A Crowdsourced Social Media Portal for Parents of Very Young Children With Type 1 Diabetes

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2. SPECIFIC AIMS In response to PA-DK-14-022, we propose to design and test an intervention to improve management of type 1 diabetes (T1D) in very young children (<6 years). Parents of very young children with T1D (YC-T1D) often experience distress and anxiety that can impede T1D care, threatening the child's current and future adaptation to T1D.Typical health care often does not equip parents to contend with these issues, but YC-T1D parents can offer support/guidance to each other to promote parental coping and thus child outcomes. The many obstacles to direct interaction among parents suggest that social media may be an efficacious way to facilitate timely, meaningful and needed social support such as parenting guidance, affective support, provision of information, and sharing of creative solutions to common T1D management problems in YC-T1D. Many good social media resources exist, but there is not a focused portal that facilitates parents' access to these resources, nor have potential benefits been validated empirically. We will apply crowdsourcing methods to achieve the iterative development and initial evaluation of an online resource designed by and for YC-T1D parents with continuous input from health professionals and technical expertise in crowdsourcing and application development provided by our web development agency partners (*e-city interactive*, Philadelphia) and Nemours web development team.

Crowdsourcing is a flexible online activity that has been applied to diverse problems in many fields, including public health, with four elements: 1.) An organization that has a task it needs to be performed, (development of an online resource that meets the needs of parents of YC-T1D); 2.) A community, "the crowd", that agrees to perform the necessary tasks voluntarily (here parents of YC-T1D, T1D clinicians, and professional application developers); 3.) An online environment that allows the work to take place by enabling collaboration between the crowd and the organization, (the infrastructure proposed in this grant); and 4.) Mutual benefit for the organization and members of the crowd (better glycemic control, improved quality of life and decreased burden of care for YC-T1D and their families).

To our knowledge, crowdsourcing has not been applied to the design and development of online health behavior resources such as that proposed in this application. We will design the portal with our stakeholders based on principles of User-Centered Design and then collect preliminary data needed to justify and then conduct a rigorous controlled trial of the effectiveness of an online resource that will provide parents of YC-T1D (<6 years old) with timely, responsible, safe and effective support and guidance regarding parental management of common behavioral, affective and cognitive barriers to effective T1D care in this age group. The proposed work will address these specific aims:

Aim 1: We will use crowdsourcing methods to 1.) Identify the most important concerns about management of YC-T1D from key stakeholders (parents, pediatric endocrinologists, diabetes nurses, dietitians, psychologists and social workers) to specify content areas that the online resource should address; 2.) Collaborate with parents (with available input from T1D professionals) to design the optimal content, structure, functions and governance of a social media resource for parents of YC-T1D to improve daily T1D care and problem solving, to enhance parental coping with sources of distress and care burden that uniquely affect this clinical population and to facilitate parents' access to and use of other beneficial resources of the diabetes online community.

Aim 2: We will iteratively incorporate the knowledge, experience and perspectives gained in Aim 1 to systematically build and refine an online resource enabling parents of very young children with T1D to obtain real-time emotional support, information and parenting guidance, enabling them to cope more effectively with the daily demands of diabetes management in this population. We will rely on the web development agency partners, Nemours web development team, and ongoing stakeholder input.

Aim 3: We will conduct a randomized controlled trial of a final version of the online resource with parents of 150 children <6 years old who receive T1D care at any Nemours operating entity in the Delaware Valley and Florida or via online recruiting of eligible parents living elsewhere in the United States, using a variety of internet resources. We will explore treatment effects on metabolic, behavioral and affective outcomes of T1D care, patterns of portal utilization by parents and users' feedback on website use during and after the trial.

Having designed, built, tested, validated and refined the proposed online resource, we will be well-positioned to plan and complete a rigorous randomized controlled trial to evaluate effects of portal use/access on metabolic, behavioral, affective and social outcomes of T1D care for YC-T1D. While completing Aim 3, we will solidify partnerships with several key organizations (PEDSnet, T1D Exchange, JDRF, American Diabetes Association) to enable economical completion of a major multisite trial. The design of the proposed preliminary RCT will

position us to propose a completely electronic multisite RCT that does not require face to face contact between parents and the research team and can be completed totally in cyberspace.

3. BACKGROUND AND SIGNIFICANCE

3.1. Type 1 Diabetes in Very Young Children: The incidence of Type 1 Diabetes (T1D) is increasing faster among very young (< 6 yrs old) children (YC-T1D) than other age groups.[1-6] The public health impact of this trend is huge since these patients will have T1D longer, enduring more exposure to risks of long term complications and "metabolic memory" impeding future glycemic control.[7-15] T1D care in YC-T1D is truly challenging. [7-10] Both hypo- and hyper-glycemic exposure have been implicated in the etiology of cognitive sequelae. [16-29] Insulin sensitivity is high, [11,14-15, 30] nocturnal hypoglycemia is common, [31-35] and self-regulation of eating, sleep, and physical activity of very young children is labile. [11-15, 30, 36-44] These challenges pose major impediments to effecting consistent T1D care. Impressive technological advances have been made with insulin pumps[45-53] and continuous glucose monitors, [54-61] and the long-awaited closed-loop artificial pancreas is emerging. [62-69] But, controlled trials of these technologies in YC-T1D have yielded equivocal results [51, 59] and use of these technologies may increase the burden of YC-T1D care rather than reducing it.[70-71]

3.2. Psychological Impact of T1D Care for YC-T1D: T1D care poses major psychological challenges for YC-T1D and parents [72-90] and how they respond predicts later T1D outcomes.[91-92] YC-T1D and their parents must cope with challenges such as pain/anxiety from insulin injections or insertion of insulin pump infusion sets, blood glucose monitoring, regulation of food intake, balancing insulin with carbohydrate intake, physical activity and prevailing glycemia, remediation of hypoglycemia and hyperglycemia, sick day management, getting sufficient sleep and managing T1D care away from home.[93-99] YC-T1D and their parents face these demands while also striving to negotiate the many developmental challenges that all children encounter.

The burden of T1D care for YC-T1D also takes a psychological toll on parents. Parents face immense challenges in managing their responsibility for the T1D regimen. Parents face many psychological threats, including risks of depression, anxiety, sleep loss, and reduced self efficacy.[72-90] Many parents may also face challenges in balancing relationships with partners, relatives and friends and dedicating sufficient energy to their other children. Some parents and YC-T1D may be predisposed to succumb to these threats. For YC-T1D, these risk factors might include the child's premorbid developmental status, temperament, emotion regulation, attention, pain tolerance, and regularity of eating, sleep and activity.[100-105] Risk factors for poor T1D coping among parents include family structure (e.g., single parents), socioeconomic status, parenting skills and style, communication and problem solving, health literacy and numeracy, social support, and threats such as food or residential insecurity, safety concerns, family conflict and substance abuse that can outweigh T1D as priorities.[100-104] The psychological well-being of parents impacts T1D outcomes in YC-T1D families. [105-109] Many YC-T1D families may find that typical T1D care does not meet their needs in responding to the unique behavioral, emotional and situational challenges of raising a YC-T1D child. [72-109]

3.3. Dearth of Evidence-Based Interventions for YC-T1D: Many studies affirm the efficacy of individual and family-focused, behavioral interventions targeting T1D care in older youths. [110-113] There have been only a few modest intervention trials with YC-T1D[114-122] and few pediatric T1D centers routinely offer such services to YC-T1D families. There are many reasons for this imbalance: Few pediatric T1D centers have enough YC-T1D patients to populate a large clinical trial; The developmental and behavioral characteristics of YC-T1D children are diverse; a "one size fits all" intervention would be poorly conceived and hard to implement; Professionals may feel that YC-T1D children are simply hard to manage and "will grow out of it"; and levels of glycemic control are accepted that would be deemed suboptimal in older youths. Studies support the efficacy of many behavioral interventions in non-diabetic preschoolers, (e.g., noncompliance, mealtime problems, sleep problems, tolerance of medical procedures, and social-emotional competence). [123-124] Research also supports the merits of parent training to improve parenting knowledge and skills, children's behavioral adjustment, and parents' well-being and parenting self-efficacy.[123-124] Many of these interventions can be delivered efficaciously via electronic platforms,[124] but this evidence base has largely not affected YC-T1D research or clinical care.

3.4. Parent-to-Parent Social Support as an Appealing Intervention Focus: Social support is the provision of tangible, informative, emotional or affiliative support to a person by others.[125-129] A huge empirical literature reveals the robust effects of social support on susceptibility to disease, disease course, adherence, and health outcomes. The focus in the proposed work is on the potential benefits for the child patient of increasing the

quality, quantity and timeliness of needed social support to the child's parent(s) rather than focusing on the direct effects of social support on the patient's health. Compared with substantial empirical research on health benefits of social support directed to patients themselves, there is much less research on potential benefits of social support to parents for their children with chronic conditions such as T1D. Based on the broader social support and health literature, a good match between the nature, timing, and quality of support and the recipient's perceived needs is critical to benefit. Mobilizing timely, relevant, and credible social support from other YC-T1D parents, if achieved broadly, could facilitate family coping with T1D and yield major public health benefits.[130-133] ***The central tenet of this application is that social media has the potential to achieve this objective if it can be harnessed and designed carefully to achieve these ends.***

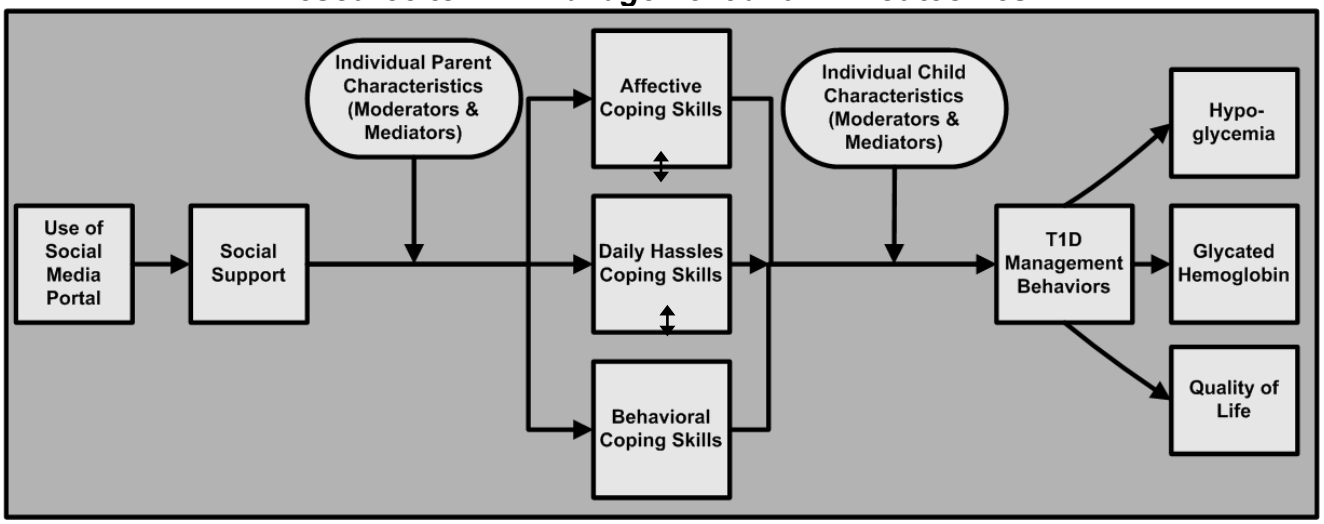
Social support influences coping with T1D in YC-T1D, and a few clinical trials of parent-to-parent support interventions show promise, [134-141], but more rigorous studies are needed.. Multi-family T1D support groups are commonplace, but there are barriers to this approach with YC-T1D families. Most centers have relatively few YC-T1D families, these families tend to have other young children, transporting young children to evening events is challenging and the developmental characteristics and needs of very young children change rapidly. These issues impeded benefit from multifamily support groups. A social support mechanism designed by and for YC-T1D parents that offers parent-to-parent support around shared challenges, is continuously accessible, and provides credible guidance to YC-T1D parents about their shared concerns could be a very effective resource. Once designed, tested and refined, such a resource could be disseminated globally at low cost. As a low intensity intervention with broad reach, targeting families with mild or emerging T1D adjustment problems, this resource could have strong preventive effects, facilitate a developmental trajectory of positive T1D coping, and enhance parents' coping and self efficacy. A modest favorable shift in the distribution of YC-T1D outcomes for many parents and children could reap huge public health benefits.

3.5. Diabetes Online Community (DOC): A vibrant diabetes online community (websites, blogs, list-serves, and groups on Facebook, Twitter, etc.) helps many people cope with T1D. We list these resources in the Appendix, but new resources will emerge and others will disappear. Many DOC sites focus on the needs of adults who are >90% of diabetes patients. There is no evidence validating benefits of any specific DOC resource and there are no well-controlled trials. One small pre-post study (n = 9) found that a web-based social support intervention increased self efficacy of parents of children with T1D.[142] Another study showed that parents who are active in the DOC perceive enhanced social support and diabetes knowledge and place significant trust in online content and relationships.[143] Few DOC resources target the YC-T1D population and, even among those with a pediatric T1D focus, content specific to YC-T1D is limited. Few YC-T1D health care providers can stay well-informed about the DOC, thus impeding their endorsements of specific sites. Most DOC resources must self-police to ensure that they are scientifically credible, and there is varying success. Serious engagement with DOC sites tends to be limited to a minority of users; many/most are passive users. The few web resources that focus on YC-T1D parenting are maintained by individuals, lack a solid funding source, and thus have limited capabilities. None provides empirically-validated and parent-endorsed parenting approaches to common YC-T1D behavior problems or offers systematic parent-to-parent support to enhance emotional coping. A deliberate, user-centered approach to the design of an accessible, focused online resource for YC-T1D parents could improve T1D outcomes in the YC-T1D population.

3.6. Conceptual Model of Social Media Effects on Diabetes Outcomes: Figure 1 (above) depicts our conceptual model, which shows how a carefully designed online resource may enhance timely, pertinent and helpful social support received by YC-T1D parents. Moderated and mediated by individual psychological characteristics of parents (i.e., demographic variables, social supports, psychiatric symptoms, parenting self-efficacy), use of our proposed parent-designed online resource may enhance parents' appraisal of, and coping with, T1D-related distress, and help them to cultivate more effective T1D-specific child behavior management and problem solving skills. Increasing the quality, quantity, timeliness and relevance of social support could yield better psychological status among parent-users, such as decreased distress, anxiety and depressive symptoms, less fear of hypoglycemia and improvements in quality of life, parenting self efficacy, and decreased T1D-related problem behaviors of their children. Thus, parents who use the online resource may be better equipped to address behavioral and affective barriers to effective T1D care, yielding more effective T1D care and problem solving. Their children, again dependent on individual characteristics (i.e., temperament, emotional regulation, impulse control, pain tolerance, and regularity of eating, sleep and physical activity) may

become more cooperative with T1D care and thus enjoy more favorable T1D outcomes (HbA1C, frequency of hypoglycemia and quality of life). These hypothesized mechanisms have driven our specification of the specific aims, research strategy, measurement plan and analytic plan.

Figure 1. Conceptual model linking social support benefits of use of the proposed online resource to T1D management and T1D outcomes.



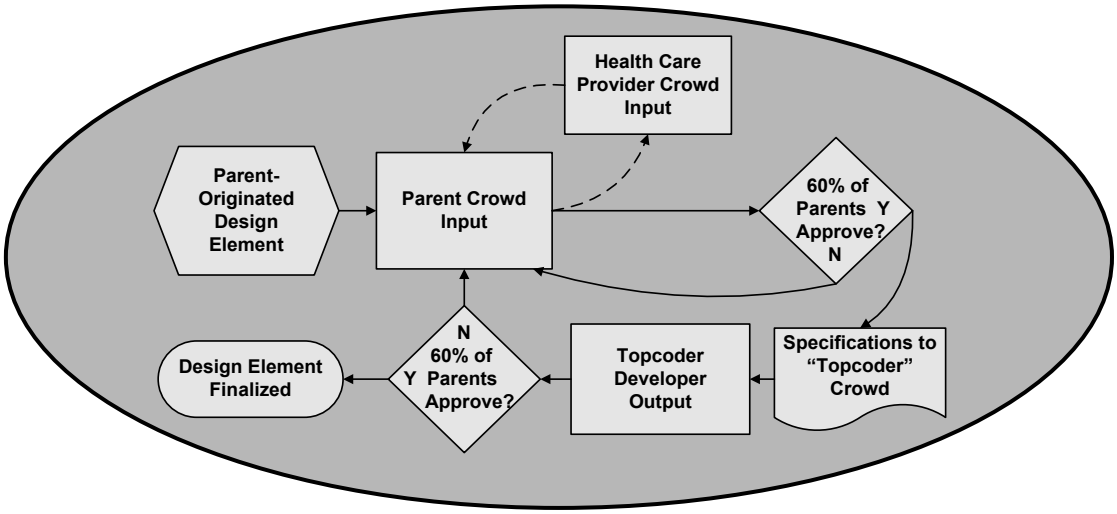
The parent-initiated, user-centered design approach [134-136] and the use of crowdsourcing [137-141] to drive the design should yield an online resource that is highly engaging, pertinent and potentially helpful. We recognize that not all parents will fully utilize or benefit from this resource. Thus, the research strategy includes plans to optimize the portal design via established principles of user engagement, to explore characteristics that differentiate users and non-users, and to identify mediators of frequent portal use and/or effects on the outcomes. Qualitative interviews of study participants at the midpoint and end of the randomized controlled trial will guide portal refinements, yielding an exceptional resource that could be tested in a much larger multi-site clinical trial. The future multi-site trial could be completed economically since the infrastructure for the consent process and the online delivery, use and evaluation of the intervention would already be in place.

3.7. Crowdsourcing[134] is a flexible online activity that has been applied to problems in diverse fields, including public health, comprising four elements: 1.) An organization that has a task it needs to be performed, (e.g., design an online resource meeting YC-T1D parents' specifications); 2.) A community (crowd), that contributes to achieving the specifications (here, three "crowds: parents of YC-T1D, T1D HCPs, and application developers); 3.) An online environment that facilitates collaboration between the crowd and the organization, (the proposed infrastructure); and 4.) Mutual benefit for the organization and the crowd (better T1D outcomes, less distress and better quality of life). Crowdsourced data has been effectively and successfully collected in health, medical, and behavioral research.[144-147] We will engage three distinct "crowds" who bring differing kinds of expertise to the design and development of an online resource:

- A large and diverse group of YC-T1D parents who will be the primary drivers of the design process;
- T1D HCPs from pediatric endocrinology, nursing, nutrition, social work and psychology; and
- The web development agency partners who will translate the design specifications generated by the first two crowds into a functional website meeting those specifications.

In Figure 2, below, we have summarized the design process graphically for a single design element. This process will be repeated iteratively for each design element until a functional final website has been created. Ideas for elements of the online resource (content, structure, functions. Governance, etc.) will originate with the Parent Crowd. With advisory input from an HCP Crowd, the Parent Crowd will iteratively develop specifications for portal elements that will be disseminated by our web developer partners.

Figure 2. Diagram of the process for design and development of the online resource based on iterative stakeholder input. Parents will originate all design concepts, to be refined and finalized via input from health care providers and application development experts.



The research team will apply several fundamental principles to the design and operation of the online resource:

- Create a YC-T1D coping resource developed by parents for parents, with assistance when requested from health professionals and application developers.
- Apply knowledge about how best to design web applications that are engaging, helpful, and easily navigated and that promote and sustain repeated use.
- Focus on providing parents with feasible, effective ways to prevent or reduce children's behavioral barriers to optimal care and diverse ways of coping emotionally with YC-T1D parenting..
- Integrate an evaluation component to enable users, prospective referring HCPs and potential sponsors to know that the resource is scientifically validated to enhance T1D outcomes in YC-T1D.
- Capitalize on users' established social media habits and preferences and provide useful guidance in selecting and using those resources optimally.
- Offer content that is medically, scientifically and psychologically sound and policed by parents, with professional consultation available on an advisory basis.
- Develop a searchable compilation of approaches to common behavioral/emotional barriers to optimal T1D care that offer varied options and that have been rated for feasibility/efficacy by other parents.
- Facilitate access by people with low health literacy/numeracy or low internet literacy
- Develop the portal for access via multiple operating systems and mobile devices.
- Anticipate the emergence and disappearance of other social media resources

3.8. Investigators: The team has expertise in all domains needed to fulfill the specific aims: extensive behavioral research in T1D (Wysocki), experience living with and researching T1D (Pierce), qualitative research (Aroian), endocrinology and social media (Lee), statistics (Hossain), crowdsourcing, application development (e-city interactive; Nemours Web Developers) and stakeholder engagement (6 Family Advisors).

3.9. Preliminary Studies: These prior studies, most of which focus on or involve YC-T1D families, have prepared us well for the proposed work:
Wysocki, T., et al., *Diabetes Care, 1989, 12*:524-529. Cross sectional evaluation of general and T1D-specific adjustment of preschoolers with T1D and their mothers. Results indicated elevated levels of child internalizing behavior disorders and parenting stress. The study validated the Preschool Diabetes Behavior Checklist.
Wysocki, T., et al *Diabetes Care, 1992, 15* (1): 43-52; Wysocki, et al., *The Diabetes Educator, 1996, 22*, (6): 587-591. Internet surveys of health professionals and parents, validating the Diabetes Independence Survey, yielding age-defined norms for mastery of 38 T1D self management skills.
Wysocki, T. & Gavin, L. *Journal of Pediatric Psychology, 2006, 31*, (5), 501-511. Cross sectional study showing that more paternal involvement in care predicted better adherence and maternal quality of life.

Antal H., et al. ***Journal of Pediatric Psychology, 2011, 36*****, (3), 318-328***. Direct observation study of very young children's and parents' behavior during at-home insulin injections.
Lochrie, A., et al ***Pediatric Diabetes, 2009, 10*** **(1), 59-66**; **Buckloh, L.M., et al.,** ***Diabetes Care, 2008, 31*****, 1516-1520; Wysocki, et al.,** ***Diabetes Care, 2011, 34,*** **(8), 1701-1705*****; and Buckloh, et al.,** ***Children's Health Care, in press***. Four studies of youth and parent knowledge of T1D complications, how they acquired it and how they cope with it from the perspectives of youth, parents and diabetes clinicians.
Wysocki, T. (PCORI grant) ***"Shared medical decision making in pediatric diabetes***": Design and testing of web platforms for facilitating shared decision making among youth with T1D, parents, and clinicians.

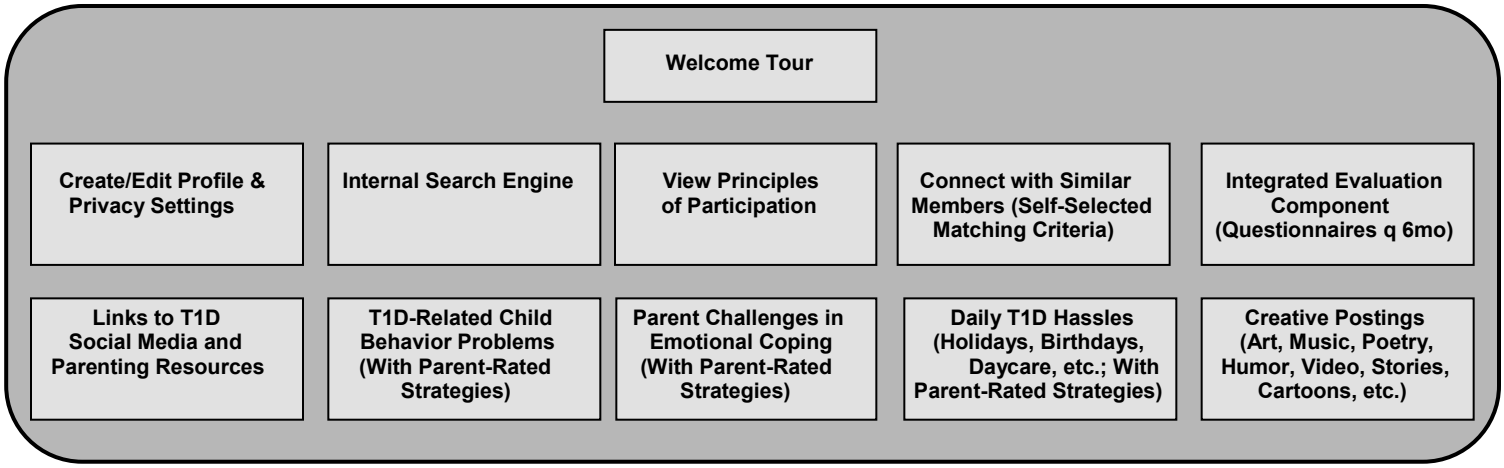
3.10. Innovation: This application is innovative in many ways:

- Use of crowdsourcing to build an online resource by and for YC-T1D parents
- Reliance on our web development partners for state of the art application development
- Use of Nemours Virtual Advisory Council platform for communication with the Parent and HCP Crowds
- Capacity to meet parents' specific social support needs in real time
- Searchable compilation of coping strategies with ratings by parents who use them
- Parent-driven governance of the web portal
- Links to other reputable DOC resources
- Possible adaptation and validation of certain T1D-specific questionnaires for the YC-T1D population
- Electronic informed consent to facilitate participation of parents
- Preparation for a large, multisite trial that could be conducted totally in cyberspace

4. APPROACH We propose the parent-driven design of an online resource (Website) followed by a preliminary clinical trial of this intervention's efficacy and estimated effect sizes. We will develop the website for parents of YC-T1D with stakeholder input including parents as decision makers and HCPs and application developers in advisory and technical support roles. A website Design & Development Phase (YR1-2) will be followed by a Randomized Controlled Trial (RCT) comparing Website versus Usual Care (YR3-4). For the website Design & Development Phase, parents and HCPs will be recruited through personal contact, organization websites, social media sites, and blogs. For the RCT, participants will be recruited through five Nemours T1D centers in Florida and the Delaware Valley. This will position us to pursue a future large, multi-site randomized controlled trial that could be completed entirely online. Applying principles of User-Centered Design in creating the portal yields unknowns about the platform's eventual content, structure, functions, and governance. The Parent Crowd, with advisory input from the HCP Crowd, and technical assistance from the web development agency and the Nemours Web Development Team, will make many design decisions like those below. The exact outcomes of those decisions are unknown, but the process of reaching the decisions will systematically reflect the input of numerous stakeholder experts.

4.1. Website Design and Development Seeking a balance between detailed plans for the proposed Website and insistence that it be designed by parents for parents, we have put forth in Figure 3 tentative platform elements for initial consideration by the Parent Crowd. These examples will be used to begin that conversation:

Figure 3. Tentative elements of an online resource designed by and for YC-T1D parents.



In addition to considering these tentative portal features, the Parent Crowd will receive advisory input from T1D HCPs and technical assistance from the web development agency and Nemours Web Developers in making many design decisions. Examples include determining the portal's ***Structure*** (e.g,, Platform appearance, name, layout, etc.; Individual or joint registration of mothers and fathers; Device compatibility); ***Content*** (e.g., Common T1D behavioral and emotional coping problems; degree of medical content; A "For Fathers Only section"), ***Function*** (e.g., Integrated evaluation system; How to interface with other social media resources; Content sharing with child's HCPs; Methods of engaging low frequency users), and ***Governance*** (e.g,, By-laws, decision making and operating principles; Monitoring of medical accuracy; Degree and nature of advocacy efforts). ***Compared with face-to-face multifamily support groups, the planned online resource could be far more robust in improving T1D management and outcomes in YC-T1D and their parents since it would be available constantly, it would draw upon the collective wisdom of a large parent community, its interactions could be archived, searchable and rated for feasibility and efficacy by parent-users and it would be focused solely on the unique needs of the YC-T1D population.***

Time Frame: We conservatively estimate that it will require up to 2 years to constitute the Parent and HCP Crowds, to design, develop and build the online resource and to integrate it into a Nemours website so that it is ready to test in a preliminary randomized controlled trial during Years 3 and 4.

Family Advisors: 6 parents of YC-T1D children have agreed to serve as Family Advisors. Three participated in preparing this application and three joined after demonstrating their enthusiasm as members of the Parent Crowd. Each Family Advisor will be paid $2,500 annually in quarterly installments as compensation for their service as Family Advisors. Four Family Advisors, who are not parents of Nemours patients, were recruited with the assistance of Jeff Hitchcock, founder of childrenwithdiabetes.com. The others are parents of Nemours patients and were recruited via nominations from NemoursT1D care providers.

The primary role of Family Advisors in developing this proposal was participation in the initial planning of the online resource through meetings via conference call. They also reviewed and commented on the grant application and study protocol providing a family perspective on how the portal is to be planned, developed, and pilot-tested. If the project is funded, we plan to invite interested parents to continue on as Family Advisors to function as members of the research team in helping us to engage many other parents and diabetes clinicians nationally in serving as a member of our Parent Crowd, leading the decision making based on crowd feedback, helping us to interpret and integrate stakeholder suggestions into the planned platform, and helping us to refine the web portal. Since many available questionnaires for T1D research were validated for studies of T1D management in school aged children and adolescents, the Family Advisors will also assist us with reviewing and possibly adapting certain of the T1D-specific questionnaires to be more pertinent to the YC-T1D population. This will enable validation of adapted measures in the preliminary randomized trial to follow, bolstering the merits of the measurement plans for a future, multisite randomized controlled trial.

Use of Nemours Virtual Advisory Council platform: Since 2011, Nemours has operated a Virtual Advisory Council (VAC) using crowdsourcing technology to engage parents of Nemours patients in decision making about varied clinic and hospital operations. Parents are nominated for membership in the VAC by Nemours clinicians and then registered to receive e-mailed inquiries with embedded links to a website operated on a www.yammer.com platform. For the proposed design and development work, we have already created a new Private Network for the Parent Crowd entitled "T1D_Toddlers" that will provide the functionality to distribute either open-ended or forced choice questions, share documents, track group members' activities on the site and compile statistical summaries of query results. A separate Private Network will be created for the HCP Crowd. This will enable efficient use of an existing infrastructure for this key element of our Phase I work and will be the mechanism through which the Parent and HCP Crowds communicate their preferences and recommendations to the research team. This utility permits a wide variety of crowd queries such as forced choice, rank-order, and other multiple choice formats as well as free text narrative responses.

Demographic Information Form (DIF): This form used in our prior studies records the child's age, date of diagnosis, sex, race, ethnicity, country of origin, language spoken at home, current T1D regimen, parental age and gender, family composition, parents' marital status, household income, and parents' occupational and educational status. We will calculate the Hollingshead Four Factor Index of Social Status, an index of socioeconomic status. Parents will describe their use of T1D internet and social media sites.

Participant Eligibility: Prior to initiating recruitment, the Portal Design and Development Phase activities will be reviewed and approved by a Nemours IRB. We will seek IRB approval to enable us to obtain informed consent electronically. This is approvable since this aspect of the planned work entails negligible risk, all of the participants are adults and there will be only existing health data obtained from or about children with T1D. Participants will be required to sign the electronic consent form and complete the DIF before proceeding.

Eligibility criteria for the Parent Crowd are: Parent, step-parent or other legal caregiver of a child diagnosed with T1D before the age of 6 years as affirmed by a HCP involved in the child's care: Child with T1D is less than 10 years old at enrollment (parents of slightly older children may offer valuable perspectives without being too far removed from their experiences); and Ability to communicate in English via the internet; and for the HCP Crowd are : Physician, Nurse, Dietitian, Social Worker, Physician Assistant, Psychologist, Exercise Physiologist or other credentialed clinician who contributes regularly to the clinical care and/or education of YC-T1D patients and parents. A maximum of 10 from any one profession will be recruited.

Recruitment of Parent Crowd: A national sample of >200 parents of YC-T1D (as many as can be recruited) will be recruited via the: 1) T1D Exchange registry; 2) www.PEDSnet.org; 3) www.childrenwithdiabetes.com and its annual Friends for Life Conference; 4) American Diabetes Association; 5) Juvenile Diabetes Research Foundation; 6) Recruitment announcements sent to other DOC sites. Letters of support affirming our capacity to recruit parents nationally accompany this application. We will recruit a very diverse sample of parents *vis a vis* race/ethnicity (16% African American; 10% Hispanic; 12% Asian), educational attainment (20% high school or less, 60% some college or bachelor's degree, 20% advanced degree) occupational level (at least 5% in each of 9 Hollingshead occupational categories) and current use of T1D-related social media (at least 10% each: never, annual, monthly and weekly use). We propose a separate strategy for increasing the diversity of our parent crowd by conducting a focus group, the procedures of which are described below. We are optimistic about recruiting many fathers for the Parent Crowd since all participation is online and at the convenience of the participant.

Recruitment of Health Care Professional (HCP) Crowd: We will recruit ≥ 50 T1D care HCPs (pediatric endocrinologists, diabetes educators/nurses, dietitians, social workers, psychologists, and other credentialed clinicians who agree to be HCP Crowd members. Drs. Wysocki and Lee have numerous professional contacts across North America who could perform this role. We will include no more than 10 from any one profession.

Parent Input: Before engaging our partners' expertise around application design and development, we will first engage our Parent and HCP Crowds using Nemours VAC platform to develop specifications for portal content, structure and function that our web development partners will use in proposing design solutions.. Parent Crowd members will be sent Figure 3 above, with a brief summary of the website goals. Queries to the Parent Crowd are likely to evolve during the project from the general to the specific, from open-ended to forced-choice, and from qualitative to quantitative as the website design process proceeds. Parents will first respond to open-ended questions about the most important concerns about management of YC-T1D, and will then respond to open-ended questions about the optimal structure and functions of the website. Members of the Parent Crowd will each be sent a CT Payer Card; funds will be credited to a parent's card each time that parent responds to a question disseminated by the research team. The amount paid will range from $1 to $5 per question answered, adjusted by estimated time requirement ($1: < 1 min.; $2: 1-<3; $3: 3-<5; $4: 5-<10; $5: ≥ 10) and the available payment will be displayed along with the question to be addressed.

Initial open-ended questions about WEBSITE content:

1. What are the hardest parts of being the parent of a very young child with T1D?
2. What, if any, are the behavioral problems seen in your child with T1D?
3. How do these behavioral problems get in the way of your child's T1D care?
4. What are some daily hassles related to taking care of a very young child with T1D?
5. How does being a parent of a young child with T1D affect your relationships with others?
6. How does being a parent of a young child with T1D affect your feelings and emotions?
7. What do you do now to cope with all of these challenges?
8. What kinds of help would you like the website to give parents like you?

Initial open-ended questions about structure and function, of the website:

9. What would be the ideal layout, design, and structure of the website?
10. What other social media websites would you like to see it modeled after?
11. If you use existing diabetes social media websites, what are things you like about what they do? Dislike?
12. What would you like to see change in how your child copes with T1D care as a result of using the website?
13. How would you like to change as a result of using the website?

Dr. Aroian will train and supervise content analysts in qualitative analysis of responses to identify content themes and subthemes the website should address. Several of Dr. Wysocki's research staff are very experienced in qualitative content analysis. Parent queries will remain open until thematic saturation is achieved (i.e., no new concerns emerge). Trained content analysts will use a descriptive level of analysis, using well-accepted content analysis methods via HyperRESEARCH software to extract the primary themes that emerge from the interviews. Analysts will be trained to a criterion of 90% inter-rater reliability. Themes will be incorporated into content areas based on consensus of the researchers and Family Advisors.

Following these initial open-ended queries, participants will be asked to prioritize the content themes and functional and structural elements emanating from parents' responses to the initial queries by rank ordering (from most to least essential). With web developer guidance, the Parent Crowd will then review initial design specifications broadly outlining the proposed content, structure and functions that would then be designed in detail through multiple design iterations, with each design solution subsequently evaluated by the Parent and HCP crowds.

Recruitment of focus group to increase diversity among Parent Crowd Participants: In order for our website to be accessible and useful to the entire population, we should strive to achieve exceptional diversity in our enrolled samples in terms of household income, education, health literacy/numeracy and internet and social media fluency. We propose an additional recruitment strategy to obtain input in the design and development of our online resource from parents who are racial and ethnic minorities and/or who are economically disadvantaged (i.e., child is on Medicaid or uninsured). We will recruit up to 20 parents meeting these criteria to participate in a focus group.

First, with the assistance of Nemours informatics, we will conduct an EMR query to obtain the first and last name, mailing address, phone number, and email address (if available) of mothers and fathers of Nemours Orlando, Jacksonville, and Wilmington patients who meet *all* of the following criteria:

- Type 1 diabetes diagnosis
- Age as of date of query is 9 years or younger
- Age at date of type 1 diabetes diagnosis was 5 or younger

And who meet at least one of these criteria:

- Race: Non-White (any race but White)
- Ethnicity: Hispanic
- Insurance: Medicaid or uninsured

We conducted a feasibility assessment of possible Nemours patients meeting the same criteria, albeit with a de-identified database, and found that there were 212 potential participants meeting the above criteria.

We will send the flyer entitled "Recruitment of a Diverse Parent Crowd" to all parents of Nemours patients in the database via email (if available) or regular mail (if email is not available). Our study email address (crowdsource@nemours.org) and PI's phone number are provided on the flyer. Parents are instructed to contact the research team to sign up for the focus group. As mentioned, we will recruit up to 20 parents from the database. If 20 parents do not contact us and consent to participation within two weeks of distribution of the flyer, then our research coordinator will telephone parents to invite them to participate. We will be conducting the focus group across three Nemours sites (Orlando, Jacksonville, Delaware) via videoconference. The date/time of the focus group will be determined pending IRB approval, but will likely take place in the evening to accommodate work schedules. Each site will have 1-2 trained focus group facilitators who are all existing members of the research team. We have already asked our existing Parent Crowd 16 questions regarding parental burden and emotions, impact on the young child with T1D and other family members, and health care

interactions, and we have integrated the responses into a social-ecological framework which will drive the content of the online resource. The purpose of this focus group will be to obtain these parents' perspectives of raising a very young child with T1D by asking similar questions to assure that our website content is generalizable across demographic groups. The 16 questions posed to the Parent Crowd have been condensed into 6 questions (below) which will be asked by the focus group facilitator to prompt discussion. Parents will also be asked to complete a demographic form prior to the start of the focus group. At the end of the focus group, parents will be invited to join the Parent Crowd and continue to participate in the design and development of the online resource. Participants will be paid $25 for their time and effort on a CT payer card which we are already using to pay Parent Crowd participants for their responses to questions.

We request a waiver of the requirement for documentation of *full* informed consent for focus group participation. We completed a waiver for documentation of informed consent, as participants will read and sign an abbreviated consent form (attached). Given that there is minimal risk of participation in this focus group we did not think the full consent process was necessary. Parents will be provided the abbreviated consent form prior to beginning the focus group and completing the demographic form. The consent form document will be read to them by the focus group facilitator. They will be encouraged to ask questions about participation in the focus group prior to signing the consent form. Once signed, they will be given a copy of the form which provides all necessary information about the study procedures, risks, and confidentiality. As mentioned, at the end of the focus group, parents will be invited to join the Parent Crowd. Given that all parents provided electronic consent to participate in the Parent Crowd (Website Design and Development Phase), all focus group participants will be required to provide the same electronic consent. Thus, an abbreviated consent is being requested only for focus group participation.

HCP Crowd Input: The Family Advisors will decide which Parent Crowd decisions will be reviewed by the HCP Crowds via the Nemours VAC platform. Serving in an advisory capacity, HCPs will review the proposed design elements, identify additional areas for consideration, and indicate whether all proposed content is consistent with existing scientific evidence. Content areas will be further refined in accord with their recommendations. If any new or different information is proposed, parents will be asked to evaluate this information again.

Application Developer Input: Once the initial ideas for website content, structure and function are approved by parents, HCPs, and the research team (including the Family Advisors), draft specifications will be reviewed with the web development agency, who will develop a roadmap of design challenges to be distributed to their expert application developers in building the resource. Cindy Caldwell of Nemours web development team will be continuously involved throughout the design process to ensure that the website platform can be readily integrated into the Nemours.org public website. As elements of the website become available from the web development agency, parent and HCP stakeholders will review each element again. If parents identify any problems with the element, they will be asked to provide further input. This will be reviewed again by HCPs who will function in an advisory capacity. This cyclical process will continue for all elements until there is a final product that is acceptable to all stakeholders (see Figure 2).

Final Website Design: Once parents, HCPs, and the researchers approve the completed portal, the Nemours Web Development Team will incorporate the final platform into a functioning online resource on a Nemours website, with access limited to participants randomized to Website. The Parent Crowd will determine how HCP input will be integrated into the portal. A last step in constructing the portal will be to populate the compilations of behavior management, emotional coping and daily hassle strategies so that the RCT can begin with some helpful resources in place. The Parent Crowd and Family Advisors will determine if this content will be parent-initiated or HCP-initiated strategies or if a hybrid model of incorporation of ideas will be used. These resources will give step by step instructions, guidelines for determining appropriate uses of each strategy and opportunities for rating of the feasibility and effectiveness of each strategy by parent-users. The website will include a mechanism for expanding these compilations based on user experience over time. Family Advisors will beta test the finished platform and any issues will be resolved before the RCT is opened for enrollment.

4.2. Randomized Controlled Trial (RCT): During Years 3-4, we will conduct an RCT of the website compared with Usual Care (UC) in a sample of up to 300 parents of children with T1D (<6 years old). Details follow:

Participants: The RCT will enroll up to 300 parents of children <6 years old who receive T1D care at any of five Nemours Children's Health System sites in the Delaware Valley and Florida or who are recruited online

using a variety of internet resources from among eligible parents who live elsewhere in the United States. . As noted in Facilities and Resources, Nemours YC-T1D population was recently estimated at 213 patients, with a slightly increasing trend over the past 4 years. We anticipate that about 25% will be ineligible for one or more reasons and that another 10-15% will not be interested in participating in the study. With a 60% recruitment rate, we project that parents of up to 120 Nemours patients will enroll and that we will recruit the remaining parents via the various online methods, all of which are established, publicly available resources of the Diabetes Online Community that are already frequented by parents of this clinical population. Since parents will collect and ship dried blood spot samples from children who do not receive T1D care at Nemours, study participants must reside in the United States due to logistic and cost considerations associated with international shipping of these samples. One parent's participation is required, but two parents of the same child will be encouraged to take part, in which case the mother and father will complete the measures separately. We estimate that 75 fathers will enroll, but we will enroll any/all who wish to do so. Minorities and those with economic or educational disadvantages may have limited access to social media. If necessary to achieve sample composition consisting at least of 28% racial minorities and of 7% Hispanic ethnicity, we will continue selective recruitment of racial and ethnic minorities after concluding recruitment of non-Hispanic Whites in order to oversample from these groups to ensure that our parent sample is very diverse. There is no minimum duration of T1D, nor is there an HbA_{1C} cutoff as the website is intended for all YC-T1D parents.

Inclusion criteria: Parent or legal guardian of a child with physician diagnosis of T1D; Parent age ≥18 years; Child with T1D is currently <6 years old; Parent able to read and comprehend English; Regular access to the internet.

Exclusion criteria: Inability to read/comprehend study questionnaires and decision aids in English; Participating parent or the child with T1D lives outside of the United States.

Recruitment and Informed Consent: The study, including this recruitment plan, will be approved by a Nemours IRB before recruitment begins.. All Nemours health care providers who see T1D patients will receive an e-mail notice describing this study and our plan to contact all potentially eligible parents of Nemours T1D patients about enrollment, All potential Nemours participants that meet enrollment criteria will be identified through Nemours EMR and will receive an emailed study flyer approved by Nemours Marketing and Communications Department,, followed by phone and/or direct contact in the clinic. Online recruitment of the remaining participants will be facilitated by our internet marketing consultant, Ms. Amy Ohmer, who will disseminate word of our study and the IRB-approved study flyer using any of several announcements that we have drafted and that have been approved by the Nemours IRB. Internet resources will include Facebook groups such as Diapers and Diabetes and T1D Mod Squad; websites of diabetes organizations such as Children with Diabetes, Children's Diabetes Foundation, and JDRF; and blogs such as Naturally Sweet Sisters. The RCT entails a large group of people using the website together, so we will recruit and enroll all participants over a 1-2 month interval and begin all of them in the trial as close to concurrently as possible. The Nemours IRB has approved our proposal that parental permission and informed consent be obtained electronically since this is adequate participant protection and because it can provide valuable experience to justify this same approach in a future multi-site clinical trial, as we plan.

Study design: The design is a 2X3 randomized treatments design with 2 groups (Website and Usual Care/UC) and 3 measurements (0, 6, and 12 Months). To enable moderation and mediation analyses, randomization will be stratified by site; each site will randomize families to Website and UC in a 2:1 ratio. The primary outcome is change in HbA_{1C} over 6 mos. Usual Care at Nemours is designed to conform to the 2017 ADA *Standards of Medical Care in Diabetes*. All patients will receive the same care offered to patients outside of this study. Those randomized to Website will receive all of the elements of Usual Care, supplemented with access to the online resource for 1 year after randomization.

Optional Supplemental Methods of Communication with Participating Parents: Participants randomized to Website will also be provided with the option to receive website updates (i.e., new articles posted, active parent-to-parent forum discussions) via an emailed newsletter, Facebook, and/or Twitter. All three of these communication tools will serve the same purpose, which is to encourage participants to visit the website by providing updates through resources that many of them already use frequently (i.e., email and social media). The Facebook group (The New Normal T1D) and Twitter handle (@thenewnormalt1d) will set up as "private" and "protected" such that only select people (i.e., website participants) would be able to access the Facebook

group and see tweets. Users will not be able to post on the Facebook page or tweet to us or each other, thus conversations among users (outside of our website) will not be possible. We are working with the Nemours Social Media Manager to set these up to meet the appropriate privacy specifications. Participants will be required to opt in to receiving the newsletter when they register for the website. Participants will also be to opt in to receiving website updates through Facebook and/or Twitter. If they indicate "yes" then they will be added to the Facebook page and/or encouraged to follow @thenewnormalt1d on Twitter, respectively. Parents randomized to UC will be invited to use the website for 6 months following the first 6 months of the randomization phase of the trial. After the trial is completed, every effort will be made to maintain the website indefinitely.

Measurement Strategy: The measurement plan aligns directly with the conceptual model. Little is known about variables that might influence and be influenced by parent use of the planned website, so the measurement plan for this trial is broad in scope. This will magnify participation burden, but the collection of a thorough assessment of model constructs will best facilitate planning a future, larger trial, to evaluate the model in its entirety and to determine if parent or child characteristics moderate or mediate website benefits. Hence, parents will be paid for completing scheduled measures on an escalating basis: Baseline $25; 6 months: $50 and 12 months: $75. Questionnaires will be completed online using existing REDCap capabilities. T1D-specific measures were reviewed by the Family Advisors and adapted for the YC-T1D population. The conceptual model constructs associated with each measure are denoted as follows: Social Support (SS), Individual Parent Characteristics (IPC), Affective Coping (AC), Behavioral Coping (BC), Individual Child Characteristics (ICC), T1D Management Behaviors (DMB), Hypoglycemia (H), Glycated hemoglobin (A1C), and Quality of Life (QOL). Certain measures, as described in the Human Subjects section, yield clinical cutoff scores. Parents or children whose scores on those measures exceed a clinical cutoff will be contacted promptly and assisted in arranging an appointment with a qualified mental health professional in their areas. The Eyberg Child Behavior Inventory and the Brief Symptom Inventory-18 are commercially available. Per communication with the publishers (PAR and Pearson, respectively; see Appendix A), we have received approval pending completion of license/fee agreements to administer these measures online via REDCap.

Measures obtained at Baseline only:

Demographic information (IPC and ICC): The same demographic form used in the Website Design and Development Phase will be collected from RCT participants at baseline.

Perceived spousal support (SS): The Family Management Measure[148] assesses how families manage caring for children with chronic conditions like T1D. We will use the 8-item Parental Mutuality scale that measures parents' perceptions of support, shared views, and satisfaction with how the partners work together to manage the child's condition. The scale will be completed only by parents living with adult partners. The scale has adequate internal consistency (α=0.73 for mothers, α=0.77 for fathers), inter-rater reliability (r=0.44), and test-retest reliability (r=.71), and correlations in the expected direction with measures of related constructs.

Eyberg Childhood Behavior Inventory (ECBI) (ICC): The ECBI[161] is a widely used parent-report measure of problematic behaviors of children $\geq$ 2 years old. Parents rate the frequency of 36 child behaviors on a Likert scale, that ranges from 1 (*never*) to 7 (*always*), and to then indicate whether they consider each behavior to be a problem (yes/no). The ECBI has strong reliability and validity.[162] The ECBI will be administered at Baseline only to provide a comparator for evaluation of the convergent validity of the Preschool Diabetes behavior Checklist described below.

Diabetes-specific routines (BC): The Pediatric Diabetes Routines Questionnaire (PDRQ)[37] measures the frequency of routines formed around managing diabetes in the family. Item frequency is measured on a 5-point Likert scale ranging from 0 "never" to 4 "everyday" and "not applicable." Internal consistency (α=0.88) and test-retest reliability (r=0.81) estimates were strong. Construct validity was supported through relations with general child routines, family rituals, diabetes treatment adherence, and diabetes-specific family support. Completion of the PDRQ at the Baseline evaluation only will permit evaluation of the scale's predictive validity.

Measures obtained at Baseline, 6 months, and 12 months:

Parent self-efficacy (IPC): The Parental Self-Efficacy Scale for Diabetes Management (PSESDM)[153] was adapted from a prior measure for adult patients to measure parental self-efficacy for diabetes management of young children. The 8-item scale has adequate internal consistency (α=0.84). Criterion validity was established. Higher scores were associated with more favorable HbA_{1C} and quality of life in children.

Parent general psychological distress (IPC): The Brief Symptom Inventory–18 (BSI-18)[154-155] is a widely used self-report screening measure that yields norm-referenced scores for Somatization, Depression, Anxiety and a Global Severity Index. Respondents rate their current status in terms of 18 physical and emotional complaints; on a scale from 0 (*not at all*) through 4 (*very much*). The BSI-18 has strong reliability and validity. [154-155]
Parent-Preschool Diabetes Adjustment Scale (PP-DAS): This is a 36-item measure constructed for this study in collaboration with our Parent Crowd and Family Advisors. The scale was designed as an effort to capture parents' status relative to the key domains of psychological adjustment revealed in our earlier qualitative study.
Benefit Finding Scale: This brief 16-item scale has been validated in several prior studies [156-157] and will be used in this study to evaluate changes in parents' propensity to identify beneficial effects of their child's T1D on themselves, their children and their family relationships. Scale reliability has been consistently satisfactory to excellent in prior studies.
Parent fear of hypoglycemia (AC and BC): The 26-item Hypoglycemic Fear Survey – Parents of Young Children (HFS-PYC) measures parents' fear about their children's hypoglycemia.[158-160] It yields two subscales, assessing parents' behaviors related to preventing hypoglycemia and their worry that their child may experience hypoglycemia. Parents rate how often each item is true for them on a 5-point Likert scale (1=never to 5=very often). The HFS-PYC has good internal consistency (*α's*=0.86, 0.62, and 0.89) and test-retest reliability (*r's*=0.91, 0.73, and 0.91) for the Total, Behavior, and Worry Scores, respectively.
Diabetes-specific child behavior problems (BC and ICC): The Preschool Diabetes Behavior Checklist (PDBC) was constructed for this study with extensive input from family advisors and the Parent Crowd. The scale measures the frequency of child behavior problems in children with T1D ages 2 to 6 years. The 32 items measure the child's behavior in the areas of general adjustment to T1D, glucose testing, dietary intake, and insulin delivery.
Diabetes Self-Management (DMB): The Diabetes Self Management Profile, Self-Report, Parent Form (DSMP-SR) [163] was derived from the previously validated DSMP structured interview. The 24-item scale quantifies treatment adherence. Mean + SD DSMP total scores (maximum possible = 84) were 54.7 + 12.6 for 145 parents. Internal consistency was *α*=0.80 and correlation with HbA_{1C} was *r=0.*46.
Glycated Hemoglobin (HbA_{1C}): For parents of children who receive T1D care at a Nemours facility, the child's most recent HbA_{1C}, an index of average glycemia over the prior 2-3 months, will be obtained from the electronic medical record for the prior 12 months and for each T1D encounter occurring during the child's study enrollment. For participants enrolling online from non-Nemours centers, glycemic control will be measured via HbA1c collected using HemaSpot SE Blood Spot Collection Devices (dried blood spots [DBS]) obtained at 0, 6 and 12 months and analyzed at CoreMedica Laboratories in Lee's Summit, MO. Correlations between DBS and standardized venous HbA1c are high and sensitivity and specificity for DBS for HbA1c are excellent[165,166]. Higher values indicate higher average blood glucose over the prior 2-3 months.

Measures obtained at 6 months and 12 months only:
Website utilization: For each website user, we will track time-stamped logins and logouts, duration of login periods, hits on and duration of activity within specific website elements, etc. to provide careful tracking of extent and type of website use by each registered parent.
Qualitative interview: Parents will complete a qualitative interview at 3 months, 6 months and post-RCT, or earlier if the parent withdraws. The interview will obtain parents' perspectives of the website, suggested changes to content and design, advantages and disadvantages, reasons for low utilization, etc. We expect that this interview will yield relatively brief and focused responses from parents. Trained content analysts will employ a descriptive level of analysis, using a well-accepted method of content analysis via HyperRESEARCH software to extract the primary themes that emerge during these interviews. Analysts will be trained to a criterion of 90% inter-rater reliability. Dr. Aroian will direct incorporation of these themes into the website.

Table 1. Measurement schedule for the randomized controlled trial phase of the proposed work.

Measure	Baseline	6 Months	12 Months
Demographic Information	•		
HbA1C	•	•	•

Family Management Measure: Parent Mutuality Scale	•		
Parenting Self-Efficacy Scale for Diabetes Management	•	•	•
Brief Symptom Inventory-18	•	•	•
Parent-Preschooler Diabetes Adjustment Scale	•	•	•
Benefit Finding Scale	•	•	•
Hypoglycemia Fear Survey-Parents of Young Children version	•	•	•
Preschool Diabetes Behavior Checklist-Revised	•	•	•
Eyberg Child Behavior Inventory	•		
Diabetes Self-Management Profile-Self Report Form	•	•	•
Pediatric Diabetes Routines Questionnaire	•		
Mid-RCT and Post-RCT Qualitative interview (Website group @ 3, 6 &12 months)		• •	•

RCT Analytic Plans: The RCT analysis plan aligns with the focus of PA-DK-14-022, i.e., to develop an intervention that is ready for testing in a rigorous, multisite RCT. Because this is conceived as a preliminary RCT, we have put forth hypotheses below, but the plan emphasizes deriving effect size estimates for powering future trials on the main efficacy endpoints and analysis of website use and benefit. The planned RCT sample size of 150 families (2:1 for Website: UC) will suffice to estimate efficacy and to derive effect size estimates for use in a future trial with formal hypothesis testing.

Fundamentals: The Full Analysis Set will include parents who contribute data at either 6 or 12 mos.[167-169] The Completer Analysis set will include those who provide data at 0, 6 and 12 mos.. [167169] Efficacy analyses will be done on both sets.[167-169] The statistician will make appropriate analytic adjustments for instances in which data are determined to be Missing at Random and Missing Completely at Random. [167-169] In addition to multiple imputation, sensitivity analyses will be performed for assessing the robustness of the estimation in case of Missing Not At Random. Descriptive statistics will be calculated for all measures and distributions of obtained data will be summarized graphically in aggregate and by group. Assumptions for all proposed models will be checked before statistical analyses. [167-171] Appropriate transformations or non-parametric methods will be used in cases of violated model assumptions. [167-171] Sensitivity analyses will be conducted when assumptions underlying specific analyses cannot be verified using actual study data. Psychometric properties of all questionnaires will be calculated based on this sample's results, including internal consistency, 6 and 12-month test-retest reliability and predictive validity, All tests will be performed against a two-sided alternative at the $\alpha = 0.05$ significance level and a 95% confidence interval or a p-value will be provided for inferential purposes. All analyses will be performed using the most recent version of the SAS statistical software package.[172] 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 Website and UC at baseline. [167-171] Analyses of primary and secondary end points will be adjusted for imbalanced baseline characteristics.

Primary Analyses: Linear mixed effects modeling will be the primary analytic approach. [172-177] Holmbeck's [178] methods will be used to evaluate moderation and mediation of treatment effects. Candidate moderators will include demographic variables and scores for each measure obtained at baseline. Candidate mediators will include scores on each questionnaire obtained at 0, 6 and 12 months. With three measurement points, these methods will be capable of detecting linear and quadratic longitudinal associations among study variables. We will test these primary hypotheses:

H1: Compared to UC participants, Website participants will have significantly more favorable status at 6 and 12 months on HbA_{1C} (primary outcome) and secondary outcomesconsisting of change in questionnaire scores at follow-up visits.

H2: Website treatment effects will be moderated by parental socioeconomic status and questionnaire scores at baseline visits

H3: Website treatment effects will be mediated by changes in change in questionnaire scores at follow-up visits.

H4: Among Website participants, the above treatment effects will be mediated by Website utilization (More utilization predictive of more beneficial effects).

Perhaps more importantly, this feasibility trial will yield rich data that will be used for estimation of effect sizes and sample size requirements for a future multi-center trial,[179-180] and will enhance that application by:

1. Estimating Website-UC effect sizes (Cohen's *d* index)[179-181] at 6 and 12 months on the primary and secondary outcome variables.
2. Exploring utilization of the online resource, by examining demographic variables and individual characteristics of parents and children as moderators of Website use, and change in time-varying variables as mediators of change in Website use over 6 and 12 mo.[173-178]
3. Use of Structural Equation Modeling to evaluate and refine the conceptual model put forth earlier.[181]
4. Analyzing Mid-RCT and Post-RCT qualitative interviews of participants will provide additional information to drive refinements in the WEBSITE for future trials that could enhance WEBSITE use and benefit.

Limitations: The innovations in this application leave some important unknowns in that we have put forth only a tentative framework for the planned online resource. The final structure, content, functions and governance of the website will be specified in detail and then evaluated during the grant period. Major strengths lie in the collective experience of the research team and stakeholders, capitalizing on the "wisdom of the crowd" inherent in our stakeholder-driven strategy, and the careful constitution of three crowds to ensure balance between the central "parents as experts" approach with appropriate medical, crowdsourcing and web development technical expertise. A systematic process has been put forth for iterative design and development of the online resource, a process that we believe will result in an exceptional resource for these families. Another limitation is that some RCT parents may use the website sparingly or not at all. The study will yield extensive information about influences on WE use and we will use parents' post-RCT perspectives to guide further portal refinements. We will also emphasize usability issues in the design and development phase.

We are asking for reviewers' confidence in our premise that the collective parent and HCP expertise that we will assemble and utilize, the sound conceptual framework, the inclusion of technical experts in crowdsourcing, application development, social media and qualitative research, and the carefully designed randomized controlled trial, measurement plan and analysis plan will yield a readily disseminable intervention that could eventually be tested economically with a very large and diverse sample of parents. We believe that the resource we propose to develop can result in modest improvements in care and outcomes for a very large number of young children with T1D, thus achieving major public health impact with a rather small investment.

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Human Subjects Protection:
The Nemours Office of Human Subjects Protection is accredited by the Association for Accreditation of Human Research Protection Programs and is one of the few exclusively pediatric programs to be so recognized. (See http://www.nemours.org/pediatric-research/approval/human-subjects-protection.html). All research with humans is reviewed and approved by a Nemours IRB under Federal-Wide Assurance # 00000293 before research activities take place and monitored throughout implementation and dissemination of the research. Dr. Wysocki chairs Nemours IRB #2 and so this work will be submitted to IRB #1, which he does not chair. The two major phases of this project are: 1. User-centered design and development of the website, which is nearing completion; and 2. Randomized controlled trial of Website use, which we are now proposing to initiate. We propose to obtain parental permission and informed consent electronically because we believe this offers excellent protections to the parent participants, a very convenient means for distribution of "signed and dated" consent documents to them and we anticipate proposing electronic informed consent in a larger, multi-site randomized controlled trial in the future. We designed the randomized controlled trial so that it requires no direct face to face interaction between the researchers and participants, a feature that would greatly facilitate replication in a much larger multi-site trial in the future.

PHASE 2: Randomized, Controlled Trial of the Effects of 12 Months' Use of a an Online Resource for Parents of Very Young Children with Type 1 Diabetes Once the online resource is nearly ready to accept users, the randomized controlled trial protocol will be submitted for review and approval by Nemours IRB #1. The study would be an interventional study that appears to pose no more than minimal risks to participants. All of the participants will be adult parents/legal caregivers of children with type 1 diabetes under the age of 6 years at enrollment. The researchers will not interact directly with the children, but they will be considered secondary participants in this research since the intervention is designed to promote their health, safety and well-being.

Human participants' involvement, characteristics and design: We seek to enroll parents or other legal caregivers of eligible children receiving T1D care at any operating entity of Nemours Children's Health System or elsewhere in the United States if enrolled via online recruitment. We estimate that we can easily enroll a sample of up to 300 families when this RCT is opened to enrollment. While parents are the primary participants and will all be adults at the time of enrollment, their young children with T1D are secondary participants since their behavior and health outcomes are measured in the study. Participants will include adult parents/caregivers who self-identify as parents/caregivers of up to 300 children who were diagnosed with T1D before the age of 6 years, whose children carry a physician diagnosis of T1D and receive care at anyNemours Children's Health System location in the Delaware Valley or Florida, (or elsewhere in the United States if recruited online). and whose children are not yet 6 years old at the time of enrollment. We have estimated that 225 mothers and 75 fathers will provide consent to participate, but would be delighted to enroll every father of every eligible child. The study design will be a 2X3 randomized treatments design with 2 groups (Website and Usual Care; UC) and 3 measurement points (0, 6 and 12 months). Families (mother-father dyads and their children with T1D) will be randomized, stratified by insulin modality (pump or injections) and recruitment method (Nemours or online enrollment), in a 2:1 (Website:UC) ratio to optimize how much can be learned about moderation and mediation of SMP effects and to elucidate SMP utilization and its correlates. All children will receive T1D care at a Nemours diabetes center in Florida or the Delaware Valley, or elsewhere in the United States if enrolled online.. Children enrolled in this trial will receive T1D care that is equivalent to what similar children not enrolled in the study would receive at the same centers.

Informed Consent Process: Using IRB-approved, electronic informed consent infrastructure established in ongoing research at Nemours by Dr. Kathryn Blake (1-R01HL114899-01: Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial), parents will electronically authenticate an IRB-approved informed consent form that will include all of the federally required elements of informed consent and that fulfills Nemours pertinent policies and procedures. Per Nemours policy, assent is not required for children under 7 years of age to participate in research if appropriate parental permission has been obtained, as it will be in this case.

Sources of research data This study will involve parental completion of questionnaires at baseline, 6 and 12 months and either 1. For parents of Nemours patients, access to the child's electronic health record for retrieval of recent HbA_{1C} results and documentation of symptomatic and severe hypoglycemic episodes or 2.).

For parents recruited online, parents will collect and submit dried blood spots. Parents' use of the online resource will also be tracked automatically. At 3, 6 and 12 months after randomization or upon withdrawing the study, parents randomized to Website Access will be asked to complete a qualitative interview about their experiences with use of the website and their suggested refinements.

Potential risks: The most likely risks are privacy threats and possible loss of confidentiality, but it would be difficult to characterize the potential for harm to participants since the questions do not address illegal, unethical or stigmatizing behaviors and all of the participants are adults who may simply decline to answer any question that is perceived to be threatening. Participants randomized to UC may be at somewhat higher risk of deterioration in metabolic, behavioral and affective outcomes than those randomized to SMP. There is little reason to believe that parent or child participants will fare more poorly due to study involvement than if they had not enrolled.

There may be some potential that the online resource created for this trial may contain statements that are medically false or misleading. In conversations with Jeff Hitchcock, director of www.childrenwithdiabetes.com, parents who utilize that website are exceptionally skilled at self-policing of the website content and are quite comfortable in challenging incredulous or unsupportable statements made by other website users. That, together with the ready availability of monitoring and feedback by expert T1D health care providers, should reduce this risk to negligible. It should be kept in mind that parents of children with T1D are often exposed to inaccurate information about the disease and its management and must develop ways of contending with it. It is very likely that the proposed online resource will provide in this respect a safer environment to parents due to "safety in numbers" than they tend to experience in their daily lives.

Some parents may demonstrate clinically significant psychiatric symptoms, either pre-existing for exacerbated by exchange of information with other parents about the sources of distress inherent in YC-T1D parenting. Affective and sleep disorders would be most likely and perhaps as many as 20-25% of the parent crowd could have clinically significant psychiatric symptoms.

Adequacy of protections against risks: No questionnaires will include participants' names or other identifying information. All study records will either be stored electronically on secure network servers or in hard copy in locked file cabinets in private offices. All study patients and their parents will be monitored carefully by their health care teams and referred for additional services as indicated by those observations. Study participants should fare no differently from similar patients and parents who do not take part in the study.

Parents in this phase of the research will be completing the Brief Symptom Inventory, a psychiatric symptom screening measure, and the Eyberg Child Behavior Inventory, a screening measure of childhood behavioral problems, at 0, 6 and 12 months, affording an opportunity to detect clinically significant symptom levels as well as deterioration in psychiatric status at each measurement point. Parents whose scores exceed a clinical cutoff of T-score $\geq$ 65 on the Brief Symptom Inventory, or whose children score above the Eyberg Child Behavior Inventory clinical cutoff scores of 127 for Intensity or 11 for Number of Problems, will be contacted by telephone as soon as possible after the elevated score is obtained and assisted by the research team in obtaining a referral to a psychologist, psychiatrist or qualified mental health service provider in their region for further evaluation and possible treatment.

Special attention will be given to monitoring of deterioration in diabetes outcomes among UC participants. All Nemours sites include multidisciplinary resources to which patients can be referred for augmented care and education in nursing, nutrition, psychology, and social work should the child's health status or psychological adjustment require such actions.

Potential benefits to participants and others: Participants in the Website group may benefit in a variety of ways from use of the online resource, but this cannot be guaranteed. Participants may appreciate the opportunity to help others who face the challenges of living with T1D in this age group.

Importance of the knowledge to be gained: The study will yield extensive information from parents for parents about the content, structure, function and governance of a social media portal for parents of very young children with type 1 diabetes. There is no other study that has compiled this kind of information from parents for this specific purpose. Nor has any study returned to the same parents to ensure that their perspectives have been reflected appropriately in the subsequent stage of refined website design and execution.

Data and safety monitoring plan: The study poses no greater than minimal risk but it does involve a clinical trial of a behavioral intervention. In our opinions, the level of risk that is likely to be encountered by participants in this study does not rise to the level that requires an independent or external DSMB. Instead, Drs. Wysocki, Pierce and Lee will serve as safety officers who will oversee participants' experiences, receive any unanticipated problem reports or participant complaints, ensure IRB notification as required by Nemours policies and procedures, and implement indicated safety precautions or other human subjects protection actions. Special attention will be given to monitoring of deterioration in diabetes outcomes among UC participants.

REPRESENTATION OF FEMALES, MINORITIES AND CHILDREN

Inclusion of Females

Females are expected to represent a majority of parent-participants in both the Social Media Portal Design and Development Phase (~76%) and the Randomized Controlled Trial (~67%). Females absorb the bulk of responsibility for T1D care for children under 6 and we expect that they may be more frequent users of the social media portal once it is completed.

Female children will represent about half of the child participants in the Randomized Controlled Trial.

Inclusion of Minorities

There is little direct scientific evidence indicating that racial or ethnic minority status, economic disadvantage or low health literacy/numeracy are associated differentially with benefit accrued from using a social media portal such as that proposed here. However, given the robust nature of health care disparities in other contexts, it is reasonable to suspect that these groups may derive less benefit from this resource than other, more advantaged, demographic groups. We have therefore designed the research plan to enable evaluation of these questions and to give disadvantaged populations equitable access to the potential benefits of participation in this research. In addition to oversampling of racial and ethnic minorities, we will strive to achieve exceptional diversity in our enrolled samples in terms of household income, education, health literacy/numeracy and internet and social media fluency

In the randomized controlled trial, we expect to enroll 84 parents (28% of the sample) who are members of racial minority groups, including African Americans (11%), Asians (9%) and Multiple/Other (11%). In terms of ethnicity, Hispanics will account for about 7% of the participants in the RCT.

Inclusion of Children

We project that 300 parents (225 "mothers" and "75 fathers") of 225 distinct children with T1D will enroll in the study. In the randomized controlled trial, these 225 children will be secondary participants in that parents will complete questionnaires about them and routinely obtained clinical data will be retrieved from their electronic medical records. We expect their racial and ethnic composition to parallel that of their parents (about 28% racial minorities and about 7% of Hispanic ethnicity). Recruitment of racial and ethnic minorities is limited in this trial by the racial and ethnic composition of the available clinical population.. We will strive to enroll every family of every eligible child, but we estimate that parents/caregivers of about 225 children with T1D will actually enroll.

Multiple PI Leadership Plan

Tim Wysocki, PhD, ABPP and Jessica Pierce, PhD will serve as Multiple Principal Investigators on this grant. Our rationale for organizing the application in this way rests on these considerations:

- Dr. Wysocki has a very strong track record of obtaining external funding for his program of research on family adaptation to pediatric T1D and in the implementation, management, analysis and dissemination of that research. He also has an extensive background in human subjects protection and the responsible conduct of research.
- Dr. Wysocki has multiple commitments that prevent him from dedicating more than 20% of his time and effort to this work. Providing opportunities for Dr. Pierce to learn the grant submission and management process offers a serendipitous way for him to pursue this innovative and exciting work at a somewhat lower level of effort that he can deliver with certainty.
- Dr. Pierce is an emerging investigator who brings special qualifications to the project, in that she was diagnosed with type 1 diabetes at an early age and she is exceptionally familiar with the diabetes online community.
- Dr. Wysocki is experienced in website design and development based on stakeholder-driven design and construction of two web platforms for decision aids in his ongoing PCORI-funded study.
- As a young adult diagnosed with T1D at age 5, Dr. Pierce can readily engage with young parents of children with T1D under age 6. Dr. Wysocki is well known to many pediatric T1D clinicians across the US who he can recruit to serve as members of the health care provider crowd.
- Dr. Wysocki is located at Nemours Children's Clinic in Jacksonville, while Dr. Pierce's office is at Nemours Children's Hospital in Orlando. Having a physical presence in both sites will facilitate careful and consistent implementation of the proposed work. Dr. Pierce and Co-Investigator Dr. Aroian are both located in Orlando and can meet face to face conveniently.
- Dr. Pierce has strong research interests in applications of developmental psychology concepts and methods to the understanding of adaptation to the demands of type 1 diabetes during the extreme ends of the pediatric age continuum. Her ongoing research on the transition to adult care for emerging adults with T1D complements her interests in the population of very young children with T1D.
- While Dr. Wysocki has no firm retirement plans, it is possible that he will retire during the 4-year period of award should this application be funded. If that were to happen, Dr. Pierce would be well prepared to assume responsibility for project completion.

We therefore propose the following division of responsibilities as part of this Multiple PI leadership plan:

Responsibility Domain	Dr. Wysocki	Dr. Pierce
Corresponding Investigator	X	
Coordinate Family Advisors activities		X
Develop/implement human subject protection plan	X	
Populate parent crowd/community		X
Populate health care provider crowd/community	X	
Interactions with Appirio, Inc.	X	
Interactions with Nemours Web Development Team		X
Interactions with Karen Aroian, PhD, RN around qualitative research methods		X
Manage interactions with parent and health care provider crowds		X
Integrate parent and health care provider crowd input into platform design		X
Manage interactions with application developer crowd	X	
Integrate application developer crowd input into platform design	X	
Engage and coordinate with Co-Investigator Joyce Lee, MD, MPH	X	
Manage research specialist and coordinator staff		X
Manage fiscal aspects of the project	X	
Interactions with statistician Jobayer Hossain, PhD	X	
Verify data quality	X	X
Ensure responsible conduct of research	X	X
Assemble and coordinate writing teams	X	X

Disseminate project findings	X	X
Plan and prepare subsequent grant applications	X	X

Roles/areas of responsibility of the MPIs

• Fiscal and management coordination: Dr. Wysocki will have primary responsibility for fiscal management of the project and for personnel actions.

• Process for making decisions on scientific direction and allocation of resources: Drs. Pierce and Wysocki will achieve consensus on such decisions and, in the very unlikely event of an unresolved disagreement, bring the issue to Dr. Vicky Funanage, Director of Nemours Biomedical Research, for resolution.

• Data sharing and communication among investigators: Drs. Pierce and Wysocki will have equal access to study data via a shared drive location with secure limited access.

• Publication and intellectual property (if needed) policies: Dr. Wysocki's center has clearly stated policies and procedures for publications and other academic products that are based on the pertinent American Psychological Association's *Ethical Principles for Psychologists.*

• Procedures for resolving conflicts: We will follow the APA ethical principles and, in the very unlikely event of an unresolved disagreement, bring the issue to Dr. Vicky Funanage, Director of Nemours Biomedical Research, for resolution.