ISPAD/JDRF Research Fellowship 6 Month Progress Report
PI: Paul Enlow, PhD
Project Title: Racial/Ethnic Disparities in Healthcare Delivery among Youth with Type 1 Diabetes

## Six Month Progress Report

I am pleased to submit this Six Month Progress Report for the ISPAD/JDRF Research Fellowship project, “Racial/Ethnic Disparities in Healthcare Delivery among Youth with Type 1 Diabetes.” The PI is Paul Enlow, PhD, Assistant Research Scientist in the Nemours Center for Healthcare Delivery Science (CHDS). Melissa Alderfer, PhD, Center Director (Delaware Valley) and Principal Research Scientist in the Nemours CHDS, is the supervisor of this project. This progress report details all study activities between January 1, 2020 and June 30, 2020, the date which this report was prepared.

## Statement of Problem and Research Question

Racial and ethnic differences in type 1 diabetes (T1D) are well-documented[1-3]. Although the prevalence of T1D is highest among non-Hispanic white (NHW) youth, the incidence is increasing fastest among those of racial/ethnic minority groups as their total numbers within the population rise[4,5]. Moreover, African-American and Hispanic adolescents have worse glycemic control and higher rates of diabetic ketoacidosis compared to NHW adolescents[2,6,7]. Even more startling are recent reports that rates of mortality among African-American youth with T1D and type 2 diabetes are twice that of NHW youth[8]. Although some evidence suggests racial/ethnic differences in HbA1c are related to genetics[9], other biomarkers of T1D-related health outcomes (e.g., fructosamine, glycated albumin) are not[10] suggesting that disparities in diabetes health outcomes are not fully explained by biological and genetic factors[11]. Further, while individual (e.g., non-adherence)[7] and family characteristics (e.g., conflict, involvement)[12,13] may partially explain these disparities, recent studies have suggested that racial and ethnic disparities in T1D care may also play a role.

Both the quantity and quality of T1D care may be compromised for youth of racial and ethnic minority groups[31]. For example, youth with T1D from racial/ethnic backgrounds are less likely to have a regular endocrinology provider than NHW youth[14] and are more likely to miss routine medical appointments[15], thereby decreasing access to and continuity of care. In regard to quality of care, non-black Hispanic youth are less-likely than NHW youth to report that their care takes their personal and family context into consideration[14]. Further, when used appropriately, both insulin pumps and continuous glucose monitors (CGMs) are associated with better health outcomes in youth with T1D[7,16] including improvements in glycemic control[17-23] but racial/ethnic disparities are also apparent here. NHW youth are more likely to use continuous glucose monitors (CGM) than youth from minority groups[24] and African-American and Hispanic children are less likely than NHW youth to receive insulin pump therapies[7,25,26], even after controlling for sex, age, diabetes duration, insurance status and SES[2,26]. This suggests that observed inequities are not fully explained by large, systemic variables (e.g., insurance, SES). Given that optimal use of insulin pumps and CGMs can improve health outcomes in youth with T1D, interventions aimed at reducing inequities in the access to and use of diabetes technologies may help reduce racial/ethnic disparities in health outcomes[27].

Although researchers have identified some ways to reduce disparities in T1D outcomes[28-32], no treatments have specifically targeted access to and use of diabetes technologies. An important first step in developing such interventions is understanding the mechanisms underlying the observed disparities. Consequently, the ***overall objective*** of this study is to understand the barriers and facilitators to accessing, and optimally using, diabetes technologies among racial and ethnic minority youth with T1D and to explore the resources and support needed to overcome these barriers. We will use qualitative methods to accomplish **two specific aims**:

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**Aim 1:** Gather patients', caregivers', and providers' perceptions of the barriers and facilitators to (1) accessing insulin pumps and CGM and (2) the optimal use of insulin pumps and CGM among youth from racial/ethnic minority backgrounds.

**Aim 2:** Engage patients, caregivers, and providers in identifying potential solutions to overcome barriers to accessing and optimally using insulin pumps and CGM.

Upon completion of these aims, the ***expected outcome*** is to have identified intervention targets at patient-, caregiver-, healthcare provider-, and healthcare system-levels to reduce disparities in access to and optimal use of diabetes technologies. Further, we anticipate having potential strategies to overcome some of these barriers, which we could integrate into interventions for patients, caregivers, healthcare providers, or communities. We will be well-positioned to pursue funding for projects that integrate findings from these aims to develop and pilot-test disparity-reducing interventions.

## Methods

### Overview of Study Design

The proposed study uses a cross-sectional mixed-methods approach to accomplish the study aims. We are collecting qualitative data from patients, caregivers, and healthcare providers via individual interviews. In addition, we are collecting quantitative data related to variables that are conceptually related to use of diabetes technology, including quality of life, diabetes self-efficacy, and diabetes numeracy. Furthermore, we are collecting data on social determinants of health (e.g., food and housing insecurity, neighborhood violence) and experiences with racism to examine whether these constructs relate to use of diabetes technology.

## Progress to Date

### Assembled Research Team and Family Advisory Boards

After receiving the notice of award in November 2019 we assembled the multidisciplinary research team including Melissa Alderfer, Ph.D., Susana Patton, Ph.D., Anthony Gannon, MD, Kirk Dabney, MD, and two research coordinators and prepared to the start the proposed project. We also reached out to Nemours diabetes care teams in Wilmington, DE and Orlando, FL and asked them to identify patients and caregivers who would make good additions to the Family Advisory Board. A Family Advisory Board consisting of three caregivers and two adolescents was formed. Of note two of the caregivers and both adolescents on the advisory board are Spanish-speaking and were therefore able to provide feedback on the procedures and materials for Spanish-speaking families. The Family Advisory Board met with the PI and both research coordinators in February 2020. During this meeting, the family advisors were oriented to the objectives of the current study as well as the proposed methodology. The family advisors provided feedback on the proposed methodology, questionnaires, and interview guides to enhance clarity of the questions and increase the likelihood that that data obtained will help answer the research questions.

### Created Quantitative Data Collection and Management Processes

REDCap, a secure web application for administering surveys and managing survey data, is being used in this study to collect and manage data on participant demographics, social determinants of health, diabetes-related quality of life, diabetes self-efficacy, diabetes numeracy, and diabetes distress. The research coordinators (Courtney Thomas and Alejandra Perez-Ramirez) have built all required REDCap surveys for the project and participants will complete these surveys by weblink. After consultation with Dr. Dabney and the Nemours Office of Healthy Equity and Inclusion, it was decided that it would be pertinent to assess adolescents' and caregivers' experiences with racism, as this can be conceptualized as a social determinant of health. Therefore, adolescent and caregiver versions of the Schedule of Racist Events were added to the measures of the project and built into the REDCap survey.

### Developed Interview Guides

Starting in January 2020, we also began to develop interview scripts for patients, caregivers, and healthcare providers. Drafts of the interview guides were reviewed by Dr.'s Patton, Gannon, and Dabney and revised accordingly. As previously noted, the Family Advisory Boards reviewed the interview guides and made suggestions about ways to improve the guides. The interview guides were originally finalized in March, 2020, prior to the COVID-19 pandemic emerging widely in the United States. The adolescent, caregiver, and healthcare provider interview guides were then revised to incorporate questions about COVID-19 and how it affected recent delivery of diabetes care. The revised adolescent and caregiver guides were reviewed by the Family Advisory Board, and the revised healthcare provider guide was reviewed by Dr. Gannon. The interview guides were finalized in May, 2020.

### Began Recruitment & Data Collection

We proposed to recruit ~20 patients who receive their T1D care at Nemours and ~20 caregivers of youth with T1D (40 total). We will also recruit ≥ 10 healthcare providers, and not more than 5 providers from a single group (i.e., nurse practitioners, endocrinologists). To recruit caregivers and adolescent patients, we are contacting caregivers by email and include a study flyer containing a short description of the study, eligibility criteria, and contact information for the study coordinator. In the recruitment email, we also ask the caregivers if their teen is interested in participating. After recruitment, patients, caregivers, and healthcare providers participate in separate, individual interviews planned to last approximately 30 minutes, after which participants are asked to complete the REDCap survey.

The IRB approved our procedures in February, 2020 and participant recruitment was planned to begin in March, 2020. We postponed opening recruitment at that time due to the COVID-19 pandemic hitting the United States. During this waiting period, we refined the interview guides by adding COVID-19 questions, as described above, and conducted a thorough review of the electronic medical record to identify 232 potential participants.

In May, 2020 we consulted with the research team members and Family Advisory Boards to determine whether recruitment could begin. Both the research team and Family Advisory Boards felt that it would be appropriate to begin recruitment in June.

As of the writing this report, we have invited caregivers and adolescents from 20 families and 8 healthcare providers to participate in this study. Table 1 shows recruitment information for the families who have been approached at the time of this report. Overall, the recruitment rate for caregivers and adolescents is approximately 25%; as of the time of writing this report no healthcare providers have been responded to the initial recruitment emails. Based on the number of eligible participants that were identified, this recruitment rate will allow us to obtain the proposed sample of 20 adolescents and 20 caregivers. We anticipate a similar recruitment rate for healthcare providers, which will allows us to recruit the proposed sample of at least 10 healthcare providers.

**Table 1. Recruitment Rates as of 6/30/20**

| | Approached | Declined | Recruited |
|---|---|---|---|
| **Caregivers** | 20 | 1 (5%) | 5 (25%) |
| **Adolescents** | 20 | 1 (5%) | 5 (25%) |
| **Healthcare Providers** | 8 | 0 | 0 |

## Projected Duration of the Study

Progress on this project was delayed by 3 months due to the COVID-19 pandemic. Currently we are recruiting approximately 5 caregivers and 5 adolescents per month. We also anticipate a similar recruitment rate for healthcare providers. At this rate, we expect data collection to last 4 months (September, 2020), which is similar to what was originally proposed. We will also begin simultaneously transcribing and analyzing the qualitative data. This process is anticipated to last approximately after the conclusion of data collection. Therefore, we anticipate that the study will be completed by November, 2020.

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