ISPAD-Breakthrough T1D 2024 Fellowship Progress Report

Title: Factors contributing to Automated Insulin Delivery Variability in Diabetes Outcomes (AViD Outcomes) Study

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Project Timeline: July 2024 – June 2026

Summary:

Jayde Hooven-Davis, M.D. is a third year Pediatric Endocrinology fellow at UPMC Children's Hospital of Pittsburgh. Her co-primary mentors are Christine March, M.D., M.S., Assistant Professor of Pediatrics in the Division of Pediatric Endocrinology, and Ingrid Libman, M.D., Ph.D., Professor of Pediatrics and Epidemiology and Director of the Diabetes Program within the Division of Pediatric Endocrinology. Dr. Hooven-Davis is exploring the behavioral, clinical and psychosocial factors which contribute to variations in glycemia among youth adopting automated insulin delivery systems. She has completed her retrospective cohort study of >700 patients who have adopted this technology at a large academic center from January 2020 to June 2024, and is currently completing data analysis with her statisticians. Group-based trajectory modeling is being utilized to show glycemic trajectories within the first 18 months of AID initiation and multinomial regression analysis is identifying predictors of latent class assignment. She has also compared glycemic outcomes and user engagement among Tandem Control IQ and Insulet Omnipod 5 users. She will be presenting some of her data at ISPAD Annual Meeting in Montreal in November 2025 and currently has two manuscripts in preparation for submission in fall-winter 2025-2026. She is currently conducting her mixed methods study with adolescents adopting this technology and their parents. She plans to complete her data collection this fall with subsequent analysis and manuscript preparation in the winter-spring 2026. She is completing a Master's degree in Clinical Research at University of Pittsburgh's Institute for Clinical Research Education with an anticipated graduation date of May 2026.

Background:

Rapid advances in diabetes technology over the past decade have revolutionized type 1 diabetes (T1D) management. Automated insulin delivery (AID) systems pair an insulin pump with blood glucose data from a continuous glucose monitor (CGM) to automate some aspects of insulin delivery using a control algorithm. Clinical trials and real-world data have found that commercially available AID systems improve glycemic control as evidenced by an increase in time in range (TIR, glucoses between 70 -180 mg/dL) by 5.6% to 15.6%. This is a clinically significant improvement to reduce the risk for microvascular complications. In addition to the substantial benefits for glycemia, families using AID systems report improved sleep, less fear of hypoglycemia, and decreased diabetes distress. Given these positive outcomes, pediatric use of AID systems has increased exponentially, with global estimates nearing 900,000 users at the end of 2022.

Despite clear benefits to AID systems, there are persistent challenges to their use, including limitations with access, cost, technological barriers, and user behavioral factors. In clinical practice, many patients using AID systems still do not achieve glycemic targets as defined by the International Society for Pediatric and Adolescent Diabetes (ISPAD), including a target hemoglobin A1c of <7% or TIR >70% due to "patient-related faults" as one study describes the "human in the loop" factor within the AID algorithm. To date, many studies of AID systems focus on overall improvement and average TIR, not distinguishing why these systems perform

better in some patients and not in others. Few studies have identified predictors of improved glycemic control amongst users; moreover, these studies are limited by either assessing only one AID system, focusing on adult users, having a small sample size, or only reporting optimal insulin dosing parameters.

The proposed study will explore the clinical and human factors that may lead to variable trajectories in glycemic control (measured by TIR and HbA1c) in children and adolescents using AID systems to inform future interventions to improve glycemic outcomes for youth who are adopting this technology. We hypothesize that lower socioeconomic status, higher body mass index (BMI), longer diabetes duration, lower bolus frequency, poor device understanding, negative attitude about diabetes, decreased device satisfaction, lack of shared responsibility, and low self-management skills will be associated with higher HbA1c and less improvement in TIR with adoption of AID technology. Therefore, we propose the following specific aims:

Aim 1: Identify predictors for glycemic trajectories of patients using AID including demographics, social determinants of health, disease-related factors, and health care utilization.

Study Design: We conducted a single-center, retrospective cohort study of school-aged children (ages 6-18 years) with type 1 diabetes who initiated OP5 or CIQ between January 2020 and June 2024 at UPMC Children's Hospital of Pittsburgh. Our center sees approximately 2000 patients with type 1 diabetes annually with our patient population coming from a diverse, urban, metropolitan area and a vast surrounding suburban and rural region. Our center has adopted a standardized approach for education about the various AID systems, shared decision making in the AID selection with patients and families, and training to use the specific system. Participants were included if they were diagnosed with type 1 diabetes for at least 12 months prior to starting AID to account for the honeymoon period, initiated AID technology between the ages of 6 and 18 years, wore AID system for at least 12 months during study window, and attended at least 2 diabetes visits in their first year of AID use.

Data Collection: We obtained demographic data, insurance status, and diabetes history (date of type 1 diabetes diagnosis, age at AID initiation, prior insulin regimen) using the electronic health record at the time of AID initiation. We collected anthropometrics, hemoglobin A1c (HbA1c), 30-day CGM data from Dexcom Clarity downloads, and 30-day AID data from Glooko and Tandem Source downloads at the baseline visit prior to AID initiation and at 3-, 6-, 12- and 18-month subsequent follow-up visits.

Results: We collected data of 722 patients who started on OP5 (n=411) and CIQ (n=311) between January 2020 and June 2024 (Table 1). OP5 users were younger than CIQ users (13.5 years [IQR 10.2, 15.8] vs. 15 years [IQR 12.6, 17]), had type 1 diabetes for a shorter duration (5.3 years [IQR 2.9, 7.8] vs. 6.2 years [IQR 3.3, 9.5]), and were more likely to be first time pump users (20.4% vs. 10.3%). The majority of OP5 users (78.4%) were previously wearing non-integrated insulin pumps while most CIQ users (78.5%) were previously using predictive low glucose suspend pumps. CIQ users tended to be more overweight/obese than OP5 users (43.8% vs. 30.5%) at baseline. Higher baseline TIR was seen in OP5 users (45% [IQR 34, 56] vs. 42% [IQR 31, 55]).

Next Steps:

- We are completing group-based trajectory modeling for TIR over 18 months following AID initiation. We have identified 4 unique glycemic trajectories. We will subsequently be completing multinomial regression modeling to identify predictors for latent class

assignment including age, duration of T1D, prior treatment, baseline TIR, user engagement, intervisit communication, sociodemographic factors.
- We will be writing the manuscript for GBTM this fall.
- We are wrapping up analysis and manuscript writing for the OP5 vs. Control IQ comparison. This data will be presented at ISPAD Montreal in November 2025.
- We will be finishing manuscript preparation by September 2025.

Aim 2: **Explore device knowledge, attitudes, and self-management skills of adolescents using AID systems**.

Approach: In adolescents (ages 13-18 years) who use AID, we will use mixed methods to understand the different perspectives among those with optimal and poor glycemic control, defined as TIR ≥70% or <45%, respectively (n=15 for each group).[15] We will use semi-structured interviews to assess knowledge about their AID device, attitudes toward diabetes and device use, and motivating factors for management behaviors. We will collect quantitative measures of device satisfaction, self-efficacy, and shared responsibility with caregivers using validated scales.[16-18] Qualitative data will be analyzed with a consensus coding approach using two reviewers, and a thematic analysis will identify and distinguish key themes between the two groups. Quantitative measures will be paired with the qualitative data in a joint display.

Current Status: We are currently recruiting and conducting this study. We have completed 8 patient interviews to date.

Next Steps:
- We will continue to recruit for this study throughout the fall of 2025.
- We will begin coding and subsequent thematic analysis concurrently beginning in September 2025.
- We will submit preliminary data to ADA for abstract in winter 2025-2026.
- We will submit manuscript for publication in late spring 2026.

Future Directions: Following the ISPAD fellowship, Dr. Hooven-Davis is currently in the process of applying for Assistant Professor positions in Pediatric Endocrinology, with a faculty position beginning in July 2026. She is currently in the process of writing a career development award (K12 grant) where she proposes to develop a multicomponent intervention (AID-UP) to tackle the complex interplay between behavioral, educational and social needs of adolescents and their families using advanced diabetes technology.