at all	Not Applicable
1. . . . obtain support in clinical/technical decision making?	7	6	5	4	3	2	1	N/A
2. . . . make consistent recommendations for all clients?	7	6	5	4	3	2	1	N/A
3. . . . apply standards consistently across your team?	7	6	5	4	3	2	1	N/A
4. . . . takes personal onus off decisions regarding prescriptions?	7	6	5	4	3	2	1	N/A
5. . . . validate my clinical/technical decisions?	7	6	5	4	3	2	1	N/A
6. . . . apply policies consistently within your own caseload?	7	6	5	4	3	2	1	N/A
7. . . . apply policies accurately?	7	6	5	4	3	2	1	N/A
8. . . . provide support with colleagues' clinical technical decision making	7	6	5	4	3	2	1	N/A
9. . . . share innovative ideas	7	6	5	4	3	2	1	N/A
10. . . . obtain clinical/technical advice	7	6	5	4	3	2	1	N/A
11. . . . become more competent	7	6	5	4	3	2	1	N/A
12. . . . share success	7	6	5	4	3	2	1	N/A
13. . . . keep current with knowledge regarding changing policies?	7	6	5	4	3	2	1	N/A
14. . . . learn about application of new technology/strategies?	7	6	5	4	3	2	1	N/A
15. . . . obtain various clinical/technical perspectives?	7	6	5	4	3	2	1	N/A
16. . . . keep current with equipment and new technology in this field of clinical practice?	7	6	5	4	3	2	1	N/A
17. . . . develop effective problem solving?	7	6	5	4	3	2	1	N/A
18. . . . ensure quality of services?	7	6	5	4	3	2	1	N/A
19. . . . generate new ideas with colleagues?	7	6	5	4	3	2	1	N/A

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CLINICIAN/PHYSICIAN SATISFACTION QUESTIONNAIRE

INSTRUCTIONS: For each statement listed below, circle the number that best describes your agreement or disagreement with that statement, regarding today’s clinic appointment with the patient. Use this code:

- | | |
|--------------------------------------|--------------------------|
| 1. Strongly Disagree | 4. Mildly Agree |
| 2. Mildly Disagree | 5. Strongly Agree |
| 3. Neither Agree Nor Disagree | |

	SD				SA
	1	2	3	4	5
1. This was a very satisfying visit for me.	1	2	3	4	5
2. I got all the detail I needed regarding the patient’s history.	1	2	3	4	5
3. This patient constantly complains.	1	2	3	4	5
4. This patient is very personable.	1	2	3	4	5
5. I would have liked to spend more time with this patient.	1	2	3	4	5
6. I obtained all the details I wanted on the patient’s problem /symptoms.	1	2	3	4	5
7. I established effective rapport with this patient.	1	2	3	4	5
8. My time was well spent in the visit.	1	2	3	4	5
9. This patient trusts me a great deal.	1	2	3	4	5
10. I was effective in influencing this patient’s behavior.	1	2	3	4	5
11. I felt adequately trained and confident in treating this patient.	1	2	3	4	5
12. I think this visit was necessary.	1	2	3	4	5
13. This patient understood my explanations of the medical problem and treatment.	1	2	3	4	5
14. I obtained enough detail from this patient regarding his/her psychosocial condition.	1	2	3	4	5
15. This visit was boring and unchallenging.	1	2	3	4	5
16. I conducted as detailed a physical exam as I would like.	1	2	3	4	5
17. There are aspects of my relationship to this patient that I would like to change.	1	2	3	4	5
18. I understood all that this patient wanted to tell me.	1	2	3	4	5
19. This patient demands a lot of personal attention.	1	2	3	4	5
20. I spent more time with this patient than I would have liked.	1	2	3	4	5
21. The behavior of the parent and/or patient was affected by the camera.	1	2	3	4	5
22. My behavior was affected by the camera.	1	2	3	4	5

Transdisciplinary Versus Usual Care for Type 1 Diabetes in Adolescence, Randomized Controlled Trial

REDCap Instructions For Data Collection

Principal Investigator: Tim Wysocki, Ph.D., A.B.P.P.

Title: Co-Director, Center for Healthcare Delivery Science and Principal Research Scientist

Study Sponsor: The National Institutes of Health

Organization:

Nemours Children's Clinic
Department of Biomedical Research
807 Children's Way
Jacksonville, FL 32207-8426

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(Press CTRL key + Click to follow link in document)

Measurement Schedule

		V1	V2	V3	V4	V5
		0	3	6	9	12
(~Months) Measures	Burden (Min/Visit)					
Demographic Information (P)	10	•				
HbA1C; Device downloads	20	•	•	•	•	•
Health Care Use Survey--Sections 1 & 2 (P; EMR)	5	•	•	•	•	•
Hilliard et al Quality of Life Scales--QOLD (A, P)	15	•		•		•
Diabetes Self Management Profile-Self Report--DSMP (A,P)	15	•		•		•
Problem Areas in Diabetes Scale PAID (A,P)	15	•		•		•
Collaborative Parent Involvement Scale (A)	5	•		•		•
Family Centered Care Assessment Scale--FCCA (A,P)	10	•		•		•
Readiness Assessment for Emerging Adults with Diabetes Diagnosed in Youth--READDY(A)	10	•		•		•
Diabetes Choices Questionnaire (DCQ) (A)	10	•		•		•
Team Decision Making Questionnaire--TDMQ (HCP)	10					•
Physician Satisfaction Questionnaire--PSQ (HCP)	5					•

Setting Up a REDCap Account

In order to use the REDCap software, you must first have a REDCap Account. If you don't already have an account please follow the steps below.

Steps to set up a REDCap Account:

1. Click on the link below and complete the electronic form.

http://www.nemoursresearch.org/snap/admin_forms/redcapacct.php

- The form only requests a few basic items:
 - Name
 - Email address
 - Description of what you'd use REDCap for
- Please check the following in the form: (others if they apply)
 - I have a Nemours.org email address
 - I only want to enter data into established databases
 - I understand that collecting PHI for human subject research must be reviewed and approved by the Institutional Review Board.

2. Then the site will present you with a "User Agreement and e-signature verification form" (PDF), which you can print, fill out, scan, and email to rcsupport@nemoursresearch.org (instead of sending by mail). Once this form is received you will be able to create an account.

You have to submit both a signed copy of the agreement and the electronic version.

3. You will receive an e-mail notification as soon as your REDCap account has been set up.
4. If you would like to watch any of the videos on the REDCap Training Resources page, a REDCap login is not needed to watch.

<https://apps.nemoursresearch.org/redcap/index.php?action=training>

Accessing REDCap Projects and Patient Records

1. Go to: <https://apps.nemoursresearch.org/redcap/>
2. Log in to REDCap: enter your username and password
3. Click on the second tab on the top: My Projects
4. There are two TC Study projects for this study, one for the Parents and one for the Adolescents:
 - **Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT— PARENT Version**; and,
 - **Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT— ADOLESCENT Version**
5. As patients are enrolled into the study, data will have to be entered into **both** projects and surveys will need to be sent **from both** projects, one for the child and one for the parent; **the study ID#s need to be the same!**
6. Once the project is opened, on the left side menu under Data Collection, there are two ways to access the patient records: 'Record Status Dashboard' and 'Add/Edit Records':

The screenshot shows the REDCap interface for the project 'Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version'. On the left sidebar, under the 'Data Collection' section, the 'Record Status Dashboard' and 'Add / Edit Records' options are circled in red. The main content area features the Nemours logo, the project title, and a 'Quick Tasks' section with several actionable items:

- Codebook**: The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing field attributes.
- Manage Survey Participants**: Invite participants to complete your survey by emailing a public survey link or building a participant list for batch notification.
- Export data**: Export your data from REDCap to open or view in Excel or various stats packages.
- Create a report**: Build custom reports for quick views of your data, and export reports to Excel/CSV.
- Check data quality**: Build or execute data quality rules to find discrepancies and errors in your project data.
- User Rights**: Grant new users access to this project or modify user privileges for current users.
- Online Designer and Data Dictionary Upload**: Create new fields/questions on your data collection instruments or modify existing ones using the Online Designer or by uploading a Data Dictionary. Quick link: [Download the current Data Dictionary](#)
- Copy this project**: Create an exact duplicate of this project, which copies over all data collection instruments, any surveys that exist, as well as the option to copy all users and reports

7. If you click on 'Record Status Dashboard' on the left side menu, you will be able to see the 75 pre-assigned study ID#s for your site. (You will only be able to view and access records from the site to which you are assigned). From here, you will be able to view the data collection status of all records and it is easier to keep track of which study ID# to choose when entering a new family into the study. For example, in this screen shot, for the Delaware Group study ID #s 101 and 102 have already been assigned to families (once each measure is completed and submitted, the bubble turns green). When the next new family is enrolled, you would know to click on the next available study ID# (103) to assign to that family and begin entering the data.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] Create custom dashboard

Displaying Data Access Group: [Delaware Group]

Displaying records: [Page 1 of 1: "1" through "75"] of 75 records ALL (75) records per page

Displaying: Instrument status only | [Link status only](#) | [All status types](#)

Record ID #	Visit1_Baseline										
	Participant Summary Form	Visit Information	Health Care Use Survey--Section 2	Demographic Information Form	Health Care Use Survey--Section 1	FCCA_Parent	PAID-Problem Areas In Diabetes-Parent	QOLD-PA	QOLD-PC	Diabetes Self Management Profile - Flexible_P	Diabetes Self Management Profile - Conventional
1 (Study ID TC101)	●	●	●	●	●	●	●	●	●	●	●
2 (Study ID TC102)	●	●	●	●	●	●	●	●	●	●	●
3 (Study ID TC103)	●	○	○	○	○	○	○	○	○	○	○
4 (Study ID TC104)	○	○	○	○	○	○	○	○	○	○	○
5 (Study ID TC105)	○	○	○	○	○	○	○	○	○	○	○

8. Once you click on the study ID#, it will automatically take you to the next screen which is the Record Home Page of that Study ID# Record:

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Choose action for record

Record ID # 3 (Study ID TC103)
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form	●		
Visit Information	○	○	○
Health Care Use Survey--Section 2	○	○	○
Demographic Information Form	○		
Health Care Use Survey--Section 1 (survey)	○	○	○
FCCA_Parent (survey)	○	○	○
PAID-Problem Areas In Diabetes-Parent (survey)	○	○	○
QOLD-PA (survey)	○	○	○
QOLD-PC (survey)	○	○	○
Diabetes Self Management Profile - Flexible_P (survey)	○	○	○
Diabetes Self Management Profile - Conventional_P (survey)	○	○	○
PSQ: Physician Satisfaction Questionnaire			○
TDMQ: Team Decision Making Questionnaire_HCP1			○

9. The second way to access the patient records is by clicking on 'Add/Edit Records':

The screenshot shows the REDCap interface. On the left sidebar, the 'Add / Edit Records' option is circled in red. The main content area features the Nemours logo and the study title: 'Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version'. Below the title, there is a section titled 'Add / Edit Records' with the text: 'You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.' A yellow box highlights 'Total records: 10'. Below this is a dropdown menu for 'Choose an existing Record ID #' with a list of 10 records: 1 (Study ID TC101), 2 (Study ID TC102), 3 (Study ID TC103), 4 (Study ID TC104), 5 (Study ID TC105), 6 (Study ID TC201), 7 (Study ID TC202), 8 (Study ID TC203), 9 (Study ID TC204), and 10 (Study ID TC205). Below the dropdown is a 'Data Search' section with a 'Choose a field to search' dropdown (set to 'All fields') and a 'Search query' input field.

- This second method of accessing patient records will take you to the same Record Home Page (as above in # 8 from the Record Status Dashboard)

Entering Data into Patient Records in REDCap

Visit 1 (Baseline) Study Procedures

There may be variations within the recruitment method but regardless of the process used in recruiting participants, the data entry must follow certain steps:

1. The family must always first go through the consent process—the caregiver must sign the consent form and the adolescent must sign the assent form prior to any study procedures being performed.
2. Once the family has been consented/assented and enrolled into the study, please have the parent complete the Contact Information Form and be sure to obtain both the caregiver's email address *and* also the adolescent's email address. This **MUST** be collected or you will not be able to send families the measures to complete through REDCap. If an Adolescent does not have their own private e-mail address, coordinators will offer to assist adolescents in creating a free one (Some providers may not allow this for kids under 14 without parental permission). If the adolescent/parent prefer not to establish an e-mail address for the adolescent, both REDCap links will be sent to the parent with clearly stated instructions about respecting the adolescents' privacy/confidentiality in questionnaire completion:



Contact Info
Form.docx



Steps for creating
an email account fo

3. At the Baseline Visit (and at all future Study Visits) Give Family the **Health Care Use Survey-Section 2** and explain to the family that each time they come in for a Study Visit, we will be collecting this data on how long the entire visit takes from the time they leave home to go to their appointment until they return, broken down into segments of time. The Parent may have to estimate some of the times. You will need to collect this form at the end of each Study Visit to be able to enter the data into REDCap following the visit:



Health Care Use
Survey--Section 2.do

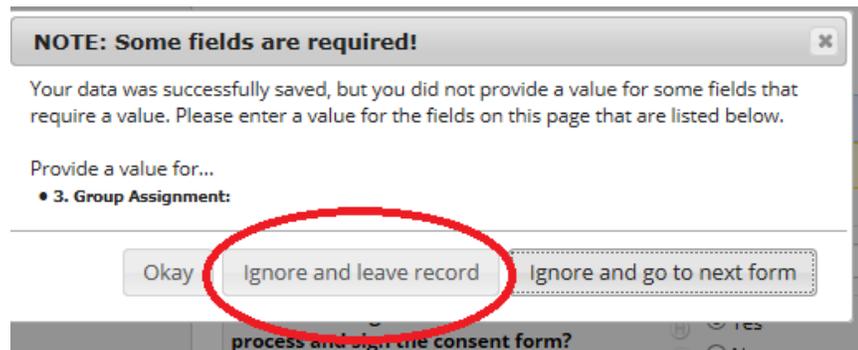
4. Give the family the handout for completing surveys online and review it with them:



TC_REDCap Survey
Handout.docx

5. If the measures will be completed online, before the link can be sent to the family, the 'Participant Summary Form' will need to be accessed for both projects, the **Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: Randomized Controlled Trial--Parents** version and the **Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: Randomized Controlled Trial--Adolescents** version. Once you are in the study participant's record (Record Home Page):

- Open the Participant Summary Form (click on the bubble in red, under Visit 1)
- Enter the Study ID# (consecutive Study ID#s: Delaware site—start with TC101, TC102, etc. and Orlando—start with TC201, TC202, etc.)—**this step may have already been done for you**
- Answer Questions, 1-2 for the Parent and 1-3 for the Adolescent at this time:
 1. Since the family must have already been consented/assented previously, click on 'Yes' to question 1: 'Did the caregiver complete the consent process and sign the consent form?'—for the parent version, and 'Did the adolescent complete the assent process and sign the assent form?'—for the adolescent version).
 2. In which of the following age groups is the participant?—for the Adolescent version only: click the age range of the Adolescent Participant (either 8-11 or 12-17)—this will be used to release the corresponding surveys
 3. **Enter the email address** (that was obtained in the Contact Information form) in item #2 for the Parent version and #3 for the Adolescent version. If the email addresses are not entered then the measures will not be able to be sent to the family.
- Do **not** complete the Group Assignment at this time. This will be entered into the record *after* the family has completed all of the Visit 1 measures and the family's randomization has been requested from Alex Taylor in Jacksonville.
- If the family decides to drop out, you will need to come back to this form and enter the reason why they are no longer being followed.
- Under 'Form Status Complete?': leave it as '**Incomplete**' for now, but press the '**Save & Exit Form**'; you will get a Note saying to provide a value for Group Assignment—just click the 'Ignore and leave Record' (you will complete this form *after* Visit 1):



There are 2 ways to send a link to complete the surveys:

6. A.) To send a link with the Visit 1 (Baseline) measures, in each of the Projects (Parent and Adolescent versions), click on the 'Manage Survey Participants' on the left sidemenu, under 'Data Collection':

REDCap
 Logged in as ataylor | Log out
 My Projects
 Project Home
 Project Setup
 Project status: Development
 Data Collection
 Manage Survey Participants
 - Get a public survey link or build a participant list for inviting respondents
 Record Status Dashboard
 - View data collection status of all records
 Add / Edit Records
 - Create new records or edit/view existing ones
 Record ID # 1 (Study ID TC101)
 Select other record
 Applications
 Calendar
 Data Exports, Reports, and Stats
 Data Import Tool
 Data Comparison Tool
 Logging
 Field Comment Log
 File Repository

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:
 Incomplete Incomplete (no data)
 Unverified Partial Survey Res
 Complete Completed Survey

Choose action for record

Record ID # 1 (Study ID TC101)
 Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_6 Months	Visit3_12 Months
Participant Summary Form	<input type="radio"/>		
Demographic Information Form (survey)	<input type="radio"/>		

- Make sure you are in the 'Participant List' tab (see below for both parent and child versions).
- In the drop down menu for 'Participant List belonging to': **choose the first survey listed for the corresponding visit** so for Visit 1 choose the "General Information Form GIF_Parent"- Visit 1 for the Parent version and the "Collaborative Parent Involvement Scale-A Visit 1 Baseline for the Adolescent version (**For this and subsequent visits, you will always choose the first survey listed for that corresponding visit or else the correct surveys will not be sent to the participants):

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes : Randomized Controlled Trial--Parents

Manage Survey Participants

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows you to send a customized email to anyone in your list and track who responds to your survey. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List belonging to: **Demographic Information Form-- Visit1_Baseline**

Displaying 1 - 6 of 6

Email	Survey	Invitation Sent?	Link	Survey Access Code and QR Code	Survey Queue
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit1_Baseline	<input type="checkbox"/>			
[No email listed]	"QOLD-PA" - Visit1_Baseline	<input type="checkbox"/>			
[No email listed]	"QOLD-PC" - Visit1_Baseline	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Flexible_P" - Visit1_Baseline	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Conventional_P" - Visit1_Baseline	<input type="checkbox"/>			
[No email listed]	"FCCA_Parent" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"QOLD-PA" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"QOLD-PC" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Flexible_P" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Conventional_P" - Visit2_6 Months	<input type="checkbox"/>			
[No email listed]	"FCCA_Parent" - Visit3_12 Months	<input type="checkbox"/>			
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit3_12 Months	<input type="checkbox"/>			
[No email listed]	"QOLD-PA" - Visit3_12 Months	<input type="checkbox"/>			
[No email listed]	"QOLD-PC" - Visit3_12 Months	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Flexible_P" - Visit3_12 Months	<input type="checkbox"/>			
[No email listed]	"Diabetes Self Management Profile - Conventional_P" - Visit3_12 Months	<input type="checkbox"/>			

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes :
Randomized Controlled Trial - Adolescents**

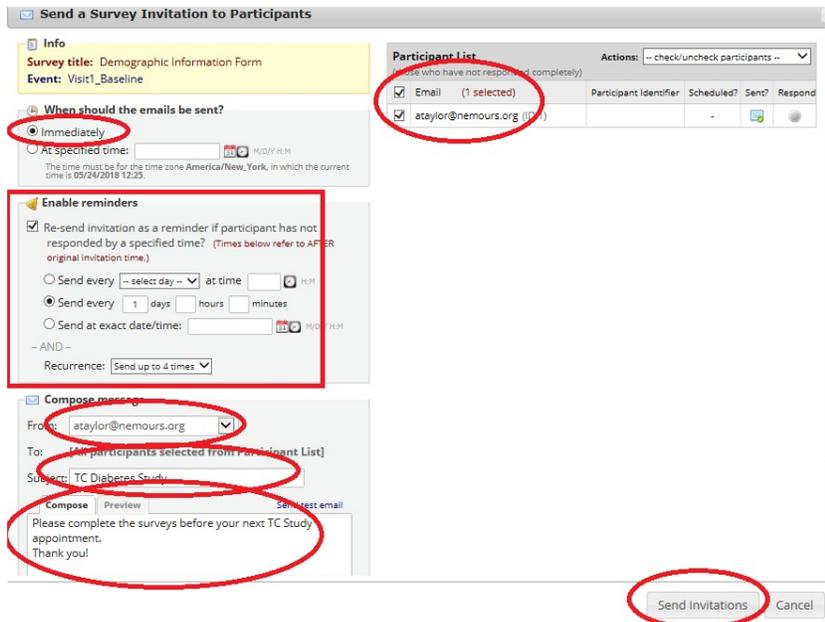
Manage Survey Participants



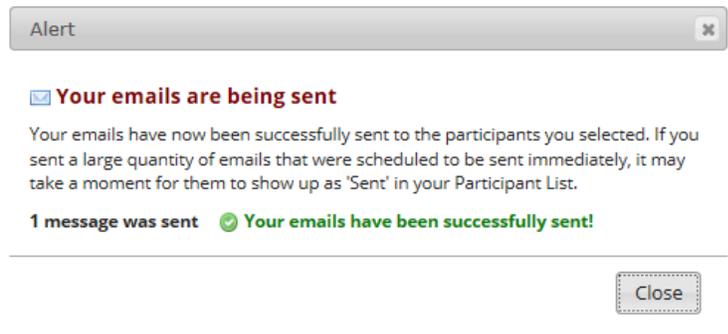
The Participant List option allows you to send a customized email to anyone in your list and track who responds to your survey. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

- Once you have chosen the first Visit 1 measure, directly below it click on 'Compose Survey Invitations' (see below):

- On the left side of the Invitation, you will notice that your email address automatically populates in the 'From:' section of the compose message.
 - In the **Subject** Line you may type: TC Diabetes Study
 - In the box below the Subject, type a message to the family; you may customize it (e.g., 'Please complete the surveys before your next clinic visit. Thank you!')
 - On the right side you will see a list of participants that you can send visit 1 measures out to (the participant email addresses are collected from your entry in the Participant Summary Form); make sure that only the boxes to the left of the corresponding participants that you want to send visit 1 surveys to are checked
 - You can set up the email to go out immediately and also set up reminder emails to go out (customize how often you want them to go out, if participants have not completed their surveys):



- Then click on ‘Send Invitations’ on the bottom right of the Invitation; you should get a message saying your emails were sent successfully:



- The sent emails will appear on the bottom of your Participant List within a fewseconds—see example below

B. Second way to send participants an email with a link to complete surveys:

Go to the participant’s study record then under the corresponding Visit column, choose the first measure designated as a ‘survey’: (Click on the bubble across from the first measure that is designated a ‘survey’, under the corresponding Visit):

Record ID # 1 (Study ID TC101)
Delaware Group

Data Collection Instrument	Visit1 Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>		
Visit Information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health Care Use Survey--Section 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic Information Form (survey)	<input type="radio"/>		
Health Care Use Survey--Section 1 (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FCCA_Parent (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PAID-Problem Areas In Diabetes-Parent (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
QOLD-PA (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
QOLD-PC (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DSMP - Flexible_P (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DSMP - Conventional_P (survey)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PSQ: Physician Satisfaction Questionnaire			<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP1			<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP2			<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP3			<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP4			<input type="radio"/>

On the top right, click on the drop down menu 'Survey options' then choose 'Compose survey invitation':

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RCT--PARENT Version**

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Demographic Information Form

Editing existing Record ID # 1 (Study ID TC101)

Event Name: **Visit1_Baseline**

Record ID #: 1

Today's Date: 06-25-2018

1. First Name of person completing this form:

2. Last Name of person completing this form:

3. Age of person completing this form (in years):

4. Country of birth of person completing this form:

Survey options dropdown menu:

- Open survey
- Log out + Open survey
- Compose survey invitation
- Survey Access Code and QR Code
- Survey Queue

Once in the 'Compose Survey Invitation', follow the same steps as in the first way to send survey invitations above.

7. To check to see if participants have completed their surveys:

- Go to 'Manage Survey Participants' (under 'Data Collection' on the left side menu)
- Make sure to be on the Participant List tab, then go down to the bottom of the list until you find your participant study # and click on the Survey Queue link (last column):

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version

Manage Survey Participants

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List belonging to "Demographic Information Form" - Visit1_Baseline

Displaying 1 - 10 of 10 Add participants Compose Survey Invitations Export list

Email	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code	Survey Queue
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
[No email listed]	Disabled		-				
ataylor@nemours.org (ID 1)	Disabled		-				

- When you open the participant's queue you should be able to see what surveys have been completed and which ones they have left, for example, in this screen shot, 3 of 5 surveys have been completed:

Close survey

Thank you for taking the survey.

Have a nice day!

Survey Queue Get link to my survey queue

Listed below is your survey queue, which lists any other surveys that you have not yet completed. To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
✓ Completed	Demographic Information Form - Visit1_Baseline
✓ Completed	FCCA_Parent - Visit1_Baseline
✓ Completed	PAID-Problem Areas In Diabetes-Parent - Visit1_Baseline
Begin survey	QOLD-PC - Visit1_Baseline
Begin survey	Diabetes Self Management Profile - Conventional_P - Visit1_Baseline

- Also, open each of the completed visit measures to make sure that they have been completed. Participants are free to not answer any questions that they do not want to answer. However, we want to be sure that any items left blank unintentionally are identified and completed.
 - To view the actual measure responses, go to 'Add/Edit Records' (under 'Data Collection' on the left side menu) and choose the subject number from the drop-down menu. On the 'Record Home Page', click on the green bubbles to open each of the measures. Review each measure to ensure that all items are completed. If item responses are missing, go to the 'Actions' drop-down menu at the top of the screen and select 'This Survey with Saved Data':

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Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

FCCA_Parent This survey with saved data

Data Access Group: Delaware Group ?

Survey response is read-only

Response was completed on 05/24/2018 1:31pm. You have not been given permission to edit survey responses. However, your permissions may be changed on the User Rights page in order to allow editing of survey responses. **2 people (the survey respondent and 1 user)** have contributed to this completed survey response. **1 person** has contributed to it since its time of completion.

Record ID # 3 - Visit1_Baseline (Study ID TC103)

Record ID #	3
Family-Centered Care Assessment for Families (FCCA-F)	
This is a survey to measure the quality of family-centered care that a health care provider gives to your child. There are no right or wrong answers. Please answer every question. The survey uses the words "health care provider" throughout to mean the pediatrician who has given you this survey.	
	1--Almost Never 2--Rarely 3--Sometimes 4--Usually 5--Almost Always
1. My child's health care provider talks with me using words I understand.	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
2. My child's health care provider supports me in the role that I want to	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5

A pdf of the measure will open and you can print this measure. At the family's visit (or over the phone, depending on the timing), let the participant know about these items and ask if they intentionally left those items blank. If yes, that's fine. If no, have them complete the missing items on the paper copy.

To enter the hard copy data after completed, open the measure by clicking the green bubble on the 'Event Grid'. In the red box at the top of the screen, click the 'Edit Response' box. Enter the responses from the hard copy and click 'Save Record'.

- **To send participants a follow up reminder to complete their surveys**, simply click on the 'Get link to my survey queue'; then in the pop up window click 'Send' and the participant will get the reminder with a link to the measures still left to complete.

[Close survey queue](#)

Survey Queue Get link to my survey queue

Listed below is your survey queue, which lists any other surveys that you have not yet completed. To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
✔ Completed	General Information Form GIF_Parent
✔ Completed	Diabetes Technology Questionnaire Baseline_Parent
Begin survey	Diabetes Self Management Profile DSMP_Parent
Begin survey	Hypoglycemia Diary_Parent

REDCap Software - Version 6.2.1 - © 2014 Vanderbilt University

Get link to my survey queue

To obtain your survey queue link, which will allow you to return to your survey queue in the future, you may copy and paste the link displayed in the text box below, or you may have it emailed to you at your email address.

Copy and paste the survey queue link

— OR —

Send the survey queue link in an email

7. **Summary of Visit 1 Procedures:**

- 1) Participants will be consented/assented using the most current forms on IRBNet
- 2) Parent will complete the Contact Information form
- 3) Go over the TC_REDCap Survey Handout with Parent
- 4) Give Parent a hard copy of the Health Care Use Survey-Section 2; have them complete it during the Study Visit and remind them to give it back to you at the end of the study visit (REMEMBER TO COLLECT THIS SURVEY)
- 5) Participants will complete their measures either online or hard copy (hard copies can be found in the TransdisciplinaryCare file in the shared drive, in the Measures-RCT folder); the research coordinator will give the family:
 - GIF: General Information Form—(P) Parent only
 - Health Care Use Survey—**Section 1**—(P) Parent only
 - DSMP: Diabetes Self Management Profile—(P, A) both Parent and Adolescent
 - QOLD: Quality of Life with Diabetes Scale—(P, A) both Parent and Adolescent (2 versions for both P and A: Ages 8-11 and Ages 12-17)
 - FCCA: Family-Centered Care Assessment—(P, A) both Parent and Adolescent
 - PAID: Problem Areas In Diabetes—(P, A) both Parent and Adolescent
 - CPI: Collaborative Parent Involvement Scale—(A) Adolescent only
 - DCQ: Diabetes Choices Questionnaire—(A) Adolescent only
 - READDY: **R**eadiness for **E**merging **A**dults with **D**iabetes **D**iagnosed in **Y**outh—(A) Adolescent only
- 6) Research Coordinator will obtain the child's HbA1c that was done at the child's endocrinology clinic visit; this will be entered into the TC RCT Adolescent Project_Adolescent version in REDCap (see pg. 19)
- 7) Research Coordinator will obtain a copy of the download of each of the adolescent's Diabetes Device(s); this data will be entered into the TC RCT Adolescent Project_Adolescent version in REDCap (see pg. 19)
- 8) **At the end of the Study Visit, the Research Coordinator will collect the Health Care Use Survey-Section 2 from the Parent (they may have to estimate the last few items)**

9) After the family has left, Research Coordinator will contact Alex Taylor (email) to obtain randomization for the family

9) In REDCap, enter the remaining data for Visit 1:

- **Parent version:**

➤ **Participant Summary Form:** click on the red bubble under visit 1

- Enter the Group Assignment
- Under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Participant Summary Form Data Access Group: Delaware Group

Editing existing Record ID # 3 (Study ID TC103)

Event Name: Visit1_Baseline

Record ID # 3

Study ID

1. Did the caregiver complete the consent process and sign the consent form? Yes No

2. What is the parent/legal guardian's email address (MUST be different from the Adolescent's email address):

The next question will only be entered AFTER the family has completed all the baseline measures and they have been randomized.

3. **Group Assignment:** Website Access Intervention Group UCP Control Group

4. Participant is no longer being followed for the reason below: Didn't complete the baseline visit Dropped out after baseline visit Dropped out after 6 month visit Completed all 3 visits

Form Status

Complete?

- You will then be returned back to the Record Home Page

➤ **Visit Information:** (click on the clear bubble under visit 1)—**DO NOT COMPLETE THIS FORM UNTIL AFTER THE FAMILY HAS COMPLETED ALL THEIR SURVEYS!!** (Or else the family will receive the Visit 2 surveys in addition to the Visit 1 surveys)

- Enter the date the visit was scheduled for
- **Question 2 must be answered in order to be able to send out measures for the next visit;** if yes was clicked then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
- This form **must always be completed at each visit**, even if the family did not come in for that visit (if it is not completed, you will not be able to send out measures at future visits)
- Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version**

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Visit Information Data Access Group: Delaware Group

Editing existing Record ID # 3 (Study ID TC103)

Event Name: Visit1_Baseline

Record ID # 3

THIS FORM IS NOT TO BE COMPLETED UNTIL THE PARENT HAS COMPLETED ALL THEIR SURVEYS!

1. Date of scheduled visit

2. Did this visit happen?
* must provide value
 yes
 no this visit will be skipped

3. visit date

Form Status

Complete?

- If the measures were completed on hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 1 that corresponds to each of the measures.
- Confirm that all bubbles under Visit 1 are in green:  or 

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
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Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Choose action for record

Record ID # 3 (Study ID TC103)
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form			
Visit Information			
Demographic Information Form (survey)			
FCCA_Parent (survey)			
PAID-Problem Areas In Diabetes-Parent (survey)			
QOLD-PA (survey)			
QOLD-PC (survey)			
Diabetes Self Management Profile - Flexible_P (survey)			
Diabetes Self Management Profile - Conventional_P (survey)			
Delete all data on event:			

Legend for status icons:

-  Incomplete
-  Incomplete (no data saved)
-  Unverified
-  Partial Survey Response
-  Complete
-  Completed Survey Response

- Confirm that there are no missing item responses on the Visit 1 questionnaires.
- **Adolescent version:**
 - **Participant Summary Form:** click on the red bubble under visit 1
 - Enter the Group Assignment
 - Under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Record'

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Save & Exit F
Save & ...
-- Cancel --

Participant Summary Form

Editing existing Record ID # 1

Event Name: Visit1_Baseline

Record ID # 1

Study ID
* must provide value

1. Did the adolescent complete the assent process and sign the assent form?
 Yes
 No
* must provide value

2. In which of the following age groups is the participant?
 8-11 years of age
 12-17 years of age
* must provide value

3. What is the Adolescent's email address (MUST be different from Parent's email address):

* must provide value

The next question will only be entered AFTER the family has completed all the baseline measures and they have been randomized.

4. Group Assignment:
 SC: Standard Care
 TC-FF: TC Face to Face
 TC-TH: TC Telehealth
* must provide value

Participant is no longer being followed for the reason below:
 Didn't complete the baseline visit
 Dropped out after baseline visit
 Dropped out after 6 month visit
 Completed all 3 visits

Form Status

Complete?

- You will then be returned back to the Record Home Page
- **Visit Information:** (click on the clear bubble under visit 1)-- **DO NOT COMPLETE THIS FORM UNTIL AFTER THE FAMILY HAS COMPLETED ALL THEIR SURVEYS!!** (Or else the family will receive the Visit 2 surveys in addition to the Visit 1 surveys; this is a glitch in REDCap)
 - Enter the date the visit was scheduled for
 - Question 2 **must** be answered in order to be able to send out measures for the next visit; if yes was clicked then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - **This form must always be completed at each visit, even if the family did not come in for that visit (if it is not completed, you will not be able to send out measures at future visits)**
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Visit Information

Editing existing Record ID # 1
Event Name: Visit1_Baseline

Record ID # 1

THIS FORM IS NOT TO BE COMPLETED UNTIL THE ADOLESCENT HAS COMPLETED ALL THEIR SURVEYS!

1. Date of scheduled visit Today HO-DY

2. Did this visit happen?
* must provide value
 yes
 no this visit will be skipped reset

3. visit date Today HO-DY

Form Status

Complete?

[Save & Exit Form](#) [Save & ...](#)

[-- Cancel --](#)

- You will then be returned back to the Record Home Page
- **A1c Lab Results:** click on the clear bubble under visit 1
 - Enter the HbA1c lab results for Visit 1
 - Enter the date of the HbA1c lab results
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

A1c Lab Results

Editing existing Record ID # 1
Event Name: Visit1_Baseline

Record ID # 1

Enter the HbA1c lab results for each visit.

Enter the HbA1c lab result for this visit:

Enter the date of the HbA1c results: Today HO-DY

Form Status

Complete?

[Save & Exit Form](#) [Save & ...](#)

[-- Cancel --](#)

- You will then be returned back to the Record Home Page
- **Diabetes Device Download Summary:** click on the clear bubble under visit 1
 - Enter the Visit number (this form will be completed at 5 visits so make sure to enter the visit #) and the date of the download
 - Note: Families may have more than one meter, download data from all meters they bring to their visit
 - After the visit let Alex know how many device downloads were obtained since the Adolescent can earn \$5 for each device that is downloaded
 - Enter all the data from the device download corresponding to the Diabetes Device(s) the Adolescent uses, onto this form
Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#) [Save & Exit Form](#) [Save & ...](#) [Cancel](#)

Diabetes Device Download Summary
Current instance: 1/1

Editing existing Record ID # 1 (Study ID 101)

Event Name: Visit1_Baseline

Record ID #

Visit #:

Visit Date: 06-05-2018

Diabetes Device Download: Home Glucose Meter Questions

Does the patient use a Blood Glucose Meter at Home? Yes No

Diabetes Device Download: Insulin Pump Questions

Is the Patient on an Insulin Pump? Yes No

Diabetes Device Download: Continuous Glucose Monitor (CGM) Questions

Is the patient on a CGM? Yes No

Form Status

Complete?

- You will then be returned back to the Record Home Page
 - If the measures were completed on hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 1 that corresponds to each of the measures.
 - Confirm that all bubbles under Visit 1 are in green:  or 
- Record Home Page view:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--ADOLESCENT Version

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Record ID # 1 (Study ID)

Data Collection Instrument	Visit1_Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form			
Visit Information			
A1c Lab Results			
Collaborative Parent Involvement Scale_A (survey)			
FCCA_Adolescent (survey)			
PAID-Problem Areas In Diabetes Paid-Adolescent (survey)			
QOLD-C (survey)			
QOLD-A (survey)			
Diabetes Self Management Profile - Flexible_A (survey)			
Diabetes Choices Questionnaire DCQ_A (survey)			
READDY_A (survey)			

Legend for status icons:
 Incomplete Incomplete (no d
 Unverified  Partial Survey Ret
 Complete  Completed Surve

- Confirm that there are no missing item responses on the Visit 1 questionnaires.

o IF THE FAMILY WILL BE COMPLETING THEIR SURVEYS ONLINE AFTER THE BASELINE VISIT 1. FOLLOW STEP 6 ON PAGES 9-12.

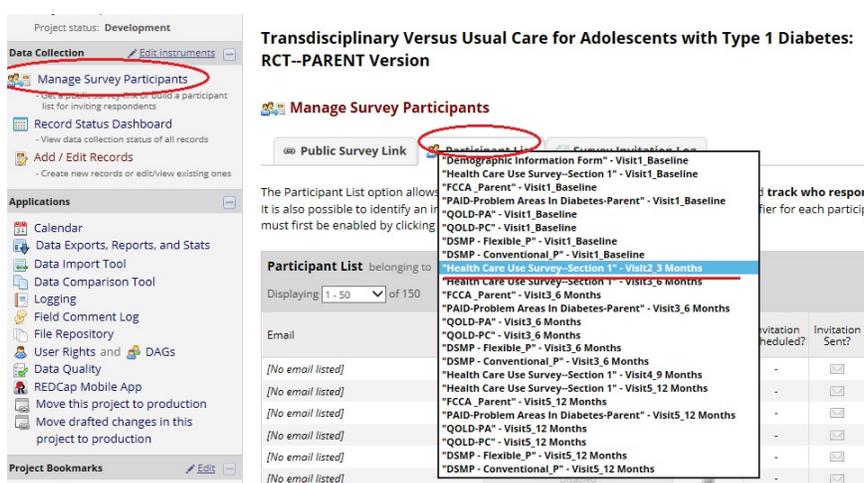
Visit 2 (3-month) Study Procedures

At Visits 2 and 4, the only surveys that the Family will complete are the Health Care Use Surveys (Section 1 and Section 2 Surveys).

The Research Coordinator will collect the data and input into REDCap, the following measures: Health Care Use Survey –Section 2 (located in the Parent TC REDCap project) and the HbA1c and the Device Download Summary (located in the Adolescent project).

Approximately 2 weeks before the Family's Visit 2 appointment, email the Parent the link to complete the Health Care Use Survey—**Section 1** through REDCap:

- In REDCap, click on 'Manage Survey Participants', then make sure you're in the 'Participant List' tab; in the drop down following 'Participant List belonging to:' Choose **the Health Care Use Survey—Section 1 –Visit2_3 Months:**



- Or, you can also send out the link to the Health Care Use survey—Section 1 by clicking on the bubble under Visit2_3 Months across from the Health Care Use Survey—Section 1:

Study ID # TC104
Delaware Group

Data Collection Instrument	Visit1_Baseline	<u>Visit2_3 Months</u>	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>				
Visit Information	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health Care Use Survey--Section 2	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic Information Form (survey)	<input checked="" type="radio"/>				
<u>Health Care Use Survey--Section 1 (survey)</u>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FCCA_Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
PAID-Problem Areas In Diabetes-Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PA (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PC (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
DSMP - Flexible_P (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
DSMP - Conventional_P (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
PSQ: Physician Satisfaction Questionnaire					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP1					<input type="radio"/>

- Then Compose Survey Invitation:
Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Health Care Use Survey--Section 1

Data Access Group: Delaware Group

Invitation status: **Survey options**

- Open survey
- Log out + Open survey
- Compose survey invitation
- Survey Access Code and QR Code
- Survey Queue

Editing existing Study ID # TC104

Event Name: **Visit2_3 Months**

Study ID # TC104

Date of Visit: Today

1. In the past 3 months, has your adolescent with type 1 diabetes required an Emergency Department Admission for a diabetes-related reason? Yes No

2. In the past 3 months, has your adolescent with type 1 diabetes required a Hospital Admission for a diabetes-related reason? Yes No

reset

- Then click on ‘Compose Survey Invitation’:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Manage Survey Participants

[Public Survey Link](#) [Participant List](#) [Survey Invitation Log](#)

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List belonging to **Health Care Use Survey--Section 1* - Visit1 Baseline**

Displaying 1 - 50 of 150 [Add participant](#) [Compose Survey Invitations](#)

Email	Participant Identifier	Responded?	Invitation Scheduled?	Inv S
-------	------------------------	------------	-----------------------	-------

- Make sure that the Survey Title in the upper left hand corner says “Health Care Use Survey—Section 1” and make sure to pick the email address of the correct Study ID# you want to send the link to and Customize your survey invitation— For Visits 2 and 4 you may want to let them know that for these Visits, they will only be completing one survey (HCUS) (see example below) then ‘Send Invitation’:

Send Survey Invitation to Participant "TC104"

Immediately

At specified time: M/D/Y H:M
The time must be for the time zone America/New_York, in which the current time is 06/27/2018 09:40.

Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time? (Times below refer to AFTER original invitation time.)

Send every -- select day -- at time H:M

Send every 2 day hours minutes

Send at exact date/time: M/D/Y H:M

- AND -

Recurrence: Send up to 4 times

Compose message

From: ataylor@nemours.org

To: ataylor@nemours.org (from Email field)

Or provide another email:

(NOTE: Any email address manually entered above will be used only this one time when sending an survey invitation. Any other invitations sent out at other times will instead go to the email address found in the Participant List for this participant.)

Subject: RE: TC Diabetes Study

Compose Preview Send test email

Dear Parent,
 Please click on the link below to complete your questionnaire prior to your scheduled Study Visit. For this Visit you will only be completing one survey online.
 Thank you!

Send Invitation Cancel

- If the Parent does not complete the survey before the Visit 2 appointment, give them a hard copy to complete then after the visit enter the data from the form into REDCap.
- In the Record Home Page of the Participant, click on the the green bubble corresponding to the Health Care Use Survey—Section 1:

Study ID # **TC104**
 Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	●				
Visit Information	●	○	○	○	○
Health Care Use Survey--Section 2	●	○	○	○	○
Demographic Information Form (survey)	●				
<u>Health Care Use Survey--Section 1 (survey)</u>	●	○	○	○	○
FCCA_Parent (survey)	●		○		○
PAID-Problem Areas In Diabetes-Parent (survey)	●		○		○
QOLD-PA (survey)	○		○		○
QOLD-PC (survey)	●		○		○
DSMP - Flexible_P (survey)	●		○		○
DSMP - Conventional_P (survey)	○		○		○
PSQ: Physician Satisfaction Questionnaire					○
TDMQ: Team Decision Making Questionnaire_HCP1					○

- Enter the responses from the Parent's hard copy of the Health Care Use Survey—Section 1:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) VIDEO: Basic data entry

Health Care Use Survey--Section 1

Current instance: 2/2 Data Access Group: Delaware Group

Invitation status: Survey options

Editing existing Record ID # 2 (Instance #2) (Study ID TC102)

Event Name: **Visit1_Baseline**

Record ID #: 2

Visit #: 2

Date of Visit: 06-07-2018 Today M-D-Y

1. In the past 3 months, has your adolescent with type 1 diabetes required an Emergency Department Admission for a diabetes-related reason? Yes No

2. In the past 3 months, has your adolescent with type 1 diabetes required a Hospital Admission for a diabetes-related reason? Yes No

3. In the past 3 months, has your adolescent with type 1 diabetes required a visit to an Urgent Care or Primary Care Clinic for a diabetes-related reason? Yes No

If your adolescent with type 1 diabetes required MORE THAN ONE VISIT to any of the health care services (Emergency Department Admission, Hospital admission, or Visit at an Urgent Care or Primary Care Clinic) for a diabetes-related reason in the past 3 months, please click on.....in order to access another Health Care Use Survey and complete just the information corresponding to the correct health care service.

Visit 2 Instructions:

Approximately 2 weeks prior to the Family's Study Visit 2, email the Parent a link to the Health Care Survey—Section 1 through REDCap (see pg 21)

When the Family first arrives at their appointment, make sure to give the Parent a hard copy of the Health Care Use Survey-Section 2; have them complete it during the Study Visit and remind them to give it back to you at the end of the study visit (REMEMBER TO COLLECT THIS SURVEY)

If the Parent did not complete the Health Care Use Survey-Section 1 prior to the Visit 2, then also give them a hard copy to complete at the study visit then you can enter the data into REDCap after the visit.

REMEMBER TO COLLECT THE HEALTH CARE USE SURVEY(S) PRIOR TO THE FAMILY LEAVING

For visits 2 (at 3 months) and Visit 4 (at 9 months), the only data you will be entering into REDCap are the A1c, the device download summary data, and the Health Care Use Survey data. The A1c and the device download summary forms are located in the REDCap TC RCT--ADOLESCENT Project and the Health Care Use Survey (both Section 1 and Section 2) forms are located in the REDCap TC RCT—PARENT Project

- **In REDCap, go to each of the measures: the A1c Lab Results (obtain the A1c results from EMR or endo clinic) and the Diabetes Device Download Summary (use the hard copy to collect the required data from the Adolescents' downloads then copy those results into the REDcap survey) for Visit 2 (3 months), in the TC Adolescent Project, under Visit 2_3Months**

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Incomplete (no data saved) ?
- Partial Survey Response
- ✔ Completed Survey Response

Choose action for record

Study ID # TC102 successfully edited

Study ID # **TC102**
Delaware

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	●				
Visit Information	●				
<u>A1c Lab Results</u>	●	○	○	○	○
<u>Diabetes Device Download Summary</u>	●	○	○	○	○
Collaborative Parent Involvement Scale_A (survey)	✔				
FCCA_Adolescent (survey)	✔				
PAID-Problem Areas In Diabetes Paid-Adolescent (survey)	●				
QOLD-C (survey)	●				
QOLD-A (survey)	○				
DSMP - Flexible_A (survey)	●				
Diabetes Choices Questionnaire DCQ_A (survey)	●				
READDY_A (survey)	●				

- **Diabetes Device Download Summary:** click on the clear bubble under visit 2
 - Note: Families may have more than one meter, download data from all meters they bring to their visit (can enter data for up to 3 Meters)
 - After the visit let Alex know how many device downloads were obtained since the Adolescent can earn \$5 for each device that is downloaded
 - Enter all the data from the device download corresponding to the Diabetes Device(s) the Adolescent uses, onto this form
 - Then Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

KC1--ADOLESCENT VERSION

Actions: Modify instrument Download PDF of instrument(s) VIDEO: Basic data entry

Diabetes Device Download Summary

Data Access Grc

Editing existing Study ID # TC102

Event Name: **Visit2_3 Months**

Study ID # TC102

Visit Date: 06-28-2018 Today M-D-Y

Diabetes Device Download: Home Glucose Meter Questions

1. Does the patient use a Blood Glucose Meter at Home? Yes No

1a. How many Home Glucose Meters does the Adolescent use?

Diabetes Device Download: Insulin Pump Questions

2. Is the Patient on an Insulin Pump? Yes No

Diabetes Device Download: Continuous Glucose Monitor (CGM) Questions

3. Is the patient on a CGM? Yes

1 Home Glucose Meter

2 Home Glucose Meters

3 Home Glucose Meters

- In order to access the Health Care Use Survey—Section 2 for Visit 2 (3 month), in the TC Parent Project, under Visit 1_Baseline, click on the plus sign to the right of the green bubble for that measure (this will open up the form); make sure to specify that this data is for Visit 2 (3 months) and the date of the data (disregard that you are accessing the Visit 2 measures through the Visit 1_Baseline measures); then finish entering the data



Study ID # **TC104**
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>				
Visit Information	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Health Care Use Survey--Section 2</u>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic Information Form (survey)	<input checked="" type="radio"/>				
Health Care Use Survey--Section 1 (survey)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FCCA_Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
PAID-Problem Areas In Diabetes-Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PA (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PC (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
D\$MP - Flexible_P (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
D\$MP - Conventional_P (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
PSQ: Physician Satisfaction Questionnaire					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP1					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP2					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP3					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP4					<input type="radio"/>

- Complete the Health Care Use Survey—Section 2:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Save & Stay
-- Cancel --

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) VIDEO: Basic data entry

Health Care Use Survey--Section 2

Data Access Group: Delaware Group ?

Editing existing Study ID # **TC104**

Event Name: **Visit2_3 Months**

Study ID # TC104

Date of Visit: Today M-D-Y
* must provide value

1. Enter the time in minutes you spent for today's appointment on:
Travel time to appointment (minutes):

2. Enter the time in minutes that you spent for today's appointment on:
Time waiting for visit to begin (in minutes):

3. Enter the time in minutes that you spent for today's appointment on:
Length of visit time with care provider(s) present (in minutes):

4. Enter the time in minutes that you spent for today's appointment on:
Length of time spent checking out (in minutes):

5. Enter the time in minutes that you spent for today's appointment on:

- If the Parent did not complete the Health Care Use Survey—Section 1 before the Visit 2 appointment, have them complete it at the visit and enter the data:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

[Save & Exit Form](#)
[Save & Stay](#)
[-- Cancel --](#)

Health Care Use Survey--Section 1

Data Access Group: Delaware Group ?
Invitation status: [Survey options](#)

Editing existing Study ID # **TC104**

Event Name: **Visit2_3 Months**

Study ID # TC104

Date of Visit:
 Today M-D-Y

1. In the past 3 months, has your adolescent with type 1 diabetes required an Emergency Department Admission for a diabetes-related reason?
 Yes
 No [reset](#)

2. In the past 3 months, has your adolescent with type 1 diabetes required a Hospital Admission for a diabetes-related reason?
 Yes
 No [reset](#)

3. In the past 3 months, has your adolescent with type 1 diabetes required a visit to an Urgent Care or Primary Care Clinic for a diabetes-related reason?
 Yes
...

Visit 3 (6 month) Study Procedures

1. Prior to sending out the Visit 3 measures, make sure their Visit 3 is still scheduled then approximately 2 weeks prior to their scheduled visit, email Parent and Adolescent a link to their Visit 3 surveys through REDCap
There are 2 ways to send emails with links to complete surveys:
2. **A. To send a link with the Visit 3 measures**, in each of the Projects (Parent and Adolescent versions), click on the 'Manage Survey Participants' on the leftside menu, under 'Data Collection':



The screenshot shows the REDCap interface. In the 'Data Collection' section of the left sidebar, 'Manage Survey Participants' is circled in red. Below it are 'Record Status Dashboard' and 'Add / Edit Records'. The 'Study ID # TC104' is selected. The 'Applications' section includes 'Calendar', 'Data Exports, Reports, and Stats', 'Data Import Tool', 'Data Comparison Tool', 'Logging', 'Field Comment Log', 'File Repository', 'User Rights and DAGs', 'Data Quality', 'REDCap Mobile App', and options to move the project to production. The 'Project Bookmarks' section shows 'TC: Adolescent version'.

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Incomplete (no data saved) ?
- Partial Survey Response
- ✔ Completed Survey Response

Study ID # **TC104**
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	●				
Visit Information	●	●	●	●	●
Health Care Use Survey--Section 2	●	●	●	●	●
Demographic Information Form (survey)	●				
Health Care Use Survey--Section 1 (survey)	●	●	●	●	●
FCCA_Parent (survey)	●		●		●
PAID-Problem Areas In Diabetes-Parent (survey)	●		●		●
QOLD-PA (survey)	●		●		●
QOLD-PC (survey)	●		●		●
DSMP - Flexible_P (survey)	●		●		●
DSMP - Conventional_P (survey)	●		●		●
PSQ: Physician Satisfaction Questionnaire	●				●

- Make sure you are in the 'Participant List' tab (see below).
- In the drop down menu for Participant List belonging to: **choose the first survey listed for the corresponding visit**, so for Visit 3 (6 month surveys) choose the "FCCA Parent"-Visit 3 6 Months for the Parent version and the "Collaborative Parent Involvement Scale A" -Visit 3 6 Months for the Adolescent version (always choose the first survey listed for the corresponding visit or else the correct surveys will not be sent to the participants):

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version**

Manage Survey Participants

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows... It is also possible to identify an in... must first be enabled by clicking

o responds to yo
h participant (this

Participant List belonging to
Displaying 1 - 12 of 12

Email

[No email listed]
[No email listed]
[No email listed]
[No email listed]

Demographic Information Form" - Visit1 Baseline
"FCCA Parent" - Visit1 Baseline
"PAID-Problem Areas In Diabetes-Parent" - Visit1 Baseline
"QOLD-PA" - Visit1 Baseline
"QOLD-PC" - Visit1 Baseline
"Diabetes Self Management Profile - Flexible P" - Visit1 Baseline
"Diabetes Self Management Profile - Conventional P" - Visit1 Baseline
"FCCA Parent" - Visit3 6 Months
"PAID-Problem Areas In Diabetes-Parent" - Visit3 6 Months
"QOLD-PA" - Visit3 6 Months
"QOLD-PC" - Visit3 6 Months
"Diabetes Self Management Profile - Flexible P" - Visit3 6 Months
"Diabetes Self Management Profile - Conventional P" - Visit3 6 Months
"FCCA Parent" - Visit5 12 Months
"PAID-Problem Areas In Diabetes-Parent" - Visit5 12 Months
"QOLD-PA" - Visit5 12 Months
"QOLD-PC" - Visit5 12 Months
"Diabetes Self Management Profile - Flexible P" - Visit5 12 Months
"Diabetes Self Management Profile - Conventional P" - Visit5 12 Months

Invitation Sent? Link S A Co QI

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--ADOLESCENT Version**

Manage Survey Participants

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows... It is also possible to identify an in... must first be enabled by clicking

who responds t
ach participant

Participant List belonging to
Displaying 1 - 3 of 3

Email

1) ataylor@nemours.org (ID 1)
2) ataylor@nemours.org (ID 2)
3) ataylor@nemours.org (ID 3)

"Collaborative Parent Involvement Scale A" - Visit1 Baseline
"FCCA Adolescent" - Visit1 Baseline
"PAID-Problem Areas In Diabetes Paid-Adolescent" - Visit1 Baseline
"QOLD-C: Quality of Life and Diabetes-Child" - Visit1 Baseline
"QOLD-A" - Visit1 Baseline
"Diabetes Self Management Profile - Flexible A" - Visit1 Baseline
"Diabetes Choices Questionnaire DCQ A" - Visit1 Baseline
"READDY A" - Visit1 Baseline
"Collaborative Parent Involvement Scale A" - Visit3 6 Months
"FCCA Adolescent" - Visit3 6 Months
"PAID-Problem Areas In Diabetes Paid-Adolescent" - Visit3 6 Months
"QOLD-C: Quality of Life and Diabetes-Child" - Visit3 6 Months
"QOLD-A" - Visit3 6 Months
"Diabetes Self Management Profile - Flexible A" - Visit3 6 Months
"Diabetes Choices Questionnaire DCQ A" - Visit3 6 Months
"READDY A" - Visit3 6 Months
"Collaborative Parent Involvement Scale A" - Visit5 12 Months
"FCCA Adolescent" - Visit5 12 Months
"PAID-Problem Areas In Diabetes Paid-Adolescent" - Visit5 12 Months
"QOLD-C: Quality of Life and Diabetes-Child" - Visit5 12 Months
"QOLD-A" - Visit5 12 Months
"Diabetes Self Management Profile - Flexible A" - Visit5 12 Months
"Diabetes Choices Questionnaire DCQ A" - Visit5 12 Months
"READDY A" - Visit5 12 Months

Invitation Sent? Link

- Once you have chosen the first Visit 3 measure, directly below it click on 'Compose Survey Invitations':

**Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version**

Manage Survey Participants

Public Survey Link Participant List Survey Invitation Log

The Participant List option allows you to send a customized email to anyone in your list and track who responds to your survey. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List belonging to "FCCA Parent" - Visit3 6 Months

Displaying 1 - 12 of 12 Add participant Compose Survey Invitations

Email	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code & QR Code
[No email listed]	Disabled		-			
[No email listed]	Disabled		-			

B. Second way to send participants an email with a link to complete surveys:

Go to the participant's study record then under the corresponding Visit column, choose the first measure designated as a 'survey': (Click on the bubble across from the first measure that is designated as a 'survey', under the corresponding Visit):

Study ID # TC104
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>				
Visit Information	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health Care Use Survey--Section 2	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic Information Form (survey)	<input checked="" type="radio"/>				
Health Care Use Survey--Section 1 (survey)	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
FCCA_Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
PAID-Problem Areas in Diabetes-Parent (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PA (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-PC (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
DSMP - Flexible_P (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
DSMP - Conventional_P (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
PSQ: Physician Satisfaction Questionnaire					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP1					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP2					<input type="radio"/>
TDMQ: Team Decision Making Questionnaire_HCP3					<input type="radio"/>

On the top right, click on the drop down menu 'Survey options' then choose 'Compose survey invitation':

Health Care Use Survey--Section 1

Record ID # 1 successfully edited

Current instance: 1/1

Data Access Group: Delaware Group

Invitation status: Survey options

- Open survey
- Log out + Open survey
- Compose survey invitation
- Survey Access Code and QR Code
- Survey Queue

Editing existing Record ID # 1 (Study ID TC101)

Event Name: Visit3_6 Months

Record ID #: 1

Visit #: [input field]

Date of Visit: [calendar icon] Today M-D-Y

1. In the past 3 months, has your adolescent with type 1 diabetes required an Emergency Department Admission for a diabetes-related reason? Yes No

2. In the past 3 months, has your adolescent with type 1 diabetes required a Hospital Admission for a diabetes-related reason? Yes No

- When you open the participant's queue you should be able to see what surveys have been completed and which ones they have left
- To send participants a follow up reminder to complete their surveys simply click on the 'Get link to my survey queue'; then in the pop up window click 'Send' and the participant will get the reminder with a link to the measures still left to complete.

3. **Check for missing item responses** by opening each of the completed measures and making sure all items were completed.

- If item responses are missing, go to the 'Actions' drop-down menu at the top of the screen and select 'This Survey with Saved Data'. A pdf of the measure will open and you can print this measure.
- At the family's visit, review the measure with them and ask if they intentionally left those items blank. If yes, that's fine. If no, have them complete the missing items on the paper copy.
- Enter these responses in the appropriate measure in REDCap and 'Save Record'.

4. **Summary of Visit 3_6 Months Procedures:** First make sure that families are still scheduled for their next study visit:

- 1) Participants will complete their measures either online or hard copy (these can be found in the Transdisciplinary Care file in the shared drive, in the Measures-RCT folder):

- Health Care Use Survey—**Section 1**—(P) Parent only
- DSMP: Diabetes Self Management Profile—(P, A) both Parent and Adolescent
- QOLD: Quality of Life with Diabetes Scale—(P, A) both Parent and Adolescent (2 versions for both P and A: Ages 8-11 and Ages 12-17)
- FCCA: Family-Centered Care Assessment—(P, A) both Parent and Adolescent
- PAID: Problem Areas In Diabetes—(P, A) both Parent and Adolescent
- CPI: Collaborative Parent Involvement Scale—(A) Adolescent only
- DCQ: Diabetes Choices Questionnaire—(A) Adolescent only
- READDY: **R**eadiness for **E**merging **A**dults with **D**iabetes **D**iagnosed in **Y**outh—(A) Adolescent only

- Approximately 2 weeks prior to the family's scheduled Visit 3_6 Months, the Research Coordinator will send the family (parent and child separately) an email through REDCap with the link for them to complete their Visit 3_6 Month measures online.
- The Research Coordinator will check to see if the family has completed their measures about 5 days prior to the family's scheduled study visit, and if they have not completed their measures then the Research Coordinator will send out a follow up reminder email.
- Prior to the study visit, the Research Coordinator will also check completed measures for missing item responses by opening each of them and making sure all items were completed. If there are missing item responses, the RC will print out the measure and have the family complete on the paper copy at their study visit. After completion, the RC will enter these responses in the appropriate measure in REDCap and 'Save & Exit Form'.
- When the family comes to the clinic for their Visit 3, if they still have not completed their measures (or have some with missing items), then they will need to complete them at their Visit 3 Study visit by hard copies of the measures. (The Research Coordinator will need to check if the measures were completed prior to their appointment). Or, these can be done online at their visit.

- 2) When the family arrives for their Visit 3 appointment, make sure to give the Parent a hard copy of the Health Care Use Survey—Section 2; **REMEMBER TO COLLECT IT BEFORE THE PARENT LEAVES**

- 3) In REDCap, the Research Coordinator will enter the remaining data for Visit 3 but wait until **AFTER** the Visit was completed and the measures were completed by the family:
 - **Parent version:**
 - ****Visit Information form:— DO NOT COMPLETE THIS FORM UNTIL AFTER THE FAMILY HAS COMPLETED ALL THEIR SURVEYS!!** (Or else the family will receive the Visit 5 surveys in addition to the Visit 3 surveys)
 - This form **must always be completed at each visit**, if it is not completed, you will not be able to send out measures at future visits. To be completed after the visit with the family:
 - Click on the clear bubble under Visit 3_6 Month
 - Enter the date the visit was scheduled for (if no visit was scheduled, leave blank)
 - Question 2 **must** be answered in order to be able to send out measures for the next visit; click 'no this visit will be skipped' if the family did *not* complete Visit 3 or click 'yes' if was completed, then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Exit & Save Form'

 - If the measures were completed in hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 3 that corresponds to each of the measures.

 - Confirm that all valid bubbles under Visit 3 are in green:  or 

 - Confirm that there are no missing item responses on the Visit 3 questionnaires.

Child version:

- ****Visit Information form:— DO NOT COMPLETE THIS FORM UNTIL AFTER THE FAMILY HAS COMPLETED ALL THEIR SURVEYS!!** (Or else the family will receive the Visit 3 surveys in addition to the Visit 2 surveys; this is a glitch in REDCap); this form **must always be completed at each visit** (if it is not completed, you will not be able to send out measures at future visits). To be completed after the visit with the family:
 - Click on the clear bubble under Visit 3
 - Enter the date the visit was scheduled for (if no visit was scheduled, leave blank)
 - Question 2 **must** be answered in order to be able to send out measures for the next visit; click 'no this visit will be skipped' if the family did *not* complete Visit 2 or click 'yes' if was completed, then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'.

- **A1c Lab Results**: click on the clear bubble under visit 3
 - Enter the HbA1c lab results for Visit 3
 - Enter the date of the HbA1c lab results
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

- **Diabetes Device Download Summary**: click on the clear bubble under visit 3
 - Enter the Visit number (this form will be completed at 5 visits so make sure to enter the visit #) and the date of the download
 - Enter all the data from the device download corresponding to the Diabetes Device(s) the Adolescent uses, onto this form
Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

- If the measures were completed on hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 3 that corresponds to each of the measures.
 - Confirm that all bubbles under Visit 3 are in green:  or 

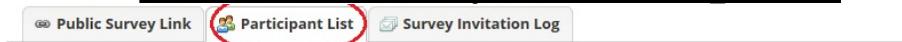
- Confirm that there are no missing item responses on the Visit 3 questionnaires.

Visit 4 (9-month) Study Procedures

At Visit 4 (like Visit 2), the only surveys that the Family will complete are the Health Care Use Surveys (Section 1 and Section 2 Surveys).

Approximately 2 weeks before the Family's Visit 4 appointment, email the Parent the link to complete the Health Care Use Survey—**Section 1** through REDCap:

- In REDCap, click on 'Manage Survey Participants', then make sure you're in the 'Participant List' tab; in the drop down following 'Participant List' belonging to: Choose **the Health Care Use Survey—Section 1-Visit4 9 Months**



The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List	Survey Title	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code	Survey Queue
[No email listed]	"Demographic Information Form" - Visit1_Baseline	-				
[No email listed]	"Health Care Use Survey--Section 1" - Visit1_Baseline	-				
[No email listed]	"FCCA_Parent" - Visit1_Baseline	-				
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit1_Baseline	-				
[No email listed]	"QOLD-PA" - Visit1_Baseline	-				
[No email listed]	"QOLD-PC" - Visit1_Baseline	-				
[No email listed]	"DSMP - Flexible_P" - Visit1_Baseline	-				
[No email listed]	"DSMP - Conventional_P" - Visit1_Baseline	-				
[No email listed]	"Health Care Use Survey--Section 1" - Visit2_3 Months	-				
[No email listed]	"Health Care Use Survey--Section 1" - Visit3_6 Months	-				
[No email listed]	"FCCA_Parent" - Visit3_6 Months	-				
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit3_6 Months	-				
[No email listed]	"QOLD-PA" - Visit3_6 Months	-				
[No email listed]	"QOLD-PC" - Visit3_6 Months	-				
[No email listed]	"DSMP - Flexible_P" - Visit3_6 Months	-				
[No email listed]	"DSMP - Conventional_P" - Visit3_6 Months	-				
[No email listed]	"Health Care Use Survey--Section 1" - Visit4 9 Months	-				
[No email listed]	"Health Care Use Survey--Section 1" - Visit5_12 Months	-				
[No email listed]	"FCCA_Parent" - Visit5_12 Months	-				
[No email listed]	"PAID-Problem Areas In Diabetes-Parent" - Visit5_12 Months	-				
[No email listed]	"QOLD-PA" - Visit5_12 Months	-				
[No email listed]	"QOLD-PC" - Visit5_12 Months	-				
[No email listed]	"DSMP - Flexible_P" - Visit5_12 Months	-				
[No email listed]	"DSMP - Conventional_P" - Visit5_12 Months	-				

- Then click on 'Compose Survey Invitation':

Project status: Development

Section: [Edit Instruments](#)

[Manage Survey Participants](#)

Record Status Dashboard

1 / Edit Records

Tools

Export, Reports, and Stats

Import Tool

Comparison Tool

Comment Log

Repository

Rights and DAGs

Quality

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Manage Survey Participants

Public Survey Link **Participant List** Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List	Survey Title	Invitation Scheduled?	Invitation Sent?	Link	Survey Queue
[No email listed]	"Health Care Use Survey--Section 1" - Visit3 6 Months	-			

Buttons: Add participant, **Compose Survey Invitations**

- Make sure that the Survey Title in the upper left hand corner says "Health Care Use Survey—Section 1" and make sure to pick the email address of the correct Study ID# you want to send the link to and Customize your survey invitation (see example below) then 'Send Invitation':

- If the Parent does not complete the survey before the Visit 4 appointment, give them a hard copy to complete then after the visit enter the data from the form into REDCap. In the Record Home Page of the Participant, under Visit4_9 months, click on the green bubble corresponding to the Health Care Use Survey—Section 1:
- Complete the Health Care Use Survey—Section 1

Visit 4 (9 month) Study Procedures

Approximately 2 weeks prior to the Family's Study Visit 4, send the Parent a link to the Health Care Survey—Section 1 through REDCap (see pg 21)

When the Family first arrives at their appointment, make sure to give the Parent a hard copy of the Health Care Use Survey-Section 2; have them complete it during the Study Visit and remind them to give it back to you at the end of the study visit (REMEMBER TO COLLECT THIS SURVEY)

If the Parent did not complete the Health Care Use Survey-Section 1 prior to the Visit 2, then also give them a hard copy to complete at the study visit then you can enter the data into REDCap after the visit.

REMEMBER TO COLLECT THE HEALTH CARE USE SURVEY(S)

For Visit 4 at 9 months (like Visit 2 at 3 months), the only data you will be entering into REDCap are the A1c, the device download summary data, and the Health Care Use Survey data. The A1c and the device download summary forms are located in the REDCap TC RCT--ADOLESCENT Project and the Health Care Use Survey form is located in the REDCap TC RCT—PARENT Project

- **In order to access the A1c Lab Results and the Diabetes Device Download Summary for Visit 4 (9 month), in the TC Adolescent Project, under Visit4_9 Months, click on the green bubble for each of the measures (this will open up the forms):**

Study ID # TC101
Delaware

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>				
Visit Information	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input type="radio"/>
A1c Lab Results	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diabetes Device Download Summary	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Collaborative Parent Involvement Scale_A (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
FCCA_Adolescent (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
PAID-Problem Areas In Diabetes Paid-Adolescent (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
QOLD-C (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
QOLD-A (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
DSMP - Flexible_A (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
Diabetes Choices Questionnaire DCQ_A (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>
READDY_A (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input checked="" type="radio"/>

- In order to access the Health Care Use Survey for Visit 4 (9 months), in the TC Parent Project, under Visit4_9 Months, click green bubble for that measure (this will open up the form):



Study ID # TC104
Delaware Group

Data Collection Instrument	Visit1_Baseline	Visit2_3 Months	Visit3_6 Months	Visit4_9 Months	Visit5_12 Months
Participant Summary Form	<input checked="" type="radio"/>				
Visit Information	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health Care Use Survey--Section 2	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic Information Form (survey)	<input checked="" type="radio"/>				
Health Care Use Survey--Section 1 (survey)	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
FCCA_Parent (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input type="radio"/>
PAID-Problem Areas In Diabetes-Parent (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input type="radio"/>
QOLD-PA (survey)	<input type="radio"/>		<input checked="" type="radio"/>		<input type="radio"/>
QOLD-PC (survey)	<input checked="" type="radio"/>		<input type="radio"/>		<input type="radio"/>
DSMP - Flexible_P (survey)	<input checked="" type="radio"/>		<input checked="" type="radio"/>		<input type="radio"/>
DSMP - Conventional_P (survey)	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>
PSQ: Physician Satisfaction Questionnaire					<input type="radio"/>
TC104: Team Diabetes Medical Questionnaire (DCM)					<input type="radio"/>

Visit 4 (9-month) Study Procedures

At Visit 4 (like Visit 2), the only surveys that the Family will complete are the Health Care Use Surveys (Section 1 and Section 2 Surveys).

Approximately 2 weeks before the Family's Visit 4 appointment, email the Parent the link to complete the Health Care Use Survey—**Section 1** through REDCap:

- In REDCap, click on 'Manage Survey Participants', then make sure you're in the 'Participant List' tab; in the drop down following 'Participant List

- If the Parent does not complete the survey before the Visit 4 appointment, give them a hard copy to complete then after the visit enter the data from the form into REDCap. In the Record Home Page of the Participant, under Visit3_6 months, click on the plus sign next to the green bubble corresponding to the Health Care Use Survey—Section 1:
- Complete the Health Care Use Survey—Section 1: Make sure to enter the Visit # and Date:

Visit 4 (9 month) Study Procedures

Approximately 2 weeks prior to the Family's Study Visit 4, send the Parent a link to the Health Care Survey—Section 1 through REDCap (see pg 21)

When the Family first arrives at their appointment, make sure to give the Parent a hard copy of the Health Care Use Survey-Section 2; have them complete it during the Study Visit and remind them to give it back to you at the end of the study visit (REMEMBER TO COLLECT THIS SURVEY)

If the Parent did not complete the Health Care Use Survey-Section 1 prior to the Visit 2, then also give them a hard copy to complete at the study visit then you can enter the data into REDCap after the visit.

REMEMBER TO COLLECT THE HEALTH CARE USE SURVEY(S)

For Visit 4 at 9 months (like Visit 2 at 3 months), the only data you will be entering into REDCap are the A1c, the device download summary data, and the Health Care Use Survey data. The A1c and the device download summary forms are located in the REDCap TC RCT--ADOLESCENT Project and the Health Care Use Survey form is located in the REDCap TC RCT—PARENT Project

- In order to access the A1c Lab Results and the Diabetes Device Download Summary for Visit 4 (9 month), in the TC Adolescent Project, under Visit3_6 Months, click on the plus sign to the right of the green bubble for each of the measures



(this will open up the forms); make sure to specify that this data is for Visit 4 (9 months) and the date of the data (disregard that you are accessing the Visit 4 surveys through the Visit3_6 months sureveys)

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--ADOLESCENT Version

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

-  Incomplete
-  Unverified
-  Complete
-  Many statuses (mixed)
-  Incomplete (no data saved)
-  Partial Survey Response
-  Completed Survey Response
-  Many statuses (all)

Choose action for record

Record ID # 1 successfully edited

Record ID # 1 (Study ID 101)

Data Collection Instrument	Visit1_Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form			
Visit Information			
<u>A1c Lab Results</u>			
<u>Diabetes Device Download Summary</u>			
Collaborative Parent Involvement Scale_A (survey)			
FCCA_Adolescent (survey)			
PAID-Problem Areas In Diabetes Paid-Adolescent (survey)			
QOLD-C (survey)			
QOLD-A (survey)			
Diabetes Self Management Profile - Flexible_A (survey)			

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

A1c Lab Results

Current instance: 2/2

Editing existing Record ID # 1 (Instance #2) (Study ID 101)

Event Name: Visit3_6 Months

Record ID #

Visit #: 4

Visit Date: 06-06-2018 Today

Enter the HbA1c lab results for each visit.

Enter the HbA1c lab result for this visit:

Enter the date of the HbA1c results:

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--ADOLESCENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Diabetes Device Download Summary

Current instance: 2/2

Editing existing Record ID # 1 (Instance #2) (Study ID 101)

Event Name: Visit3_6 Months

Record ID #

Visit #: 4

Visit Date: 06-06-2018 Today

Diabetes Device Download: Home Glucose Meter Questions

Does the patient use a Blood Glucose Meter at Home? Yes No

Diabetes Device Download: Insulin Pump Questions

Is the Patient on an Insulin Pump? Yes No

- In order to access the Health Care Use Survey for Visit 4 (9 months), in the TC Parent Project, under Visit3_6 Months, click on the plus sign to the right of the green bubble for that measure (this will open up the form); make sure to specify that this data is for Visit 4 (9 months) and the date of the data (disregard that you're accessing the V4 surveys through the Visit3_6 months surveys); finish entering data



Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes:
RCT--PARENT Version

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

- Incomplete (red circle)
- Unverified (yellow circle)
- Complete (green circle)
- Many statuses (mixed) (blue circle)
- Incomplete (no data) (grey circle)
- Partial Survey (orange circle)
- Completed Survey (green circle with checkmark)
- Many statuses (mixed) (red, yellow, green circles)

Choose action for record

Record ID # 13 successfully edited

Record ID # 13 (Study ID)

Data Collection Instrument	Visit1_Baseline	Visit3_6 Months	Visit5_12 Months
Participant Summary Form			
Visit Information			
<u>Health Care Use Survey</u>	+	+	
Demographic Information Form (survey)			
FCCA_Parent (survey)			
PAID-Problem Areas In Diabetes-Parent (survey)			
QOLD-PA (survey)			
QOLD-PC (survey)			
Diabetes Self Management Profile - Flexible_P (survey)			
Diabetes Self Management Profile - Conventional_P (survey)			

Transdisciplinary Versus Usual Care for Adolescents with Type 1 Diabetes: RCT--PARENT Version

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Health Care Use Survey

Current Instance: 2/2

Data Access Group: [No Assi

Editing existing Record ID # 13 (Instance #2)

Event Name: Visit3 6 Months

Record ID # 13

Visit #: 4

Date of Visit: 06-06-2018 Today M-D-Y

1. In the past 3 months, has your adolescent with type 1 diabetes required an Emergency Department Admission for a diabetes-related reason? Yes No

2. In the past 3 months, has your adolescent with type 1 diabetes required a Hospital Admission for a diabetes-related reason? Yes No

3. In the past 3 months, has your adolescent with type 1 diabetes required a visit to an Urgent Care or Primary Care Clinic for a diabetes-related reason? Yes No

4. Enter the time you spent for today's appointment on:
Travel time to appointment (minutes):

5. Enter the time you spent for today's appointment on:

Visit 5 Study Procedures

Summary of Visit 5 12 Months Procedures:

First make sure that families are still scheduled for their Study Visit 5 appointment:

- 1) Participants will complete their measures either online or hard copy (these can be found in the Transdisciplinary Care file in the shared drive, in the Measures-RCT folder):
 - Health Care Use Survey—**Section 1**—(P) Parent only
 - DSMP: Diabetes Self Management Profile—(P, A) both Parent and Adolescent
 - QOLD: Quality of Life with Diabetes Scale—(P, A) both Parent and Adolescent (2 versions for both P and A: Ages 8-11 and Ages 12-17)
 - FCCA: Family-Centered Care Assessment—(P, A) both Parent and Adolescent
 - PAID: Problem Areas In Diabetes—(P, A) both Parent and Adolescent
 - CPI: Collaborative Parent Involvement Scale—(A) Adolescent only
 - DCQ: Diabetes Choices Questionnaire—(A) Adolescent only
 - READDY: **Readiness for Emerging Adults with Diabetes Diagnosed in Youth**—(A) Adolescent only
 - Approximately 2 weeks prior to the family's scheduled Visit 5, the Research Coordinator will send the family (parent and child separately) an email through REDCap with the link for them to complete their Visit 5 measures online: When setting up the Invitation for the surveys, remember to always choose the first survey listed for that corresponding visit in the drop down menu for 'Participant List belonging to'; so for the Parent Invitation you will choose 'FCCA Parent – Visit 5_12 Months'; and for the Child Invitation you will choose 'Collaborative Parent Involvement Scale A'-Visit 5_12 Months from the drop down menu.
 - The Research Coordinator will check to see if the family has completed their measures about 5 days prior to the family's scheduled study visit and if they have not completed their measures, then the Research Coordinator will send out a follow up reminder email.
 - Prior to the study visit, the Research Coordinator will also check completed measures for missing item responses by opening each of them and making sure all items were completed. If there are missing item responses, the RC will print out the measure and have the family complete on the paper copy at their clinic visit. After completion, the RC will enter these responses in the appropriate measure in REDCap and 'Save & Exit Form'.
 - When the family comes to the clinic for their Visit 5, if they still have not completed their measures (or have some with missing items), then they will need to complete them at their clinic visit by hard copies of the measures. (The Research Coordinator will need to check if the measures were completed prior to their appointment). Or, these can be done online at their visit.
- 2) When the family arrives for their Visit 5 appointment, make sure to give the Parent a hard copy of the Health Care Use Survey—Section 2; **REMEMBER TO COLLECT IT BEFORE THE PARENT LEAVES**
- 3) In REDCap, the Research Coordinator will enter the remaining data for Visit 5:
 - **Parent version:**

- ****Visit Information form:**—
- This form **must always be completed at each visit:**
 - Click on the clear bubble under Visit 5_12 Months
 - Enter the date the visit was scheduled for (if no visit was scheduled, leave blank)
 - Click 'no this visit will be skipped' if the family did *not* complete Visit 5 or click 'yes' if was completed, then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Exit & Save Form'
- If the measures were completed in hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 5 that corresponds to each of the measures.
- Confirm that all valid bubbles under Visit 5 are in green:  or 
- Confirm that there are no missing item responses on the Visit 5 questionnaires.

Child version:

- ****Visit Information form:**—To be completed *after* the visit with the family:
 - Click on the clear bubble under Visit 5
 - Enter the date the visit was scheduled for (if no visit was scheduled, leave blank)
 - Question 2: click 'no this visit will be skipped' if the family did *not* complete Visit 5 or click 'yes' if was completed, then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'.
- **A1c Lab Results:** click on the clear bubble under visit 5
 - Enter the HbA1c lab results for Visit 5
 - Enter the date of the HbA1c lab results
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'
- **Diabetes Device Download Summary:** click on the clear bubble under Visit 5
 - Enter the Visit number (this form will be completed at 5 visits so make sure to enter the visit #) and the date of the download
 - Enter all the data from the device download corresponding to the Diabetes Device(s) the Adolescent uses, onto this form
Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save Save & Exit Form'

- If the measures were completed on hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 5 that corresponds to each of the measures.
 - Confirm that all bubbles under Visit 5 are in green:  or 
 - Confirm that there are no missing item responses on the Visit 5 questionnaires
- 4) **If the family does not complete Visit 5, the Research Coordinator will still need to enter data for the 'Visit Information' Form (data collection instrument in the Record Home Page): click 'no this visit will be skipped' if the family did *not* complete Visit 5.
- 5) ****Additional measures: For HCPs** (will be entered into the Parent REDCap version)
- ☐ The Research Coordinator will give Physicians or Nurse Practitioners with Primary clinical responsibility for study participants **the Physician Satisfaction Questionnaire (PSQ)** to complete in hard copy after the final study visit for each participant regardless of treatment group. The Research Coordinator then will copy the data into the PSQ in REDCap by clicking on the  clear bubble under Visit 5.
 - ☐ The Research Coordinator will give all physicians, nurses, dietitians, and psychologists who saw the study participant **the Team Decision-Making Questionnaire (TDMQ)** just after the final study visit for each enrolled adolescent, regardless of treatment group. The Research Coordinator then will copy the data into the TDMQ in REDCap by clicking on the  clear bubble under Visit 5

Child version:

- ☐ ****Visit Information form:** To be completed *after* the visit with the family:
 - Click on the clear bubble under Visit 5
 - Enter the date the visit was scheduled for (if no visit was scheduled, leave blank)
 - Question 2: click 'yes' if it was completed or 'no this visit will be skipped' if the family did *not* complete Visit 5, then Q #3 will appear: enter the date the visit occurred (sometimes visits are re-scheduled so we want both dates)
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'
- ☐ **A1c Lab Results:**
 - Click on the clear bubble under visit 5
 - Enter the HbA1c lab results and date for Visit 5
 - Then under Form Status (Complete?), in the drop down you will choose 'Complete' then 'Save & Exit Form'
- ☐ If the measures were completed in hard copies then the Research Coordinator will copy the data into the measures in REDCap by clicking on the bubble below Visit 5 that corresponds to each of the measures.
- ☐ Confirm that all valid bubbles under Visit 5 are in green:  or 
- ☐ Confirm that there are no missing item responses on the Visit 5 questionnaires.