

A MIXED METHODS INVESTIGATION OF ATTITUDES AND SELF-CARE IN INDIVIDUALS  
WITH TYPE-1 DIABETES MELLITUS AND IMPAIRED AWARENESS OF HYPOGLYCEMIA

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*I dedicate this dissertation to my wonderfully supportive family. I want to thank my parents, Shari and Bennett Matus, as well as my grandmother Brenda Mechanick, for all your sacrifices to make this achievement possible. I would also like to thank my brother, Josh Matus, for being a true best friend through the ups and downs. Finally, I would like to thank my girlfriend, Paige McKeown, for your endless love and support.*

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# ABSTRACT

A MIXED METHODS INVESTIGATION OF ATTITUDES AND SELF-CARE IN INDIVIDUALS WITH TYPE-1 DIABETES MELLITUS AND IMPAIRED AWARENESS OF HYPOGLYCEMIA

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**Background:** Self-care of individuals with type 1 diabetes (T1D) may play a significant role in development and treatment of impaired awareness of hypoglycemia (IAH). This dissertation aimed to identify and define characteristics of self-care clusters in adults with T1D, explore the interrelationships between attitudes, self-care, and IAH within clusters qualitatively, and integrate findings to develop a typology.

**Methods:** Adults (n=200, 27% Black, 61% female) with T1D (mean(SD) age: 39(15) years, T1D duration: 22(14) years) reported personal, clinical and social determinants of health, glycemic attitudes and self-care (Self-Care of Diabetes Inventory; 3 self-care scales: maintenance, monitoring, management; 1 confidence scale; scored 0-100; scores  $\geq 70$  are adequate). Cluster analysis via Ward's method was performed with self-care domains as criteria. Semi-structured qualitative interviews were performed and analyzed via directed content analysis. An integrated results matrix was employed to develop a typology of self-care in T1D.

**Results:** A typology of three self-care types was found: Expert (n= 70, 70% White, 20% IAH, insulin pump use: 63%, mean(SD) age: 45 (17) years, T1D: 25 (16) years), Inconsistent (n= 112, 75% White, 30.4% IAH, Insulin Pump use: 75%, mean(SD) age: 37 (14) years, T1D: 21 (13) years), and Novice (n= 18, 39% White, 27.8% IAH, Insulin pump use: 44%, mean(SD) age: 27 (7) years, T1D: 16 (8) years). Expert was characterized by adequate self-care across domains (Mean (SD) maintenance: 84.9 (8.8), monitoring: 85.0 (8.8), management: 72.5 (10.0)). Inconsistent was characterized by adequate maintenance (78.6 (8.9), and inadequate

monitoring (65.6 (9.77)) and management (56.8 (10.1)). Novice was characterized by inadequate self-care across domains (maintenance: 51.9 (7.7), monitoring: 56.9 (12.9), management: 44.5 (6.3)). Types differed across age ( $p<.001$ ), race ( $p<.01$ ), insulin pump use ( $p<.05$ ), Self-Care Maintenance ( $p<.001$ ), Monitoring ( $p<.001$ ), and Management ( $p<.001$ ). No differences were found in IAH or T1D duration.

**Conclusions:** This self-care typology may explain in-part heterogeneity in T1D outcomes such as IAH. Therefore, understanding a patient's self-care type may offer a more individualized approach for more effective treatment of IAH.

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# CHAPTER ONE: INTRODUCTION

This background section will highlight prevalence, impact, and implications of impaired awareness of hypoglycemia (IAH) for individuals with type-1 diabetes mellitus (T1D). Additional attention will be placed on racial disparities in prescription, treatment, and outcomes to highlight why current approaches to therapy alone may fail to address, or even exacerbate, such disparities. With this information, a hypothesis and alternative approach to understanding IAH will be presented that may position us to view and treat IAH more effectively and inclusively. Then, the purpose of the dissertation will be explicitly discussed, followed by the guiding conceptual framework of the dissertation. Lastly, the innovation of the proposed dissertation will be highlighted and the chapter will conclude with a summary statement.

## Background

Hypoglycemia-related mortality in people with T1D is as high as 10% (Cryer, 2013a). Individuals with T1D have impaired counterregulatory defenses against hypoglycemia, the most common and dangerous side effect of insulin therapy (Cryer, 2016). They, therefore, must rely on symptom perception and response as a principal defense against severe hypoglycemia (Cranston, Reed, Marsden, & Amiel, 2001; Cryer, 2016). However, up to 60% of individuals with T1D have greatly diminished hypoglycemia symptom perception, known as IAH (Y. K. Lin et al., 2019). The most significant risk factor of IAH is a history of frequent hypoglycemia episodes; therefore, repeated hypoglycemia exposure drives IAH (Cryer, 2016; C. G. Fanelli et al., 1993; Martín-Timón & Cañizo-Gómez, 2015). People with IAH have a 6-fold increased risk for severe, life-threatening hypoglycemia compared to peers with intact awareness (S. A. Amiel, 2009; Joel T. Dunn et al., 2018; Y. K. Lin et al., 2019; McCrimmon, 2009).

There exist significant racial disparities regarding prevalence of IAH, incidence of severe hypoglycemia, and use of emergency services between Whites and Blacks (Karter et al., 2017;

Lai, Lipman, Willi, & Hawkes, 2021; Lipman, Smith, Patil, Willi, & Hawkes, 2021; van Meijel et al., 2020; Willi et al., 2015). Currently there are approximately 1.6 million people with T1D living in the United States, 1.4 million of which are aged  $\geq 20$  years or older. While the incidence of T1D is significantly greater among Whites (25.4 per 100,00) than Blacks (15.5 per 100,000), Blacks experience 65% more emergency department visits than the population with diabetes as a whole (Association, 2018). Underlying this disparity, Black individuals are more likely to develop IAH than White individuals, which dramatically increases their risk for severe hypoglycemia (van Meijel et al., 2020). Thus, Black individuals have a 39% greater risk of experiencing severe hypoglycemia requiring emergency services than White individuals (Karter et al., 2017; A. K. Lee et al., 2017). Further, per capita hospital inpatient costs among Blacks are 23% higher than Whites, likely because of the greater use of emergency services (Association, 2018). Such disparities in usage and outcomes highlight the consequences of structural issues that are currently not well understood, such as disparities in prescription of therapeutics like continuous glucose monitors between White and Black individuals, but must be explored further (Lipman et al., 2021).

The goal of treatment for IAH is hypoglycemia avoidance, as strict avoidance of hypoglycemia may be efficacious in restoring awareness for those with IAH (Cryer, Davis, & Shamoon, 2003). In fact, scrupulous avoidance of hypoglycemia for as few as 3 weeks has been shown to improve hypoglycemia awareness in most affected patients (Cranston, Lomas, Maran, Macdonald, & Amiel, 1994; Dagogo-Jack, Rattarasarn, & Cryer, 1994; C. Fanelli et al., 1994). Emerging therapies, including newer insulins (Singh et al., 2009), insulin pump therapies (Beato-Víborá et al., 2015; Quirós et al., 2016), and continuous glucose monitors (Pickup, Freeman, & Sutton, 2011) have demonstrated efficacy in their respective abilities to reduce time spent in hypoglycemia and risk for severe hypoglycemia in T1D. However, these interventions have a number of limitations hinging on healthcare professionals, user factors, education,

treatment adherence, accuracy and alarm fatigue (Choudhary & Amiel, 2018). Use of these technologies to promote hypoglycemia avoidance has reduced efficacy in individuals with IAH who may possess attitudes that promote hypoglycemia exposure. (S. A. Amiel, 2014; Choudhary & Amiel, 2018; Choudhary et al., 2010; Cook et al., 2019; Y. K. Lin et al., 2019; Rogers, De Zoysa, & Amiel, 2012; Smith, Choudhary, Pernet, Hopkins, & Amiel, 2009). Therefore, those with IAH remain least able to benefit from interventions that may reduce risk for severe hypoglycemia and help restore hypoglycemia awareness (Cook et al., 2019).

Even if such emerging therapies were shown to effectively treat IAH, racial disparities in outcomes would likely persist for a couple of reasons.

First, racial and ethnic minorities may face unique challenges to prevention and treatment of IAH, as racism is acutely and chronically stressful (Harrell et al., 2011) and may potentiate physiologic changes associated with IAH. Physiologic arousal associated with experiences of racism have been linked to physiologic changes through activation of the hypothalamic pituitary adrenal cortical system, which then initiate the release of stress hormones such as cortisol, and ultimately drives allostasis in immune and cardiovascular functioning (Harrell et al., 2011). In short, the experience of racism potentiates alterations in the very physiologic systems found to be impaired in those with IAH. Thus, in the same way that exercise, a physiologically stressful event, or previous hypoglycemia may blunt future sympathoadrenal responses to hypoglycemia, it is conceivable that such sympathetic activation associated with racism could have a similar effect. Such insight may be supported by observations of gradual attenuation, or habituation, of hypothalamic-pituitary-adrenal activity after repeated exposure to the stressors due to negative feedback inhibition (Jaferi, Nowak, & Bhatnagar, 2003). While we do not know the precise role that racism may play in IAH, the disparate outcomes and potential links indicate a need to better understand the experiences of racially minoritized populations.

Next, current and emerging technological interventions have failed to acknowledge important factors that may render them inaccessible. Inequitable prescribing practices have contributed to large disparities in usage of emerging technologies among racially minoritized populations (Lipman et al., 2021; Paris et al., 2009; Valenzuela, La Greca, Hsin, Taylor, & Delamater, 2011; Wong et al., 2014). Black individuals are less likely than Whites to use insulin pumps (18% versus 72%) and continuous glucose monitors (28% versus 71%) (Agarwal, Schechter, Gonzalez, & Long, 2021). These disparities in usage persist even when accounting for socioeconomic status, demographics, healthcare factors and management (Agarwal et al., 2021). We currently cannot explain why these disparities persist, yet they are in no small part due to a variety of structural, provider-, and patient-related factors that must be identified and addressed moving forward.

Additionally, science and practice have failed to adequately address attitudes towards emerging therapies in racially minoritized populations. Recent literature highlights the importance of recognizing attitudes for diabetes therapy and intervention in racially minoritized patient populations (Adams et al., 2018; Messer et al., 2020; Prahalad, Tanenbaum, Hood, & Maahs, 2018). A study on decision-making regarding emerging therapies in Black patients with type-2 diabetes revealed that many patients chose not to pursue newer treatments due to unaddressed fears that they believed were not adequately acknowledged by their healthcare providers. (Huang et al., 2009). Thus, future strategies for health care intervention must consider attitudes of racially minoritized patients toward treatment and communication, as well as account for unique cultural and historical contexts for effective intervention (Agarwal et al., 2021). While attitudes certainly are not the only reason why disparities exist, such findings highlight that remaining blind to such factors is negligent. Therefore, reliance on technological advancements alone to combat IAH and severe hypoglycemia may widen disparities; without consideration for attitudes and values (Riegel, Dickson, & Faulkner, 2016), those most in need

may remain least likely to benefit from emerging interventions.

My developing program of research aims to examine attitudes and self-care of individuals with T1D complicated by IAH to develop interventions that promote hypoglycemia avoidance, restore hypoglycemia awareness, and reduce risk for severe, life-threatening hypoglycemic events. Those with IAH who possess particular attitudes, such as fear of hyperglycemia and lack of concern about asymptomatic hypoglycemia, are at greater risk for recurrent severe hypoglycemia (Cook et al., 2019). In fact, evaluation of a psycho-education intervention to reduce hypoglycemia exposure in individuals with IAH found that greater endorsement of particular beliefs was associated with persistence of severe hypoglycemic events post-intervention (Sepúlveda et al., 2022). We hypothesize that the population of individuals with T1D and IAH, those who have been shown to hold potentially problematic attitudes toward glycemia, may engage in self-care behaviors that may promote hypoglycemia and impede restoration of awareness. For example, some individuals with IAH have unique attitudes (Cook et al., 2019; Rogers et al., 2012), such as prioritizing avoidance of hyperglycemia over risk of hypoglycemia (Cook et al., 2019; Sepúlveda et al., 2022), which may encourage behaviors, such as knowingly using more insulin than needed (Cook et al., 2019). Such attitudes are likely rooted in deeply internalized fear of the long-term complications of diabetes; namely, the micro- and macro-vascular changes associated with hyperglycemia that result in complications such as retinopathy, neuropathy, and nephropathy (Rogers et al., 2012). Such fears may arise from experiences such as knowing others who have suffered such complications or from anxiety generated by provider interactions (Rogers et al., 2012). Thus, these attitudes arise from various sources and may influence IAH through self-care in ways currently undescribed. As a result, these attitudes make hypoglycemia avoidance difficult and impede recovery of awareness (Cook et al., 2019; Rogers et al., 2012; Jane Speight et al., 2014). Fortunately, attitudes and self-care are modifiable (Cook et al., 2019; De Zoysa et al.,

2014). For example, psychoeducational interventions using motivational interviewing and cognitive behavioral techniques delivered by diabetes educators have shown significant capacity to improve motivation and cognitions around hypoglycemia in individuals with IAH and recurrent severe hypoglycemia. (Cook et al., 2019; De Zoysa et al., 2014) However, the paucity of research concerning attitudes and self-care in adults with IAH renders determining the extent to which attitudes inform self-care currently impossible (Cook et al., 2019). We hypothesize that individuals with T1D complicated by IAH hold unique attitudes that influence their self-care, that self-care may influence hypoglycemia exposure and therefore awareness status, and that self-care may cluster in adults with T1D with particular profiles corresponding better with IAH. Exploring attitudes in relation to self-care of individuals with T1D and IAH may help explain IAH development and perpetuation.

### Gaps in the Literature

In the past decade, attitudes were explored once qualitatively (Rogers et al., 2012), once quantitatively (Cook et al., 2019), and never in tandem with, or within a framework of self-care of chronic illness (Riegel, Jaarsma, Lee, & Strömberg, 2019; Riegel et al., 2012). Further, the most recent literature notes that further research is required to explicate factors responsible for disparities in diabetes treatments and outcomes (Lipman et al., 2021). Thus, there is a research gap regarding attitudes and self-care of this population and the relationship between attitudes and self-care remains to be determined. We think that individuals with T1D complicated by IAH possess differentiating attitudes and self-care, namely self-care maintenance, monitoring, and management behaviors (Riegel et al., 2019; Riegel et al., 2012), from those with intact awareness. Self-care maintenance is defined as those behaviors performed to maintain health such as medication taking (Riegel et al., 2019). Self-care monitoring is defined as symptom monitoring, detection, and interpretation. Self-care management is the response to symptoms

when they occur (Riegel et al., 2019). We are interested in filling this gap with this dissertation.

## Conceptual Underpinnings for the Study

The conceptual framework guiding this study is shown in Figure 1. This conceptual framework is specific to those with T1D complicated by IAH and is influenced by two theories: the Middle Range Theory of Self-Care of Chronic Illness, which addresses self-care maintenance, monitoring, and management within the context of chronic illness (Riegel et al., 2019; Riegel et al., 2012), and the Middle-Range Theory of Unpleasant Symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). In the conceptual model, I assert that diabetes attitudes, self-care of chronic illness, and IAH influence one another cyclically. For example, individuals who endorse 'minimalization of hypoglycemia' are hypothesized to engage in self-care that is less attentive to monitoring and treatment of hypoglycemia. A self-care profile like this is hypothesized to result in greater hypoglycemia exposure, which may result in IAH. As IAH is characterized by the blunting of unpleasant hypoglycemia symptoms, those with IAH may further endorse minimization of hypoglycemia concerns as the unpleasant stimuli previously associated with hypoglycemia vanishes. However, we do not know at which phase individuals enter this cycle. Theoretically, we have reason to believe that entry into the cycle is highly individualistic and may occur at either (1) attitudes or (2) self-care. We postulate that those who enter at self-care likely do so due to knowledge deficits (Rogers et al., 2012) or issues with access to treatment, whereas those who enter at attitudes likely enter due to problematic beliefs and motivations. We will begin discussion of the cycle at diabetes attitudes.

Diabetes attitudes are beliefs and motivations related to glycemia in diabetes (Cook et al., 2019; Rogers et al., 2012). Three prevailing diabetes attitudes have been identified in individuals with IAH: asymptomatic hypoglycemia normalization, minimalization of hypoglycemia, and hyperglycemia avoidance prioritization (Cook et al., 2019). These attitudes



are hypothesized to inform self-care of chronic illness in T1D. However, relationships between these attitudes and the three domains of self-care (i.e., maintenance, monitoring, and management) have not been discussed conceptually or measured in research.

Asymptomatic hypoglycemia normalization is characterized by the belief that treatment of asymptomatic hypoglycemia is unnecessary and bothersome, that foregoing treatment of mild hypoglycemia is inconsequential, and that cautious diabetes care is less important than 'living life to the fullest' (Cook et al., 2019). Conceptually, it appears that holding this attitude may influence all three domains of self-care. Regarding self-care maintenance, individuals may view activities to maintain their physical functioning and mental wellbeing as barriers to 'living life to the fullest'. Regarding self-care monitoring behaviors, the normalization of asymptomatic hypoglycemia may result in complete reliance on technology such as continuous glucose monitoring devices to detect changes in glycemia, and perhaps even the assumption that these devices can adequately replace endogenous awareness, resulting in much poorer self-care monitoring. Regarding self-care management behaviors, individuals with this attitude may forego treatment of hypoglycemia despite knowledge of being hypoglycemic if the episode is mild or asymptomatic, as it is viewed as inconsequential.

Minimization of hypoglycemia is characterized by an underestimation of the effects of hypoglycemia and a willingness to depend on others if hypoglycemic (Cook et al., 2019). Individuals who endorse this attitude do not worry about hypoglycemia nor do they believe that they will experience an episode of severe hypoglycemia in the future or that hypoglycemia impairs their functionality. With low concern of hypoglycemia, reduced risk-actualization for severe hypoglycemia, and confidence that help will be provided by others if needed, individuals who endorse this attitude may have less extrinsic motivation to engage in self-care maintenance behaviors to avoid hypoglycemia and restore awareness, monitoring behaviors to detect hypoglycemia or management behaviors to correct hypoglycemia.

Hyperglycemia avoidance prioritization is characterized by frustration and worry when hyperglycemic, belief that avoidance of hyperglycemia is more important than avoidance of hypoglycemia, conceptual understanding of 'good diabetes control' as avoiding high blood sugar, and endorsement of knowingly administering more insulin than needed (Cook et al., 2019). Maintaining this attitude may influence self-care maintenance, resulting in greater endorsement of activities (such as exercising) to reduce blood sugar, monitoring, resulting in more frequent activities to monitor for hyperglycemia, and management, resulting in more vigilant and potentially severe management of hyperglycemia such as insulin stacking or over-bolusing that can result in hypoglycemia.

These conceptual relationships are supported by the Theory of Self-Care of Chronic Illness (Riegel et al., 2019) which states that beliefs and motivations influence self-care. However, we do not have data to demonstrate how these diabetes attitudes influence self-care of chronic illness (Cook et al., 2019). Prior literature has assumed that particular attitudes inhibit (Rogers et al., 2012), or act as barriers (Cook et al., 2019), to self-care that promote hypoglycemia avoidance and recovery of awareness. Authors of current literature have stated that individuals who prioritize avoidance of hyperglycemia endorse the knowing administration of more insulin than needed for a meal or glycemic correction (Rogers et al., 2012). However, diabetes attitudes have not been examined within a framework of self-care and explicit relationships underlying the development and perpetuation of IAH have not been adequately described. Thus, the model shows a hypothesized direct relationship between attitudes and self-care.

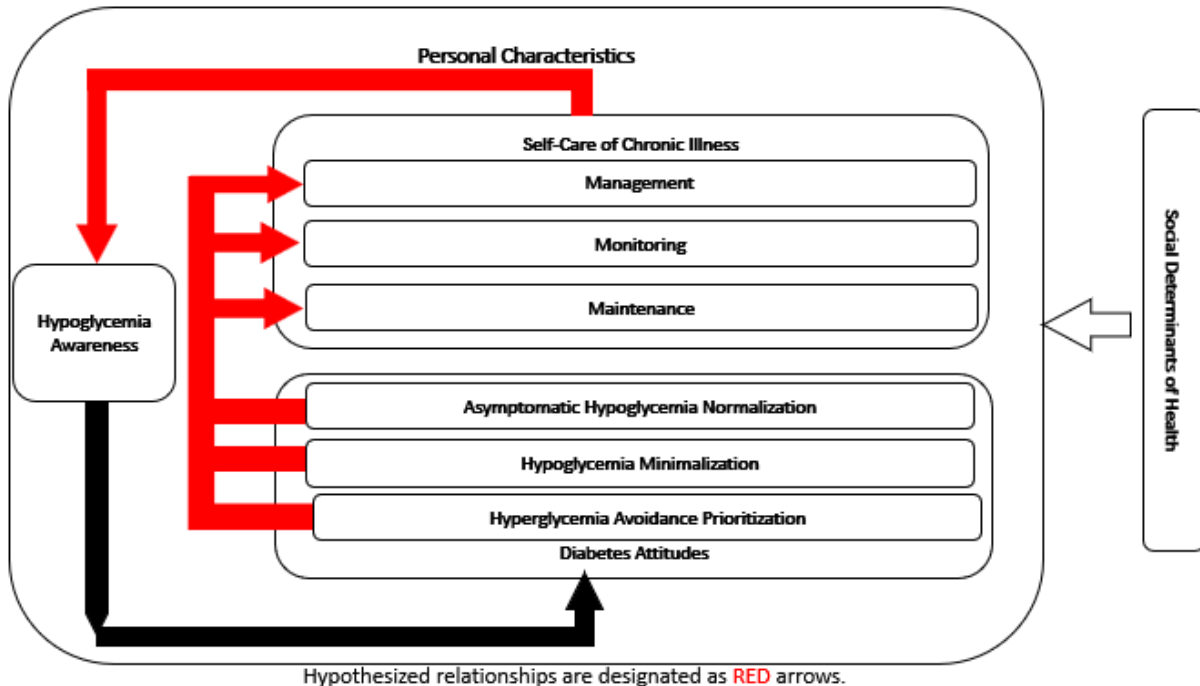
Next, we assert that self-care influences awareness status. Self-care behaviors may promote hypoglycemia, increase exposure to severe hypoglycemia and drive the neurologic and physiologic changes underlying IAH. For example, those who regularly over-bolus insulin as part of their self-care maintenance and self-care management will likely spend a larger

percentage of time in hypoglycemia: the main risk factor for developing IAH. Thus, these behaviors drive the onset of and entrenchment within IAH. Thus, we assert in this theoretical model a direct relationship between self-care and awareness status. However, the relationships between self-care domains and IAH status have not been described previously, so the relationship is displayed as hypothesized. Considering the proposed influence of attitudes on self-care and self-care on IAH, we hypothesize that attitudes will have an indirect influence on IAH status that is mediated by self-care.

Lastly, we assert that awareness status influences diabetes attitudes. IAH, through elimination of the hypoglycemia symptom experience, reinforces problematic diabetes attitudes and motivates the cycle. Those with IAH no longer generate the physiologic response to hypoglycemia, which is responsible for the symptom experience, and therefore no longer experience unpleasant hypoglycemia symptoms. According to the Middle Range Theory of Unpleasant Symptoms, symptom experience can moderate or mediate the relationship between physiologic and/or psychologic status and performance to treat a condition (Lenz et al., 1997). In individuals with intact hypoglycemia awareness, this process would involve hypoglycemia generating unpleasant symptoms such as shakiness and hunger, which are readily resolved by glucose ingestion. In IAH, individuals no longer experience the unpleasant symptoms or deficits associated with mild-to-moderate hypoglycemia that encourage (1) hypoglycemia avoidance and (2) correction of hypoglycemia when it occurs. Absent unpleasant hypoglycemia symptoms, individuals may begin to, or further, normalize hypoglycemia, minimize concerns of hypoglycemia, and prioritize unhelpful or problematic attitudes concerning hyperglycemia, further entrenching those with IAH in the proposed cycle (Cook et al., 2019). This theoretical assertion is supported by widespread findings. Physiologically, neuroimaging studies of individuals with IAH during hypoglycemia show failure to deactivate hedonic perception during hypoglycemia, which suggests that these individuals not only fail to experience hypoglycemia

symptoms, but they additionally fail to experience its danger or unpleasantness (J. T. Dunn, Cranston, Marsden, Amiel, & Reed, 2007; Rogers et al., 2012). Further, individuals with IAH fail to demonstrate the expected emotional response associated with recall of traumatic events of severe hypoglycemia as well as little to no motivation to act for future avoidance (Rogers et al., 2012).

In this dissertation, we have therefore identified diabetes attitudes and their relationship to self-care, understanding the role self-care may play in IAH, as a fundamental and targetable point for future intervention in the treatment of IAH. While current interventions, such as continuous glucose monitoring, have focused on assisting self-care to promote hypoglycemia avoidance and restore awareness, such interventions have failed to address the individual and their attitudes. Further, they do not address if, and if so how, individuals are implementing them in their self-care. To date, such interventions have been unsuccessful in restoring awareness for the majority of individuals with IAH. Our conceptual framework positions us to conduct a study that will elucidate if, and if so how, attitudes influence self-care, and how self-care clusters in this population, to begin a line of inquiry toward interventions that consider such factors in IAH development and entrenchment.



*Figure 1: Cycle of Attitudes, Self-care, and Hypoglycemia Awareness in T1D.* The model integrates self-care of chronic illness, impaired awareness of hypoglycemia, and diabetes attitudes. Self-Care of Chronic Illness is defined by the Middle-Range Theory of Self-Care of Chronic Illness (Riegel, Jaarsma, & Strömberg, 2012) and Diabetes Attitudes (Cook et al., 2019). The three integrated concepts relate to one another in a feedback loop, where self-care informs hypoglycemia awareness, hypoglycemia awareness informs diabetes attitudes, and diabetes attitudes informs self-care of chronic illness. The relationships between respective diabetes attitudes and domains of self-care of chronic illness are hypothesized. The relationships between self-care of chronic illness and IAH are hypothesized. The influence of Social Determinants of Health on awareness of hypoglycemia is known, but their influence on components of this cycle is not.

## Purpose

The purpose of this dissertation is to provide a clearer understanding of the relationships between attitudes and self-care in adults with T1D, characterize self-care profiles of individuals with T1D and identify those which correspond best with IAH, and develop a deeper understanding of the attitude and self-care relationships observed in a diverse sample of individuals with T1D complicated by IAH. As each aim builds on the prior, this dissertation ultimately provides the first description of attitudes and self-care in a diverse sample of individuals with T1D, characterization of how self-care clusters in T1D and on IAH, and exploration of attitudes and self-care in adults with T1D complicated by IAH. Illuminating the

unique relationships between IAH, self-care, and attitudes may offer actionable targets for future intervention to both prevent IAH development in those currently with intact awareness and treat IAH. This line of inquiry may fundamentally reorganize how providers approach treatment for individuals with this complication, as current interventions fail to address attitudes, self-care and their relationship in the development and perpetuation of this complication adequately.

Furthermore, as vulnerable populations lack access to many of the current and developing interventions against IAH, this line of inquiry may spur development of interventions to address the needs and priorities of those most challenged by IAH and vulnerable to severe hypoglycemia. The specific aims of this dissertation are threefold:

Quantitative Phase:

1. Identify self-care clusters that correspond best with IAH classification in adults with T1D.

*H1.* Self-care may cluster in adults with T1D, and particular self-care clusters may correspond better with IAH classification.

*Sub-aim 1:* Describe the relationship between attitudes and self-care in adults with T1D.

*H2.* Individuals with T1D complicated by IAH hold unique attitudes that influence their self-care.

*Sub-aim 2:* Describe the relationship between self-care and IAH in adults with T1D.

*H3.* Self-care maintenance, monitoring, and management each influence IAH.

Qualitative Phase:

2. Explore attitudes and self-care in a racially diverse group of adults with T1D with IAH.

*H4.* More deeply exploring attitudes and self-care within clusters of interest, namely those which correspond best with classification of IAH, may help elucidate psychobehavioral mechanisms of development and perpetuation.

### Integrated Phase

3. Integrate quantitative and qualitative findings to develop meta-insights regarding the relationship between attitudes and self-care in individuals with T1D and IAH.

*H5.* Integration of quantitative and qualitative findings will present targettable differences in attitudes and self-care associated with IAH as well as avenues for future inquiry to more deeply understand and address these psychobehavioral targets.

### Approach

This dissertation employed a mixed methods study (QUANT→qual) with an explanatory sequential design with greater emphasis placed on the quantitative portion to address the study purpose. The qualitative component then helped explain the quantitative results (Creswell & Plano Clark, 2011; Sandelowski, 2000). The first phase (quantitative) employed a cross-sectional, web-based survey using validated measures to assess hypoglycemia awareness status (Geddes, Wright, Zammit, Deary, & Frier, 2007), attitudes (Cook et al., 2019), and self-care (Ausili, Barbaranelli, & Riegel, 2020) of adults with T1D recruited from Penn Medicine, a major multi-hospital health system. Expected enrollment was 200 adults with T1D, of which 50 were anticipated to screen positive for IAH (Cook et al., 2019).

In the second phase (qualitative) a qualitative descriptive study was conducted to explore attitudes, self-care, and their relationship qualitatively using individual semi-structured interviews (Creswell & Plano Clark, 2011; Sandelowski, 2000). A criterion sample (n=20) of individuals with IAH was selected to interview, with priority given to those from clusters determined to correspond most with IAH classification, assuring racial variability in subject selection (Creswell & Plano Clark, 2011; Sandelowski, 2000). Content analysis of the interview data (Sandelowski, 2010) was performed to explore the attitudes and self-care concepts described in the quantitative phase. (Addresses Aim 2).

Integration of data occurred in the process throughout as described in the methods section, including after the qualitative phase to produce an integrated finding that leveraged the strengths of the quantitative and qualitative data (addresses Aim 3).

## Innovation

This dissertation presents the first comprehensive description of attitudes and self-care of individuals with T1D with IAH. As such, this dissertation is the first of its kind to describe the relationships between attitudes, self-care, and IAH in T1D, offer self-care profiles of individuals with T1D, and then explore self-care and attitudes within these profiles qualitatively to expand results. This research is innovative for several reasons:

1. Mixed methods designs are underutilized (McLaughlin, Bush, & Zeeman, 2016). This approach was particularly beneficial for the predoctoral training period, as it offered opportunities for development in quantitative, qualitative, and mixed methods research. Further, this design produced both hypothesis-testing data to address current gaps in the science and hypothesis-generating data to inform future lines of inquiry (Johnson & Onwuegbuzie, 2004).
2. The conceptual underpinnings of the proposed study positioned it to address the well-documented racial disparities in prevalence of IAH and incidence of severe hypoglycemia (Karter et al., 2017; Lai et al., 2021; Lipman et al., 2021; van Meijel et al., 2020; Willi et al., 2015). As the scientific research in the field of IAH is currently centered on development of technological interventions, this study was designed to identify targets for intervention that may play a critical role in the development and prolongation of IAH, which also may be addressed by more accessible interventions.
3. This dissertation is the first study to measure self-care, attitudes and IAH together in individuals with T1D. To this point, the relationship between attitudes and self-care in IAH have been postulated or assumed (Rogers et al., 2012). This study provides insight into similarities,



differences, and deficits in self-care between those with and without IAH. With this information, clinicians may be more able to assess problematic behaviors perpetuating hypoglycemia, and researchers may be better positioned to develop targeted interventions to improve problematic self-care.

4. This dissertation provides a novel description of attitudes and self-care in a racially diverse sample of individuals with T1D. As such, this study may identify common experiences and elucidate barriers to equitable care for racially minoritized populations with T1D.

## Summary

Hypoglycemia is an inevitable consequence of insulin therapy. Individuals with T1D rely on symptom perception as the primary physiologic defense against developing severe hypoglycemia. Up to 60% of individuals with T1D experience blunting of the sympathoadrenal response to hypoglycemia that results in IAH. Those with IAH have a significantly higher likelihood of experiencing severe, life-threatening hypoglycemia. Racial disparities exist between Black and White individuals regarding incidence of severe hypoglycemia and prevalence of IAH. Further, current approaches to remedying IAH rely on advanced technologies, a form of intervention that is not implemented equitably.

To reduce risk for severe hypoglycemic events and disparities, novel approaches to understanding IAH are warranted. Hypoglycemia awareness may be restored with significant hypoglycemia avoidance (with improvements in as few as 3 weeks and complete restoration within 6-months), yet many individuals are unable to achieve sufficient avoidance to restore awareness, perhaps due to self-care that causes frequent iatrogenic hyperinsulinemia, and resultant hypoglycemia. Individuals with IAH have been shown to hold unique attitudes and beliefs that may influence self-care and subsequently glycemic outcomes and hypoglycemia awareness. This dissertation was designed to determine if attitudes influence self-care and

describe how self-care may influence hypoglycemia awareness status in adults with T1D. It was additionally designed to describe and explore the common self-care profiles of individuals with T1D and identify which, if any, corresponds best with IAH status.

# CHAPTER TWO: REVIEW OF THE LITERATURE

## Background

### The Extent of the Issue

Severe hypoglycemia persists as a challenge for those living with type 1 diabetes (T1D) regardless of marked developments in both insulin analogs and therapeutic technologies such as continuous glucose monitoring (CGM) and automated insulin delivery systems (Committee, 2022; Kaur & Seaquist, 2022). Severe hypoglycemia can be understood as an episode of hypoglycemia requiring third-party assistance to treat, such as administer carbohydrate, glucagon, or other resuscitative actions (Geddes, Schopman, Zammitt, & Frier, 2008). Episodes of hypoglycemia may be distressing and life-threatening (Matus, Trout, Sawyer, & Riegel, 2022). Among those younger than 30 years, acute metabolic complications of T1D are the most frequent cause of mortality (Feltbower et al., 2008; Skriverhaug et al., 2006). While mortality related to hypoglycemia is estimated at 10%, it is likely much higher given the presence of twice as many unexplained diabetes-related deaths (Cryer, 2013b). Not infrequently, individuals are discovered “dead-in-bed” (Tanenberg, Newton, & Drake, 2010; Tattersall & Gill, 1991), a tragic consequence of likely severe hypoglycemia resulting in brain death (Auer, 2004) or fatal cardiac arrhythmia (Tu, Twigg, & Semsarian, 2010). In fact, individuals reporting an episode of severe hypoglycemia experience a 3.4-fold increase in mortality over the subsequent 5 years (McCoy et al., 2012).

In T1D, individuals experience hypoglycemia because of acute insulin excess coupled with impaired counterregulatory mechanisms to defend against hypoglycemia development (Cryer, 2013b). Due to impaired counterregulatory defenses, individuals with T1D rely on the detection and interpretation of autonomic symptoms of hypoglycemia to cue treatment of hypoglycemia before an episode becomes severe. Problematically, frequent exposure to

hypoglycemia results in an attenuation of the sympathoadrenal and sympathetic neural responses to hypoglycemia, which clinically manifests in reduction of detectable autonomic symptoms and generally impaired awareness of hypoglycemia (IAH) when hypoglycemic (Cryer, 2013b). Roughly one-third of those with T1D experience IAH, which increases their risk for experiencing severe hypoglycemia as much as 20-fold. (Pedersen-Bjergaard et al., 2004)

Approximately 1/3 of individuals with IAH have experienced severe hypoglycemia within the past year (Geddes et al., 2008; Pedersen-Bjergaard et al., 2004). While not all who experience severe hypoglycemia have IAH, those with IAH are much more likely to experience hypoglycemia than peers with intact awareness, and those who experience a single episode of severe hypoglycemia, which is approximately 10% of individuals with T1D, are significantly more likely to experience future episodes of severe hypoglycemia (Geddes et al., 2008). As a result, more than 50% of episodes of severe hypoglycemia are experienced by approximately 5% of the population of individuals with T1D (Pedersen-Bjergaard et al., 2004). In the United States, there is approximately \$18 billion in diabetes-associated healthcare expenditures and indirect costs annually (Association, 2018; Prevention).

### Physiology of Impaired Awareness of Hypoglycemia

Risk for experiencing severe hypoglycemia increases with long standing disease due to progressive development of compromised physiologic defenses against descending glycemic concentrations in the environment of hyperinsulinemia. Risk of experiencing severe hypoglycemia is 300% greater for individuals with more than 15 years compared with fewer than 5 years of disease duration (Group, 2007). Those with T1D, and particularly longer disease duration, are at great risk for developing severe hypoglycemia due to their near-complete destruction of  $\beta$ -cells (C-peptide negative) (Tsai, Sherry, Palmer, & Herold, 2006), which also results in the loss of autoregulatory capacities such as turning off endogenous insulin secretion

when hypoglycemia is impending. As insulin secretion reciprocally regulates glucagon secretion (Cooperberg & Cryer, 2010), loss of paracrine signaling from  $\beta$ -cells to neighboring  $\alpha$ -cells that insulin secretion is ceasing leads to associated defect in glucagon secretion from  $\alpha$ -cells in response to hypoglycemia (Gerich, Langlois, Noacco, Karam, & Forsham, 1973; McCrimmon, 2009; Tsai et al., 2006). Additionally, centrally mediated mechanisms for hypoglycemia avoidance are damaged in T1D too (Mundinger et al., 2016). Because of the islet inflammation that drives T1D development, individuals with T1D have shown (1) sympathetic islet neuropathy that may contribute to defects in activating glucagon secretion in hypoglycemia and (2)  $\alpha$ -cell downregulation of gene expression important for cell identity which may drive functional defects in the context of hypoglycemia (Mundinger et al., 2016). Under normal physiologic circumstances, the coupling of reduced serum insulin and increased serum glucagon delivered to the liver increases endogenous glucose production to prevent the development of hypoglycemia. In T1D, this mechanism is impaired and individuals are predisposed to hypoglycemia (Rickels, 2019).

As such, those with T1D rely on perception of autonomic symptoms of hypoglycemia-associated sympathoadrenal activation, namely epinephrine secretion, to detect and treat hypoglycemia before it becomes severe (Cryer et al., 2003; Smith et al., 2009). Central recognition of hypoglycemia by the brain activates sympathetic and parasympathetic branches of the autonomic nervous system. In addition to the physiologic actions that promote endogenous glucose production, this sympathoadrenal activation in response to hypoglycemia alerts the individual to ingest food (Cryer et al., 2003). Problematically, repeated exposure to hypoglycemia attenuates the sympathoadrenal response to hypoglycemia via allostatic lowering of the range and set point at which the sympathoadrenal response to hypoglycemia occurs, impairing both endogenous glucose production and autonomic symptom generation (Cryer, 2016; Cryer & Arbelaez, 2018). Frequent exposure to hypoglycemia, even that which is

relatively mild, progressively lowers this threshold, until the point at which an individual may become unconscious before experiencing symptoms, a complication known as known as hypoglycemia-associated autonomic failure (Cryer & Arbelaez, 2018). Individuals with hypoglycemia-associated autonomic failure are physiologically defenseless against hypoglycemia, and with such marked reduction in autonomic symptoms, unaware of hypoglycemia when it occurs (Rickels, 2019). These physiologic changes underlie the condition which is clinically referred to as IAH (Towler, Havlin, Craft, & Cryer, 1993).

Neurologically, individuals with IAH display differences in metabolism, structure, and activation of brain regions in IAH (Bednarik et al., 2017; Critchley, Mathias, & Dolan, 2001, 2002; Critchley, Wiens, Rotshtein, Ohman, & Dolan, 2004; Joel T. Dunn et al., 2018; Moheet, Mangia, & Seaquist, 2015; Nwokolo et al., 2019; Quadt, Critchley, & Garfinkel, 2018). Individuals with IAH both recruit more brain regions to preserve cognitive function during hypoglycemia and experience more profound cognitive dysfunction during hypoglycemia that persists longer following blood glucose recovery than peers without IAH (Joel T. Dunn et al., 2018; Leelarathna et al., 2013; Martín-Timón & Cañizo-Gómez, 2015; Nwokolo et al., 2019)

It is important to note that additional factors exist that are not required for the development of hypoglycemia-associated autonomic failure but may contribute to impaired awareness of hypoglycemia in individuals with T1D with comorbid complications including aspects of systematic autonomic failure (Aleppo et al., 2017), cardiovascular autonomic neuropathy (Hoeldtke, Boden, Shuman, & Owen, 1982; Meyer et al., 1998), and use of pharmacologic agents such as  $\beta$ -adrenergic blockade (Popp, Tse, Shah, Clutter, & Cryer, 1984; Rickels, 2019; Weinstock et al., 2016). For the purposes of this dissertation, we are focusing on IAH secondary to hypoglycemia-associated autonomic failure.

## Reversal of IAH

IAH is the clinical manifestation of neural allostasis to a frequently neuroglycopenic environment (Teh et al., 2010), and hypoglycemia awareness may be restored with substantial hypoglycemia avoidance (Cryer, 2013b; Teh et al., 2010). Reversal of hypoglycemia-associated autonomic failure, and subsequently IAH, requires glycemic avoidance sufficient to shift glycemic thresholds for activation of sympathoadrenal responses to hypoglycemia back toward normal range for glycemia (Rickels, 2019). Research in patients with T1D and IAH who received intrahepatic islet cell transplantation demonstrates that  $\geq 95\%$  of time spent in the target range of 70–180 mg/dL can achieve significant improvement in hypoglycemia counterregulation, symptom generation, and symptom detection in as little as 6 months (Rickels et al., 2016).

Historically, initial strategies to promote hypoglycemia avoidance to treat IAH included recommendations to set a higher HbA<sub>1c</sub> target for those with significant hypoglycemia. This recommendation was based on previous literature suggesting that intensive insulin therapy increases the risk of experiencing hypoglycemia ("Hypoglycemia in the Diabetes Control and Complications Trial. The Diabetes Control and Complications Trial Research Group," 1997). However, inadequate glycemic control may result in diabetic retinopathy, nephropathy, and neuropathy: the leading causes of blindness (R. Lee, Wong, & Sabanayagam, 2015), kidney failure (Bouhairie & McGill, 2016), and non-traumatic amputation (Li, Burrows, Gregg, Albright, & Geiss, 2012) in adults in the United States. Additionally, in the modern climate of T1D management, it appears that severe hypoglycemia impacts roughly half of individuals with long-standing T1D regardless of glycemic control, as indicated by HbA<sub>1c</sub> (Pettus et al., 2019; Weinstock et al., 2016). Therefore, recommendations to set a higher HbA<sub>1c</sub> target for those with significant hypoglycemia may no longer be appropriate as they are unlikely to impact the burden of severe hypoglycemia in T1D and may not be acceptable to those aiming to avoid or mitigate

risk for micro- and macrovascular complications of T1D.

Other approaches, including educational programs such as HypoCOMPass (S. A. Little et al., 2014), Blood Glucose Awareness Training (Daniel J. Cox et al., 2006), and Dose Adjustment for Normal Eating - Hypoglycaemia Awareness Restoration Training (De Zoysa et al., 2014) have each shown some effectiveness to promote hypoglycemia avoidance and reduce frequency of severe hypoglycemia. The HypoCOMPass was primarily rooted in intensive attention to glycemic control strategies for hypoglycemia avoidance without relaxation of glycemic control, where subjects were enrolled and randomly assigned to insulin delivery treatments by multidose daily injections or continuous subcutaneous insulin infusion and glucose monitoring by self-monitoring of blood glucose (i.e., fingerstick) with or without adjunctive CGM. In this study, time below 54 mg/dL was reduced by approximately 55%, although time below more mild hypoglycemic thresholds such as 70 mg/dL were not reported (S. A. Little et al., 2014). Modest improvements in autonomic symptom response to hypoglycemia were observed regardless of insulin delivery or glucose monitoring strategy (S. A. Little et al., 2014), although overall compliance with device use in the CGM arm was low (S. A. Little et al., 2014; Rickels, 2019).

The Blood Glucose Awareness Training is an 8-week program with weekly training to promote focus on internal sensations to cue identification and treatment of hypoglycemia. This intervention has been shown to improve blood glucose estimation amongst individuals with IAH, and reduce hypoglycemia exposure in those with intact awareness (Daniel J Cox et al., 1989).

The Dose Adjustment for Normal Eating- Hypoglycaemia Awareness Restoration Training pilot study (De Zoysa et al., 2014) assessed the effectiveness of courses aimed at addressing motivational and cognitive barriers to avoiding hypoglycemia in adults with T1D and persistent IAH despite training in flexible insulin therapy (Dafne Study, 2002). This intervention was able to restore awareness in 45% of participants by self-report classification. However,



while each intervention has demonstrated some level of effectiveness to either promote hypoglycemia avoidance or restore hypoglycemia awareness in some, many patients with IAH remain unaware and continue to have episodes of severe hypoglycemia (Rickels, 2019).

As emerging technologies become more and more available, many have looked to the implementation of tools such as CGM to improve upon previous interventions that promote hypoglycemia avoidance at the cost of requiring elevated average glycemia, or as an adjunct to education-based interventions (Rickels, 2019). While studies have shown that high levels of adherence to CGM use is associated with reduction in hypoglycemia frequency and severity without increasing average glycemia, these studies have failed to consistently demonstrate improvements in hypoglycemia awareness and eradication of severe hypoglycemia episodes with this technology (Beers et al., 2016; Choudhary et al., 2013; Hermanns, Heinemann, Freckmann, Waldenmaier, & Ehrmann, 2019; Rickels et al., 2018). In a study that assessed the effectiveness of CGM to promote hypoglycemia avoidance and restore the counterregulatory response to hypoglycemia in adults with IAH, CGM demonstrated the ability to promote approximately 40% avoidance of hypoglycemia over an 18-month intervention period, but was not able to achieve significant improvement in hypoglycemia counterregulation, symptom generation and symptom detection (Rickels et al., 2018). Contextualizing these findings against those of the Islet Cell transplant study (Rickels et al., 2016), we therefore understand that the threshold of hypoglycemia avoidance sufficient to restore hypoglycemia awareness lies somewhere between 40% and 95%. However, we do not know precisely where the threshold of avoidance to restore hypoglycemia awareness lies, but we do know that widely available interventions do not reliably meet it in this population (Rickels et al., 2018).

A limitation of emerging interventions such as CGM is that such interventions depend on patients to respond appropriately to device alerts and alarms to ingest carbohydrates or suspend insulin delivery to prevent or correct hypoglycemia (Rickels, 2019). If not implemented

properly, the devices cannot promote hypoglycemia avoidance sufficiently. In fact, factors including attitudes toward glycemia have demonstrated an influence on the effectiveness of interventions to support hypoglycemia avoidance in individuals with IAH (Sepúlveda et al., 2022). Overall, various approaches including technological interventions, educational programs, and clinical recommendations to-date have been ineffective in achieving hypoglycemia avoidance adequate to restore awareness for all individuals with IAH (Heinemann et al., 2018).

Newly developed technologies such as automated insulin delivery systems address some of these issues. In an 18-month study to assess the effectiveness of automated insulin delivery systems to reduce hypoglycemia exposure and restore the counterregulatory response to insulin-induced hypoglycemia in adults with long-standing T1D and IAH, these systems demonstrated the ability to reduce hypoglycemia exposure by 85%, with a 50-fold reduction in time spent in hypoglycemia while asleep and improvement in autonomic symptom responses to insulin-induced hypoglycemia (Anneliese J. Flatt et al., 2023). Despite the effectiveness of this intervention, reliance on technology alone to restore awareness may have unforeseen consequences due to disparities in access.

### Current Approaches Potentially Drive Disparities

Large racial disparities exist between White and Black individuals regarding T1D treatments and outcomes (Agarwal et al., 2021; Lipman et al., 2021; Willi et al., 2015). Black individuals are more likely to experience severe hypoglycemia (A. K. Lee et al., 2017) and develop IAH than White individuals. A seven-year observational study showed that Black individuals had consistently higher rates of severe hypoglycemia compared to White individuals (Karter et al., 2017). Relative to White individuals, Black individuals showed a 1.7-fold higher rate of severe hypoglycemia (Karter et al., 2017). Even in children, Black individuals were shown to be 250% more likely to experience severe hypoglycemia than White individuals when

adjusting for gender, age, diabetes duration, and socioeconomic status (Willi et al., 2015). Further, non-Caucasian ethnicity has been associated with IAH, a known risk-factor for severe hypoglycemia (van Meijel et al., 2020). Currently, research regarding avoidance of hypoglycemia and treatment of IAH is focused on technologies such as CGM or insulin pumps with automated insulin delivery.

Emerging technologies hold potential for treating IAH, but sole reliance on their use for treatment may exacerbate existing disparities in IAH and hypoglycemia-related outcomes due to inequitable implementation. Prescription and implementation of therapeutic technologies are unequal, with White children more likely to be prescribed insulin pumps and CGM systems than Black children (Lipman et al., 2021; Paris et al., 2009; Valenzuela et al., 2011; Wong et al., 2014). Similarly, Black individuals are less likely to use advanced technologies for diabetes care than White individuals (Agarwal et al., 2021; Lipman et al., 2021; Willi et al., 2015), and more likely to discontinue their use within a year (Lipman et al., 2021). Even after controlling demographic, health care, and diabetes-specific factors, these disparities persist (Agarwal et al., 2021). Relying solely on technology to address IAH neglects the importance of addressing disparities in technology access and use, which could widen existing disparities in health outcomes.

### Support for a New Approach: Examine Self-care and Attitudes in IAH

A large proportion of those with IAH have failed to benefit from interventions to promote hypoglycemia avoidance (Cook et al., 2019), perhaps in-part because individuals with IAH have been shown to hold unique attitudes that likely inform self-care behaviors that promote hypoglycemia and perpetuate IAH (Cook et al., 2019; Rogers et al., 2012). Furthermore, technological interventions that have shown promise are implemented inequitably (Agarwal et al., 2021) and sole reliance on their use as a therapeutic to treat IAH may widen disparities in

health outcomes. Therefore, there remains a need to improve understanding of potentially modifiable patient-level factors contributing to hypoglycemia exposure and IAH such as self-care. Further investigation into the self-care and attitudes of individuals with T1D and IAH, particularly in a racially diverse sample, may provide insight into the challenges of past interventions as well as a fruitful avenue for future intervention.

### *Self-Care of Chronic Illness*

Self-care is defined as a process of maintaining health through health promoting practices and managing illness (Riegel et al., 2012). The process of self-care involves self-care maintenance, self-care monitoring, and self-care management (Ausili et al., 2017). Self-care is a decision-making process influenced by reflection, motivation, beliefs/values, access to care, and symptoms (Riegel et al., 2012; Riegel et al., 2019).

Self-care may play a key role in diabetes treatment, as it improves metabolic control (Ausili et al., 2017) and quality of life (Shrivastava, Shrivastava, & Ramasamy, 2013), while also reducing risk for complications, hospitalizations, and mortality rates (Powers et al., 2015). Each phase of the self-care process and factors unique to IAH influencing that phase are discussed below.

### *Self-Care Maintenance*

Self-care maintenance in diabetes involves those behaviors performed to maintain stability and health (Ausili et al., 2020). Self-care maintenance in diabetes includes proper adherence to diabetes treatments (i.e., medication regimen, scheduled visits) and health-promoting behaviors (healthy diet) and engagement in physical activity (Ausili et al., 2017). However, adherence to this plan requires beliefs and motivations to achieve outcomes aligned with those of the developed plan. Individuals with IAH have been shown to possess differentiating beliefs from peers with intact awareness and reduced motivation to avoid hypoglycemia (Cook et al., 2019). While the experience of having symptoms can motivate

chronically ill individuals to perform self-care (Riegel et al., 2019), it is likely that the absence of symptoms observed in IAH reinforces maladaptive beliefs and lack of motivation to restore awareness (Rogers et al., 2012).

Motivation is a central concept to self-care maintenance. Motivation may be defined as the force driving humans to achieve their goals (Riegel et al., 2012). Motivation, particularly extrinsic motivation, involves performing or changing behavior to achieve a predetermined outcome that is desirable, such as health improvement (Riegel et al., 2012). Neuroimaging studies suggest that IAH is associated with altered activation of brain regions involved in reward responses and hedonic valance (Bingham et al., 2005; J. T. Dunn, Cranston, Marsden, Amiel, & Reed, 2007). In contrast to individuals with normal hypoglycemia awareness, those with IAH are not only unaware of hypoglycemia when hypoglycemic but also chronically unaware of its dangers or unpleasantness (Rogers et al., 2012). This serves as evidence that these individuals fail to experience protective emotional feedback to motivate against hypoglycemia. This may result in maladaptive self-care maintenance behaviors that potentiate hypoglycemia and drive IAH entrenchment.

### *Self-Care Monitoring*

Self-care monitoring in diabetes includes those behaviors employed to monitor, recognize, and interpret signs and symptoms (i.e., blood glucose monitoring) (Ausili et al., 2020). Self-care monitoring involves routine, vigilant body monitoring (Ausili et al., 2017). This phase of self-care aims to recognize changes (e.g., symptoms) and correctly interpret how to act (Ausili et al., 2017). This phase of self-care links self-care maintenance to self-care management (Ausili et al., 2017).

Symptom perception, the newest concept of the Situation Specific Theory of Heart Failure Self-Care (Riegel et al., 2016), plays a vital role in informing action taken in response to disease-related physiologic changes in heart failure and may play a similar role in T1D

(although there is not a situation specific theory of diabetes self-care to refer to at this time). Symptom perception is the detection of physical changes and interpretations of their meaning. Detection refers to the recognition of afferent physiological information. Interpretation refers to the attribution of a symptom experience to the appropriate source (Riegel et al., 2018). Individuals with IAH possess hypoglycemia-associated autonomic failure, resulting in the absence of physiologic cues that may be detected by individuals with hypoglycemia to interpret and link to T1D and hypoglycemia. CGM may help mitigate some of endogenous IAH through alerts and alarms (Rickels et al., 2018). However, due to inequities in technology implementation, many individuals with T1D do not have access to external monitors to alert them of hypoglycemia (Agarwal et al., 2021). Furthermore, evidence suggests that such alerts and alarms fail to address the needs of these individuals at nighttime (Rickels et al., 2018). Thus, symptom perception is limited, and self-care monitoring is likely severely altered in individuals with IAH.

### *Self-Care Management*

Self-care management in diabetes refers to those behaviors employed when signs and symptoms occur or when a health problem needs treatment (e.g., take a corrective dose of insulin when hyperglycemic, intake oral glucose when hypoglycemic). This phase of self-care involves implementation and evaluation of treatment. Failure to engage in self-care management for hypoglycemia may result in prolonged hypoglycemia that (1) potentiates neural allostasis to a neuroglycopenic environment, leading to hypoglycemia-associated autonomic failure and IAH, and (2) may result in severe hypoglycemia and death.

Both self-care maintenance and self-care monitoring influence the self-care management behaviors of individuals with IAH. For example, those with IAH may engage in self-care maintenance behaviors, such as intentionally bolusing more insulin than needed for a meal, influenced by maladaptive beliefs (e.g., overestimation of the consequences of

hyperglycemia) and motivations (e.g., hyperglycemia avoidance prioritization) (Rogers et al., 2012). This self-care maintenance behavior may then cause hypoglycemia. During self-care monitoring, this individual with IAH remains unaware of their hypoglycemia, fails to interpret bodily changes as symptoms, and therefore cannot recognize the symptoms as being linked to T1D and hypoglycemia. Without symptom detection and interpretation, self-care management does not occur (Riegel et al., 2019). At the self-care management level, an individual who prioritizes hypoglycemia avoidance may overbolus insulin intentional to correct hyperglycemia. In either instance, this individual is much more likely to experience prolonged, worsening hypoglycemia that drives chronic complications such as IAH and increases risk for acute complications such as severe hypoglycemia requiring third party assistance and death.

#### *Attitudes in Type-1 Diabetes Mellitus*

Attitudes may be understood as potentially modifiable beliefs, or sets of beliefs, and motivations which may influence behaviors that promote or hinder avoidance of hypoglycemia (Cook et al., 2019; Rogers et al., 2012). Attitudes have only recently begun to be explored in individuals with T1D complicated by IAH. In the only qualitative exploration of beliefs and coping strategies for individuals with IAH, attitudes fell into two categories: high concern, and low concern. Individuals of high concern reported experiences of hypoglycemia as frightening, disabling, and embarrassing. They recognized that action was needed to regain hypoglycemia awareness so that severe hypoglycemia may be avoided or minimized. Those with low concern presented as less motivated to address their impaired awareness of hypoglycemia (Rogers et al., 2012).

Individuals with high concern represented those with IAH who reflected the general motivation to engage in action to restore awareness yet had failed to restore awareness regardless. However, this group was relatively small (Rogers et al., 2012). According to Leventhal's Common Sense Model (Leventhal, Diefenbach, & Leventhal, 1992), the authors

speculated that this group may benefit from further information about their personal blood glucose responses to insulin, such as through careful tracking of blood glucose and insulin dosages, without further preparation for change (Rogers et al., 2012). Education-based interventions in skill-development such as Blood Glucose Awareness Training (Daniel J. Cox et al., 2006) or technologies such as real-time CGM (Hood, Dimeglio, & Riddle, 2020; Rickels et al., 2018) may have addressed the needs of this subpopulation well. Given the widespread availability of these interventions, it is quite possible that an even larger majority of individuals with IAH would now fall into the low concern group.

Those in the low concern group demonstrated less motivation to address their impaired awareness of hypoglycemia and were readily clustered into four subgroups: (a) normalization of hypoglycemia, (b) underestimation of hypoglycemia, (c) avoidance of the sick role, and (d) overestimation of hyperglycemia (Rogers et al., 2012). Individuals who (a) normalize hypoglycemia demonstrated low concern most likely secondary to knowledge deficits and subsequent misperception of cause and symptom recognition. Those who (b) underestimated hypoglycemia were supported by reliance on others, as a means for reducing the perceived consequence of severe hypoglycemia. Those who (c) avoided the sick role were those who chose to keep hypoglycemic episodes hidden from others, which encouraged them to avoid taking appropriate action themselves to avoid reactions from others. Finally, those who (d) overestimated hyperglycemia demonstrated beliefs that minimized the consequences of impaired awareness of hypoglycemia and maximized those of hyperglycemia; their low concern for hypoglycemia was a result of the heightened perceived consequences of hyperglycemia (Rogers et al., 2012). Thus, there are various attitudes that seem pertinent to this population, each which may therefore inform aspects of self-care in unique but currently unknown ways that were explored further in this dissertation.



## Summary

A large proportion of those with IAH have failed to benefit from interventions to promote hypoglycemia avoidance (Cook et al., 2019). In-part, individuals have failed to benefit from interventions because individuals with IAH have been shown to hold unique attitudes. In IAH, individuals often underestimate the consequences of hypoglycemia and disproportionately overestimate the consequences of hyperglycemia (Cook et al., 2019; Rogers et al., 2012). This value assessment likely informs self-care that promotes hypoglycemia and perpetuates IAH (Cook et al., 2019; Rogers et al., 2012). For example, individuals with IAH have endorsed knowingly administering more insulin than needed, a practice which frequently results in hypoglycemia exposure and IAH (Cook et al., 2019). Further, individuals with persistent IAH consistently report reduced motivation to regain awareness. Such attitudes may explain the reduced motivation to regain awareness and adhere to therapeutic decisions observed in IAH (Rogers et al., 2012). Such attitudes and self-care make hypoglycemia avoidance challenging and hinder recovery of awareness (Cook et al., 2019; Rogers et al., 2012; Jane Speight et al., 2014). As a result, interventions that do not address these attitudes have failed to restore awareness in half of these individuals (S. A. Amiel, 2014; Y. K. Lin et al., 2019; Rogers et al., 2012; Smith et al., 2009). Presumably other misconceptions and behaviors exist but they have not been studied. Without addressing attitudes, even costly emerging technologies may fail to promote hypoglycemia avoidance adequately to restore hypoglycemia awareness (Smith et al., 2009). This compelling evidence illustrates the importance of addressing hypoglycemia in T1D with novel approaches that may spawn more accessible interventions.

## CHAPTER THREE: METHODS

### Purpose

The purpose of this study was to describe relationships between glycemia attitudes, self-care domains, and hypoglycemia awareness classification, and to define self-care profiles and identify which self-care profile(s) corresponded most with impaired awareness of hypoglycemia (IAH) classification in adults with type 1 diabetes (T1D). Additionally, we sought to contextualize quantitative findings via qualitative, then integrative, analysis of individual semi-structured interviews exploring glycemia attitudes and self-care in a racially diverse sample of individuals with IAH from each cluster.

### Research Design

A mixed methods study with an explanatory sequential design (QUANT → qual) was employed to meet the study purpose. The explanatory sequential design produces hypothesis-testing and hypothesis-generating findings as quantitative data are collected and analyzed to address primary study objectives, then referenced for purposive sampling and contextualization within an explanatory qualitative phase (Creswell & Plano Clark, 2011). This design prioritized quantitative exploration of relationships of interest and development of self-care profiles in adults with T1D. These findings then informed purposive sampling for a qualitative phase to contextualize relationships of interest and identified clusters. The quantitative phase positioned us to describe the respective relationships between glycemia attitudes, self-care, and hypoglycemia awareness, and to develop self-care profiles and identify which clusters correspond best with IAH status in adults with T1D to meet aim 1 and sub-aims 1 and 2. Then, the quantitative findings were leveraged to identify a diverse subsample of adults with T1D and IAH with whom to follow-up for semi-structured qualitative interviewing. This qualitative phase enabled a deeper exploration of quantitative findings. In this design, the influence of quantitative

results on the qualitative research phase was intentional, as the qualitative phase depended on the quantitative results (Creswell & Plano Clark, 2011). Additionally, this design allowed for integration of findings that offered evidence for meta-inferences beyond what quantitative and qualitative data alone may achieve (Guetterman, Feters, & Creswell, 2015).

## Sample

### Sample Characteristics

Participants were enrolled from The University of Pennsylvania Rodebaugh Diabetes Center, the largest diabetes practice in Penn Medicine. This practice serves approximately 1600 adults with T1D, 1558 with an appointment within the 12-months prior to initiation of study recruitment. Of these 1558 adults, 53% were female sex at birth (47% male at birth), 21% Black (66% White), and 12% were using public insurance. Based on provider consultation, approximately 80% of the clinic patients employ continuous glucose monitoring, with 60% of those who identify as Black employing it. This diverse population allowed for enrollment of an adequate sample of vulnerable racial, socio-economic, and geographically minoritized groups.

Decisions regarding study design were employed to address individual and inter-individual-level barriers to recruitment and enrollment of racially minoritized populations (Thakur et al., 2021). First, the study was conducted remotely to address time and transportation-related barriers. Virtual enrollment, distribution of survey materials, and interviews each removed the need to travel and offered greater flexibility in scheduling for participants (Thakur et al., 2021). We did not anticipate access to technology to be a significant barrier to enrolling in our study for racially minoritized individuals given previous research (Frierson et al., 2008) and the growing prevalence of internet use, especially among racially minoritized populations (Hwang, Lee, Song, & Han, 2021). Further, to accommodate literacy-related barriers, study materials, including consent and study information documents, were written using plain language.

## Inclusion and Exclusion Criteria

Data were collected from adults, defined as individuals aged 18 years or older, with a confirmed diagnosis of T1D (via chart review) regardless of identified gender or sex at birth. This population was specifically selected to assess attitudes and self-care because this age demographic is at greatest risk for IAH due to longer duration of disease and older age. There was no scientifically justifiable upper limit on age for this study.

To be eligible, participants needed to be able to provide informed consent, access the internet, and complete a web-based virtual survey. To complete the study protocol, they needed adequate vision and hearing and English-speaking ability. Assistance from a caregiver, friend or spouse was permitted. Individuals with diabetes of a type other than T1D (e.g., Type-2, Type-3c and gestational diabetes mellitus), or who had undergone a pancreas or islet cell transplant were excluded as well as those unable to provide informed consent.

## Sample Size

An initial feasibility search suggested the ability to enroll 32% of patients at Rodebaugh Diabetes Center based on a previous study that invited adults with T1D to participate in a cross-sectional virtual survey (Cook et al., 2019). As discussed below, we needed a much smaller sample size to achieve power and thus anticipated recruiting 200 individuals, expecting 25% to have IAH (to reach a minimum of 50 with IAH) (Geddes et al., 2008; Graveling et al., 2014). Of these 200, we planned to interview approximately 10% (Dworkin, 2012), or until data saturation was reached (Saunders et al., 2018), in semi-structured individual virtual interviews for the qualitative phase.

## Effect size, sample size recommendations:

For the primary analysis, our goal was to develop self-care profiles of individuals with T1D and identify if, and if so, which clusters corresponded best with IAH. Experts have

proposed a sample size of 10-times that of the clustering variables (Dolnicar, Grün, Leisch, & Schmidt, 2014). In our analysis, we had 3 clustering variables: 1 for each of the self-care domain scales of the Self-Care of Diabetes Inventory (not including the fourth scale that measures confidence, which influences self-care but is not part of self-care *per se* (Riegel et al., 2012)). By the suggested parameters, we required a minimum of 30 individuals in our sample to conduct the proposed cluster analysis. With a sample of 200 individuals, we were sufficiently powered to conduct a meaningful cluster analysis.

For the sub-aims, our goal was to describe relationships between attitudes, self-care, and hypoglycemia awareness. We performed a power calculation ("PASS 2021 Power Analysis and Sample Size Software," 2021) to determine how large of a sample would be required to determine the extent to which the three Attitudes to Awareness and three Self-Care of Diabetes Inventory scale scores plus the Self-Care Self-Efficacy scale score were associated with awareness status, while holding six covariates constant, which was the most we could anticipate potentially including. Our preliminary power analysis determined that a sample size of 173 provides 80% power to detect an  $R^2$  of 0.1 attributed to 13 independent variable(s) using an F-Test with a two-sided significance level (alpha) of 0.05. As a buffer against attrition, we aimed to enroll 200 individuals, which achieves 87% power to detect an  $R^2$  of 0.1 attributed to 13 independent variable(s) using an F-Test with a two-sided significance level (alpha) of 0.05. If these 13 variables were not able to explain 10% of the variance observed in awareness status, their relationship to the outcome was not likely to be clinically significant or meaningful. We, therefore, were sufficiently powered to conduct this analysis.

The research protocol was reviewed by the Institutional Review Board (IRB) at the University of Pennsylvania and determined to meet eligibility criteria for IRB review exemption prior to the commencement of the study. All study participants provided informed consent before participating in the study.

## Setting and Recruitment

This study leveraged a growing contact list of all individuals with T1D within the Penn Medicine Rodebaugh Diabetes Center that was compiled for part of the T1D Exchange Quality Improvement Collaborative. This contact list of people who had agreed to share their information for research purposes contained phone numbers and email addresses of individuals receiving care through Penn Medicine with ICD-10 codes for T1D in their medical chart. The sampling approach sought to include equal numbers of males and females and oversample individuals identifying as Black. This approach was adopted to reflect the demographics and socioeconomic statuses of adults with T1D with and without IAH receiving outpatient diabetes care in a large, urban city in the United States. The recruitment and enrollment process were non-discriminatory by including all races, ethnicities, and genders. All participants were recruited and enrolled via the internet and phone.

During the quantitative survey, all participants were asked permission for follow-up for the qualitative interview. Participants could opt-in or out for second contact for the second phase of the study. Only 4 participants (2%) opted out.

## Procedure for Data Collection

### Screening

Prior to enrollment, participants were screened for eligibility. These data included a brief medical history via chart review to confirm presence of T1D, confirmation of ability to access a virtual survey, and comfort in completing a survey virtually. Those who did not fully meet the inclusion criteria were not able to participate in the study. Those who did not have access or the ability to complete a virtual survey were offered the option to complete the survey via phone conversation. When necessary, surveys were completed with assistance from a caregiver, friend, family member, etc. If someone agreed to complete the survey via phone, they were

offered the choice to complete it at that time or to schedule a follow-up call.

Potential participants were contacted via email to introduce the study and offer an opportunity to schedule a phone call to discuss it in more depth. For those who did not respond to email within 3 attempts, engagement was initiated via phone. Phone conversations were conducted to gauge interest and determine eligibility regarding criteria that could not be reviewed in the medical chart (e.g., ability to complete a virtual survey). If the individual was interested and eligible, consent was obtained for enrollment via electronic signature through the Research Electronic Data Capture (REDCap). Prior to signing the consent, potential participants spoke with the principal investigator regarding the project, reviewed the informed consent document together (virtually), and spent time discussing any questions that may have arisen. Then, potential participants were offered the opportunity to sign the consent if they were interested in participating.

### Quantitative Phase

A cross-sectional, web-based survey with validated measures was distributed to those enrolled to assess demographics, hypoglycemia awareness status (Clarke et al., 1995; Geddes et al., 2007), attitudes (Cook et al., 2019), and self-care (Ausili et al., 2020) of adults with T1D. The survey was distributed from REDCap directly to individual study participants. REDCap software allowed for forwarding survey invitations with an individualized, single-use link to an individual email of choice for each respective participant. Surveys were date- and time-stamped. Surveys were distributed to each participant after enrollment, with weekly reminders set up via REDCap to alert those who had not yet completed their survey to do so. Participants were able to complete these surveys on any internet-enabled device such as a computer, cellphone, or tablet. These surveys required all questions to be answered before submission. Those who had questions during the survey were able to reach out to the principal investigator via phone or

email. Data were collected on a rolling basis as participants consented, enrolled, and replied to our survey. REDCap sent the study principal investigator an emailed notification when each survey was completed.

### Qualitative Phase

We performed semi-structured, individual interviews with a criterion sample of individuals belonging to each self-care cluster identified in the quantitative phase, with preference placed on interviewing those identifying as Black (minimum 50% of total interviews) and from the cluster(s) corresponding best with IAH classification. Therefore, interviewing began after the quantitative phase had been completed. Within the consent, there was an item asking permission to follow-up with the participant later if they are identified as a candidate for interviewing. Those who opted in for follow-up and were identified by purposive sampling procedures for interviewing were contacted via their preferred method of contact. Participants contacted for interviewing were notified that they had been selected for the second phase, as described in the informed consent, and their interest in participating was once again gauged. Those interested in interviewing were scheduled for the semi-structured interview via a personalized invitation accompanied by a Zoom link.

Interviews were conducted on a rolling basis over Zoom, a Penn-supported, secure cloud-based video-conferencing platform. Zoom video software enables HIPAA compliance with various safeguards to address Access Control, Audit Controls, Integrity, Integrity Mechanisms, Person or Entity Authentication, and Transmission security and meets the audit requirements set forth by the American Institute of Certified Public Accountants standards for security, availability, confidentiality, and privacy (*HIPAA Compliance Datasheet*, 2020).

The interview guide covered an in-depth exploration of the patient's conception of self-care, their behaviors and confidence concerning self-care maintenance, monitoring, and



management, and their attitudes towards diabetes and self-care of diabetes. This guide was developed following initial quantitative data analysis to enable focus on the most surprising and interesting preliminary findings. The initial interview guide was therefore developed to cover topics of interest from the quantitative findings and a review of the literature, including attitudes toward hypoglycemia (Cook et al., 2019; Rogers et al., 2012) and self-care of diabetes (Riegel et al., 2012). Prior to employing the interview guide, a qualitative expert and content experts (Diabetes, self-care) were consulted for review and feedback. This guide was modified iteratively as interviews were conducted to allow for greater discussion of topics that were emerging, such as employment of technology in self-care. The interviews contained open-ended questions regarding experiences with self-care and attitudes towards glycemia. Open-ended questions were followed up with targeted questions derived from predetermined categories informed by our conceptual framework and quantitative findings (Creswell & Plano Clark, 2011). The specific questions and categories evolved and changed over the course of the interviews, as data were concurrently analyzed for iterative modification of the interview guide to address unanticipated areas of focus. Participants were asked to provide pseudonyms if their names were to be used (Moore, 2012; Saunders, Kitzinger, & Kitzinger, 2015). Field notes were recorded by hand during the interviews for non-textual or auditory information to increase rigor and trustworthiness. These notes supplemented language-focused data, assisted in preliminary coding, and provided essential context to inform data analysis (Phillippi & Lauderdale, 2018).

Audio recordings were transcribed via Zoom transcription. Each transcript was reviewed in synced playback with the recording to ensure accuracy (Davidson, 2009; McLellan, Macqueen, & Neidig, 2003). Transcription data were stored in a secure cloud-based platform, Penn+Box. Interviews were recorded and transcribed on the cloud via Zoom and uploaded and stored securely in Penn+Box.

Saturation was determined through concurrent data collection and analysis. Data from

each interview were reviewed within the context of identified themes. Data continued to be collected until no new insights or themes were identified and identified themes were robustly supported (Bowen, 2008). During the qualitative phase of the study, we utilized saturation memos (Aldiabat & Le Navenec, 2018). These memos were employed to reflect on various aspects, such as interview experiences, emerging categories, and codes from each transcript. We assessed how these codes and categories related to both the predetermined a priori codes and the newly emerged codes. The purpose was to gauge our progress in reaching data saturation.

### Reflexivity statement

All interviews were performed by one researcher (AM). My training and experiences have offered a lens through which I approached this study. As a registered nurse, scientist, and individual living with T1D, I acknowledge that my experiences may have influenced data analysis and interpretation. Furthermore, my positionality as a person with T1D may have influenced how I interacted with study participants. Mitigation of potential biases was approached via critical self-reflection of my own personal assumptions and beliefs. During the research process, I continually questioned preconceptions and sought feedback from peers and mentors. Conversations regarding T1D and self-care, as well as my interactions with participants and data, enhanced my ability to challenge my own assumptions to ensure a more holistic and nuanced understanding of the data. While reading interviews and memos, I would reflexively document my own thoughts, interpretations, and questions to reflect on. Further, the explanatory sequential design of this study assisted in mitigating the influence of personal bias on research outcomes. This study design enabled use of methodological triangulation (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014). Integration of different perspectives and sources of evidence helped to mitigate the influence of personal bias on overall interpretation of

results (Bhandari, 2023; Mathison, 1988).

Regardless of efforts to address bias, a completely objective perspective may not have been attainable. Therefore, I acknowledge that my positionality may have influenced the research process and findings to some extent. Thus, readers are encouraged to interpret the results with this information in mind and consider the potential influence of my positionality on the study findings.

## Variables and Measures

IAH: IAH was measured with two instruments. First, IAH was measured with the Clarke questionnaire (Clarke et al., 1995). The Clarke questionnaire is an 8-item instrument that characterizes exposure to moderate and severe hypoglycemia as well as glycemic thresholds for symptomatic responses to hypoglycemia. On this instrument, a score of 4 or greater implies IAH, 2 or less implies intact awareness, and a score of 3 is indeterminate (range: 0-7). Previous work has demonstrated that IAH classification based on Clarke has agreed well (kappa 0.49, sensitivity 66.7%, and specificity 85.7%) with IAH classification based on absence of autonomic symptoms at glycemia of 54 mg/dL, the gold standard measure of IAH (Flatt et al., 2022; Janssen, Snoek, & Heine, 2000). While no current self-report measure of IAH can be considered fully reliable and valid, the Clarke questionnaire is the recommended self-report measure of IAH to be employed for clinical and research purposes (Geddes et al., 2007).

Additionally, IAH was assessed with a newer tool that is currently undergoing validation (Matus et al., 2023): the Hypoglycemia Awareness Questionnaire (Speight et al., 2016). The 'impaired awareness' scale ( $\alpha=.79$ ) of this tool, comprised of 5 items, is used to assess hypoglycemia awareness status. The 'impaired awareness' scale has demonstrated convergent validity via strong correlations with existing measures of awareness (Gold:  $r_s=0.75$ ,  $P < 0.01$ ; Clarke:  $r_s=0.76$ ,  $P < 0.01$ ) (Speight et al., 2016). It has also demonstrated divergent validity via

weaker correlations with diabetes-related distress and HbA<sub>1c</sub> (Speight et al., 2016). Further, the 'impaired awareness' scale has contributed significantly to models of severe hypoglycemia (Speight et al., 2016). In a recent study to identify a diagnostic threshold for classification of IAH with this tool, a score of 12 on the 'impaired awareness' scale (range: 0-20) was shown to have strong sensitivity (83%) and specificity (80%) to predict abnormal autonomic symptom response to insulin-induced hypoglycemia (Matus et al., 2023). Therefore, individuals who scored a 3 on the Clarke questionnaire were assessed and classified based on the 'impaired awareness' scale threshold.

Attitudes: Attitudes were assessed with the Attitudes to Awareness questionnaire attitude scales (Cook et al., 2019), a 12-item instrument concerning beliefs about hypoglycemia. This questionnaire has 3 subscales, each representing a grouping of beliefs originally described in a qualitative study (Rogers et al., 2012) of adults with T1D and IAH: Asymptomatic Hypoglycemia Normalization ( $\alpha=.51$ ), Hypoglycemia Concerns Minimized ( $\alpha=.46$ ), and Hyperglycemia Avoidance Prioritized ( $\alpha=.47$ ) (Cook et al., 2019). Given the low internal consistency reliability reported previously, we assessed the reliability in our sample as well using Cronbach's alpha and had the following results: Asymptomatic Hypoglycemia Normalization ( $\alpha=.50$ ), Hypoglycemia Concerns Minimized ( $\alpha=.48$ ), and Hyperglycemia Avoidance Prioritized ( $\alpha=.41$ ). The reliability of the scales is not high but considered adequate because the scales are so brief (4-item scales) and have face and content validity (Cook et al., 2019). Each scale is scored (0-12), with higher scores indicating greater endorsement of an attitude.

Self-Care of Diabetes: Self-Care of Diabetes was assessed with the Self-Care of Diabetes Inventory, an instrument developed to offer a theoretically grounded measure of diabetes self-care (Ausili et al., 2017). The instrument has 40 items (5-point Likert type scale) grouped into 4 scales: self-care maintenance ( $\alpha=.81$ ), self-care monitoring ( $\alpha=.84$ ), self-care management ( $\alpha=.86$ ), and self-care confidence, a measure of self-care self-efficacy ( $\alpha=.89$ ) (Ausili et al.,

2017). This tool was derived from the Middle-Range Theory of Self-Care of Chronic Illness (Riegel et al., 2012), which supports its construct validity.

Recurrent Severe Hypoglycemia: Presence of recurrent severe hypoglycemia, an important clinical characteristic to account for (Ly, Gallego, Davis, & Jones, 2009), was determined with a single question (Cook et al., 2019) which refers to the American Diabetes Association definition of severe hypoglycemia:(Seaquist et al., 2013) "How many episodes of hypoglycemia have you had in the last 12 months for which you were not able to treat yourself? (You had to have treatment from someone else, lost consciousness or had a seizure)." Respondents selected a value from 0 to 19 or chose >19. To remain consistent with prior research (Choudhary et al., 2015; Cook et al., 2019), recurrent severe hypoglycemia was defined as  $\geq 2$  episodes in the past year.

Social Determinants of Health: Exposure to potentially harmful social determinants of health was measured with the Protocol for Responding to and Assessing Patient's Assets, Risks, and Experiences (PRAPARE) tool (Luzius, Dobbs, Hammig, Kirkish, & Mojica, 2022). This tool includes 15 items scored 0 – 22 via tally scoring methodology (National Association of Community Health Centers, 2016). Minor modifications were made to the instrument for our study purposes. The item regarding English proficiency was removed, as English proficiency was required for participation in our study. A binary item for 'sex at birth' was added as well, where those selecting anything other than male received 1 point, as sex may influence an individual's health and well-being and its inclusion may help elucidate sex-specific health disparities and barriers (World Health, 2010). As this tool is not validated, we assessed its internal consistency reliability in our sample via Cronbach's alpha ( $\alpha=.64$ ).

Demographic data: These data allowed for the development of a more accurate clinical and demographic picture. Items included disease duration (Y. K. Lin et al., 2019), age (Y. K. Lin et al., 2019), race, and technology use (namely implementation of continuous glucose monitors and

insulin pumps).

## Data Management

Data were collected and stored in REDCap software. REDCap is a secure web application for building and managing online surveys and databases. Every eligible and interested participant was assigned an individual record with a corresponding identification number. Within this record, potential participants either provided virtual consent and contact information, then were able to proceed to the survey, or declined consent and provided no further information. For the qualitative phase, transcripts were de-identified and stored in Penn+Box and Atlas.ti software.

## Data Analysis

Continuous demographic data were reported as mean (SD). When samples sizes were  $\leq 50$  (namely when describing interview sample), Shapiro-Wilk tests were performed to assess normality. If significant for a variable, then data were reported as Median [IQR] as opposed to Mean (SD). Continuous data were analyzed with Mann-Whitney U-tests. When there were more than two groups, Kruskal-Wallis tests were performed. When Kruskal-Wallis test results were significant, post-hoc between-group analyses were performed via Dunn test with Holm adjustment to identify which between-group relationships were significant. Categorical data including race, gender, recurrent severe hypoglycemia, CGM, and insulin pump-use were reported as counts (%) and analyzed with the chi-square test. When comparing categorical variables across more than 2 groups, Chi-square test with pairwise comparisons and Holm adjustment were used to identify which between-group relationships were significant.

Multiple imputation with multivariate imputation by chained equation (MICE) was employed to address missing data at the item level to improve power relative to scale-level missing data imputation (Mazza, Enders, & Ruehlman, 2015). MICE is an advanced method of

imputation where multiple datasets are generated from the original dataset and, for each missing value, plausible values are imputed based on other variables from the respective participant as well as patterns observed between variables in other participants of the original dataset. This approach handles multiple variable types (e.g., binary, or continuous), accounts for complexities including survey skip patterns, and improves upon the statistical uncertainty that is typically problematic of single imputations (Azur, Stuart, Frangakis, & Leaf, 2011; Zhang, 2016).

Data imputation was required for analysis of the Attitudes to Awareness instrument, but very little data were imputed overall. Seven people (3.5%) were missing at least 1 item. As the Attitudes to Awareness instrument is comprised of 3 scales, 1 person was missing 1 item for the 1st scale (99.5% complete), 1 person was missing 1 item for the 2nd scale (99.5% complete), and 7 people were missing an item for 3rd scale (96.5% complete). The individuals missing an item in scale 1 and scale 2 were 2 of the 7 individuals missing an item in scale 3. Across 600 scale scores for the Attitudes to Awareness instrument (3 scales x 200 participants), 9 scores were missing (1.5%) due to at least one item being missing. These missing items were those which were imputed.

Specific Aim 1: Identify self-care clusters that correspond best with IAH classification.

- We performed cluster analysis using Ward's minimum variance method with Self Care of Diabetes Inventory (Ausili et al., 2020) self-care maintenance, monitoring, and management scales as criteria to determine what self-care patterns correspond most with IAH classification in adults with T1D. We determined the most conservative solution to the cluster analysis using 'NbClust' (Charrad, Ghazzali, Boiteau, & Niknafs, 2014), an R-package that provides 30 indices for determining the most conservative clustering solution. The solution selected was that which was most frequently identified amongst the 30 indices as the best. To evaluate which cluster(s) membership corresponded best

with IAH classification, we evaluated which cluster(s) had either the largest total of individuals with IAH in it or had the largest percentage of individuals with IAH, given  $n$  was sufficiently large.

Sub-Aim 1: Describe the relationship between attitudes and self-care in adults with T1D.

- Three multivariable linear regression analyses were performed to determine the extent to which the three respective attitudes measured by the Attitudes to Awareness were associated with the three respective domains of self-care measured by the Self-Care of Diabetes Inventory while holding covariates (hypothesized by our conceptual model) constant. In each of the three models, one of the three self-care domains was the outcome variable while the independent variables were the attitudes hypothesized to be associated with the respective self-care domain being modelled. Hypothesized covariates accounted for hypoglycemia awareness status and exposure to potentially harmful social determinants of health.

Sub-Aim 2: Describe the relationship between self-care and hypoglycemia awareness status in adults with T1D.

- A multivariable linear regression analysis was performed to determine the extent to which self-care maintenance, monitoring, and management were associated with hypoglycemia awareness status while holding recognized and hypothesized covariates constant. These covariates included age (Y. K. Lin et al., 2019), duration of disease (Y. K. Lin et al., 2019), self-care self-efficacy or confidence (Riegel et al., 2012) and presence of recurrent severe hypoglycemia (Ly et al., 2009). In the regression analysis, the outcome of interest was hypoglycemia awareness status, a binary variable outcome, and the independent variables were the three respective domains of self-care measured by the Self-Care of Diabetes Inventory.



Specific Aim 2: Explore attitudes and self-care in a racially diverse group of adults with T1D with IAH.

- Interview transcripts were analyzed using directed content analysis (Hsieh & Shannon, 2005; Sandelowski, 2010). This approach to analysis is appropriate for our research aims because we sought to extend a pre-existing conceptual framework, to better capture a range of manifestations of our phenomenon of interest.
- We created a codebook via an integrated approach (Bradley, Curry, & Devers, 2007) based on our conceptual framework and identified categories of interest relevant to existing literature on IAH as well as content that emerged from the data. Codes were clearly defined by the research team using definitions determined using the guiding theory (Hsieh & Shannon, 2005). Codes and definitions were reviewed by a self-care expert (Creswell 2023). The definitions of these codes did not change throughout the project.
- Our coding framework was guided by Tesch's Eight Steps (Tesch, 1990). Prior to reviewing transcripts, a deductive codebook was developed based on the Middle Range Theory of Self-Care of Chronic Illness. This deductive codebook included codes for all concepts of interest that emerged as interesting from the quantitative analysis. Codes were defined in the codebook as they had been described in the guiding theory (Riegel et al., 2012) and categorized amongst similar concepts (self-care maintenance, self-care monitoring, self-care management, attitudes, etc.). Each code was accompanied by a definition explaining the meaning of the code. This codebook was then expanded upon by including emergent themes from the interviews themselves. These emergent codes were developed and employed via the following steps (Tesch, 1990):
  1. Prior to coding, all transcripts were read repeatedly and detailed memos of each were

developed.

2. 35% of transcripts were selected for a general review to identify the underlying meaning of information conveyed, with notes taken in the margins of the transcripts (Interview 3, Interview 4, Interview 5, Interview 6, Interview 7, Interview 8, Interview 9). The group of interviews was selected to ensure that each cluster from the quantitative phase was represented.
3. The information from these margin notes was reviewed to make a list of topics, where similar topics were clustered together.
4. These topics were then abbreviated and added to the codebook as codes and applied alongside the *a priori* codes.
5. Intercoder agreement was assessed by cross-checking as described in Creswell (2023), where two individuals evaluated text and determined if another coder would code the same passage of text with the same or similar codes. To do this, four (20%) coded transcripts were randomly selected and shared with a content expert to cross-check coding (Creswell, 2023). After this first round of cross-checking, areas of disagreement were identified. The coder and expert then convened to have a detailed discussion to address disagreements and clarify the coding guidelines. Segments of code were reviewed together for collaborative discussions and consensus-building.
6. Recoding was performed thereafter based on the outcomes of discussions, aiming to improve intercoder agreement. After recording, four (20%) recoded interviews were cross-checked by the content expert, areas of discrepancy were identified, discussed, and addressed. This iterative process of reviewing, discussing, recoding, and reassessing agreement was repeated until all significant disagreements were resolved and satisfactory agreement was achieved (no remaining discrepancies) (Creswell, 2023).

7. These codes were then merged into categories by grouping topics that relate to each other.
8. Final decisions were made regarding the abbreviation for each category and they were organized based on their relationship to the theoretical framework.
9. Data were assembled belonging to each category in one place for a preliminary analysis.

Specific Aim 3: Integrate quantitative and qualitative findings to develop meta-insights regarding the relationship between attitudes and self-care in individuals with T1D and IAH.

- Quantitative and qualitative findings were discussed through narrative, in which findings from the quantitative and qualitative phase were described in a single report through a contiguous approach. In a contiguous approach, quantitative and qualitative findings are reported in different sections, and then findings are organized into an integrated results matrix (McCrudden & McTigue, 2019). In this integrated results matrix, quantitative and qualitative results were juxtaposed for a side-by-side comparison and offer evidence supporting the process for drawing meta-inferences and new insights (Guetterman et al., 2015). Confirmation was determined where results from both data sets confirmed results of the other. In this case, the two data sources provided similar conclusions, increasing the credibility of the findings for both (Guetterman et al., 2015). Expansion was determined by the extent to which findings from each of the data sets diverged and expanded insights of the phenomenon of interest by (1) addressing aspects of a single phenomenon or (2) describing complementary aspects of the central phenomenon of interest (Guetterman et al., 2015). Finally, discordance was determined if the findings from the quantitative and qualitative data sets were inconsistent or disagree with one another (Guetterman et al., 2015).

In this design, there were two time-points where integration occurred. First, integration

occurred between quantitative data analysis in the first phase and the qualitative data collection in the second phase (Creswell & Plano Clark, 2011). After the quantitative data were analyzed, we allowed the quantitative results to point us toward specific results that needed further detail and towards those who would be best able to explain results. In this way, integration connected the results from the initial quantitative phase to help plan the follow-up qualitative data collection phase. Secondly, integration occurred again when the qualitative phase was complete. At this point, we integrated the two sets of connected results to draw an integrated conclusion about how qualitative results explained and extended specific quantitative results (Creswell & Plano Clark, 2011). Integration allowed us to interpret the extent and manner in which the qualitative results explained and added insight to the quantitative findings to achieve the study's overall purpose (Creswell & Plano Clark, 2011).

Rigor: Rigor was ensured through establishing standards of trustworthiness at all steps of our research process from data collection through reporting. Trustworthiness of this analysis was supported by Lincoln and Guba's evaluation criteria to establish credibility, transferability, dependability, and confirmability (Lincoln, 1985). Credibility was supported via searching for negative findings, or patterns that contradicted our conceptual framework, throughout analysis, prolonged engagement in the community and with patients, and peer debriefing. Transferability was established by providing a thick description of data and the context within which it was collected. Dependability was established through maintaining transparency of the research process by keeping records of raw data, field notes, transcripts, and memos.

To document our research process in a transparent manner, we managed folders categorized by subject matter in Penn+Box. Folder categories included decisions made during the study, meetings, reflective memos, sampling, emergent findings, and data management (Graneheim & Lundman, 2004; Korstjens & Moser, 2018). Each folder contained time-stamped documents relating to the respective categories that may be traced from the beginning of the

study through completion. Further, findings were reported alongside descriptive data of our research setting, sample population, and interview strategy (e.g., procedure and excerpts from the interview guide). This information enables other researchers to interpret how well our findings transfer to their population of interest. Confirmability was established via fostering reflexivity and triangulation. Authors reported on positionality and how their positionality may come into play during the research process to influence perspectives and interpretation.

This mixed-methods investigation lends itself to triangulation in two ways: namely methods and theory triangulation (Denzin, 2017). Methods triangulation occurred during integration, which involved assessment of the extent to which two types of data were consistent with one another. Further, as a directed content analysis guided by underlying conceptual frameworks, theoretical perspectives were employed to assess and interpret the data.

### Limitations & Strategies to Address Limitations

A limitation of this study is that the sample lacked geographic diversity. As all individuals enrolled were patients of the Penn Rodebaugh Diabetes Center in Philadelphia, most individuals resided within the greater Philadelphia region. Therefore, results may not be generalizable to settings differing greatly from a large, urban city in the United States. The qualitative phase of this study elucidated geographical context to the patterns of self-care and attitudes of individuals with IAH observed in this study. A second limitation is that an intercoder reliability statistic was not calculable based on our approach to assessing intercoder agreement. However, we performed a rigorous approach to establishing intercoder agreement as described as well as employed many methods to support dependability, credibility, confirmability, and transferability.

# CHAPTER FOUR: RESULTS

## Sample

### Sample Characteristics

Study participants were largely female and White-identifying adults with long-standing type 1 diabetes (T1D) (Table 1). The sample overall failed to meet current recommendations for Hemoglobin A1C % and many participants reported experiencing recurrent severe hypoglycemia. The sample was generally overweight by body mass index estimates. A large majority of study participants used continuous glucose monitors (CGM) and insulin pumps with insulin suspension and/or Hybrid closed loop features.

Among the study sample, 26.5% screened positive for impaired awareness of hypoglycemia (IAH). The sample reported low Clarke and Hypoglycemia Awareness Questionnaire ‘Impaired Awareness’ Scale (HypoA-Q IA) scores consistent with majority of individuals screening negative for IAH. Self-care confidence, maintenance, and monitoring were adequate (scores  $\geq 70$  are considered adequate, scores  $< 70$  are considered inadequate) for the sample, whereas self-care management was inadequate. Individuals reported relatively low endorsement of “Asymptomatic Hypoglycemia Normalization” and “Hypoglycemia Concern Minimization” compared to “Hyperglycemia Avoidance Prioritization”. On average, the sample reported exposure to several social determinants of health risks.

<b>Table 1. Characteristics and Survey Scores of Study Participants (n=200)</b>									
<b>Demographics</b>									
Categorical variables reported as Counts (%) and Continuous variables as Mean (SD)									
<b>Race</b>	<table border="0"> <tr> <td><i>Black</i></td> <td>48 (24%)</td> </tr> <tr> <td><i>White</i></td> <td>135 (67.5%)</td> </tr> <tr> <td><i>Asian</i></td> <td>7 (3.5%)</td> </tr> <tr> <td><i>Other (i.e., More than 1 race, Unknown/Unreported)</i></td> <td>10 (5%)</td> </tr> </table>	<i>Black</i>	48 (24%)	<i>White</i>	135 (67.5%)	<i>Asian</i>	7 (3.5%)	<i>Other (i.e., More than 1 race, Unknown/Unreported)</i>	10 (5%)
<i>Black</i>	48 (24%)								
<i>White</i>	135 (67.5%)								
<i>Asian</i>	7 (3.5%)								
<i>Other (i.e., More than 1 race, Unknown/Unreported)</i>	10 (5%)								
<b>Hispanic/Latino</b>	11 (5.5%)								
<b>Female</b>	122 (61.3%)								

Age	39.08 (15.47)
<b>Clinical Characteristics</b>	
Disease Duration	21.70 (14.00)
Recurrent Severe Hypoglycemia	28 (14%)
Impaired Awareness of Hypoglycemia	53 (26.5%)
Hemoglobin A1C %	7.4 (1.6)
Body Mass Index**	27.8 (6.89)
<b>Technology Use</b>	
Continuous Glucose Monitor Use	180 (90.0%)
Pump Use	136 (69.0%)
<i>With Insulin Suspension*</i>	95 (69.9%)
<i>With Hybrid Closed Loop*</i>	91 (66.9%)
<b>Hypoglycemia Awareness Status Questionnaires</b>	
Clarke Score (0-7)	2.09 (1.78)
Hypoglycemia Awareness Questionnaire Impaired Awareness Scale Score (0-20)	6.83 (4.05)
<b>Self-Care of Diabetes Inventory Scales</b>	
Self-Care Self-Confidence (0-100)	86.43 (12.97)
Self-Care Maintenance (0-100)	78.42 (12.45)
Self-Care Monitoring (0-100)	71.64 (14.08)
Self-Care Management (0-100)	61.18 (13.30)
<b>Attitudes to Awareness Scales</b>	
Asymptomatic Hypoglycemia Normalization (0-12)	2.52 (2.27)
Hypoglycemia Concern Minimization (0-12)	3.42 (2.42)
Hyperglycemia Avoidance Prioritization (0-12)	5.96 (2.37)
<b>Social Determinants of Health Risk</b>	
Social Determinants of Health Risk Tally Score (0-22)	3.36 (2.31)
*Percentage reflects percentage of those who have a pump and use it.	
** (Body Mass Index Centers for Disease Control and Prevention Parameters: Healthy = 18.5 – 24.9 kg/m <sup>2</sup> , overweight = 25 kg/m <sup>2</sup> – 29.9 kg/ m <sup>2</sup> ; obese = 30+ kg/ m <sup>2</sup> )	
Full range of possible scores shown for each scale.	

### Impaired Awareness versus Intact Awareness

Participants with IAH were older with longer disease duration and reported more recurrent severe hypoglycemia than those classified as having intact awareness (Table 2). No significant differences between groups were observed regarding race, sex at birth, glycemic

control, body mass index, or technology use.

Those with IAH differed significantly from those without IAH across various measures, including those of awareness (as these were used for group classification) and the Self-Care of Diabetes Inventory scales. Those screening positive for IAH had significantly higher Clarke and HypoA-Q IA scores and significantly worse self-care monitoring scores. Both self-care monitoring and management scores were inadequate for the IAH group, whereas only management was inadequate for the Intact Awareness group. No significant differences were observed in Attitudes to Awareness scale scores or in social determinants of health risk tally scores between groups.

<b>Table 2. Comparison of characteristics of participants with intact awareness of hypoglycemia and those with impaired awareness of hypoglycemia (n = 200)</b>			
	<b>Intact Awareness (n =147)</b>	<b>IAH (n=53)</b>	<b>p-value</b>
<b>Demographics</b>			
Categorical variables reported as Counts (%) and Continuous variables as Mean (SD)			
<b>Race</b>			.241
	<i>Black</i>	30 (20.4%)	18 (34.0%)
	<i>White</i>	105 (71.4%)	30 (50.6%)
	<i>Asian</i>	5 (3.4%)	2 (3.8%)
	<i>Other (i.e., More than 1 race, Unknown)</i>	7 (4.8%)	3 (5.7%)
<b>Hispanic/Latino</b>	7 (4.8%)	4 (7.5%)	.528
<b>Female</b>	93 (63.2%)	29 (55.8%)	.431
<b>Age</b>	37.4 (15.06)	43.74 (15.80)	<b>.010</b>
<b>Clinical Characteristics</b>			
<b>Disease Duration</b>	19.59 (13.40)	27.58 (14.07)	<b>&lt;.001</b>
<b>Recurrent Severe Hypoglycemia</b>	10 (6.8%)	18 (34%)	<b>&lt;.001</b>
<b>Hemoglobin A1C %</b>	7.5 (1.6)	7.4 (1.7)	.845
<b>Body Mass Index**</b>	28.5 (7.6)	25.75 (2.99)	.059
<b>Technology Use</b>			
<b>Continuous Glucose Monitor Use</b>	129 (87.8%)	51 (96.2%)	.135
<b>Insulin Pump Use</b>	99 (67.3%)	37 (69.8%)	.874
	<i>With Insulin Suspension*</i>	66 (66.7%)	29 (78.4%)
	<i>With Hybrid Closed Loop*</i>	62 (62.6%)	29 (78.4%)
<b>Hypoglycemia Awareness Status Questionnaires</b>			
<b>Clarke Score (0-7)</b>	1.22 (1.06)	4.51 (0.91)	<b>&lt;.001</b>
<b>Hypoglycemia Awareness Questionnaire Impaired Awareness Score (0-20)</b>	5.20 (3.14)	11.30 (2.66)	<b>&lt;.001</b>



<b>Self-Care of Diabetes Inventory Scales</b>			
<b>Self-Care Self-Confidence (0-100)</b>	87.04 (12.89)	84.73 (13.16)	.268
<b>Self-Care Maintenance (0-100)</b>	78.23 (12.43)	78.97 (12.61)	.711
<b>Self-Care Monitoring (0-100)</b>	73.36 (13.50)	66.88 (14.69)	<b>.004</b>
<b>Self-Care Management (0-100)</b>	61.02 (13.96)	61.64 (11.36)	.711
<b>Attitudes to Awareness Scales</b>			
<b>Asymptomatic Hypoglycemia Normalization (0-12)</b>	2.54 (2.23)	2.47 (2.41)	.843
<b>Hypoglycemia Concern Minimization (0-12)</b>	3.40 (2.39)	3.47 (2.49)	.856
<b>Hyperglycemia Avoidance Prioritization (0-12)</b>	5.97 (2.37)	5.92 (2.41)	.913
<b>Social Determinants of Health Risk</b>			
<b>SDOH Risk Tally Scores (0-22)</b>	3.27 (2.35)	3.60 (2.21)	.372
Key: IAH = Impaired Awareness of Hypoglycemia; SDOH = Social Determinants of Health * Percentages reflect percentage of those with a pump. ** (Body Mass Index Centers for Disease Control and Prevention Parameters: Healthy = 18.5 – 24.9 kg/m <sup>2</sup> , overweight = 25 kg/m <sup>2</sup> – 29.9 kg/ m <sup>2</sup> ; obese = 30+ kg/ m <sup>2</sup> ) Full range of possible scores shown for each scale.			

## Aim 1: Quantitative Phase

Specific Aim 1: Identify self-care clusters that correspond best with IAH classification.

Three self-care clusters were identified amongst the 200 participants (Table 3). Cluster 2 had the highest membership, followed by Cluster 1 and then Cluster 3. There were no significant between-cluster differences in terms of IAH classification. Nevertheless, Cluster 2 had the largest number of participants who screened positive for IAH, as well as the highest proportion of participants with IAH.

Significant between-cluster differences were identified in demographic characteristics, including age, race, hemoglobin A1C, and pump use. Cluster 1 was significantly older than Cluster 2 ( $p < .01$ ), and both Cluster 1 and Cluster 2 were significantly older than Cluster 3 ( $p < .01$  and  $p < .01$ , respectively). Further, Cluster 3 had a significantly lower proportion of White participants compared to Cluster 2 ( $p < .05$ ) and a lower proportion of White participants compared to Cluster 1 ( $p = .11$ ). Cluster 3 had significantly poorer glycemic control as indicated

by higher hemoglobin A1C % than either Cluster 1 ( $p < .05$ ) or Cluster 2 ( $p < .05$ ). Additionally, Cluster 3 trended toward significantly less pump use than Cluster 2 ( $p = .05$ ).

Self-care maintenance, monitoring, management, and confidence scores were each adequate in Cluster 1, whereas only self-care maintenance and confidence were adequate for Cluster 2. Self-care maintenance, monitoring, management, and confidence scores were each inadequate in Cluster 3. Significant between-cluster differences were identified in each of the Self-Care of Diabetes Inventory scales. Self-care maintenance was significantly higher in Cluster 1 than Cluster 2 ( $p < .001$ ) or Cluster 3 ( $p < .001$ ), and significantly higher in Cluster 2 than Cluster 3 ( $p < .001$ ). Self-care monitoring was significantly higher in Cluster 1 than Cluster 2 ( $p < .001$ ) or Cluster 3 ( $p < .001$ ). The difference in self-care monitoring neared significance for Cluster 2 vs Cluster 3 ( $p = .05$ ). Self-care management was significantly higher in Cluster 1 than Cluster 2 ( $p < .001$ ) or Cluster 3 ( $p < .001$ ), and significantly higher in Cluster 2 than Cluster 3 ( $p < .001$ ). Self-care confidence was significantly higher in Cluster 1 than Cluster 2 ( $p < .001$ ) or Cluster 3 ( $p < .001$ ), and significantly higher in Cluster 2 than Cluster 3 ( $p < .05$ ).

Significant between-cluster differences were identified in two of the three scales of the Attitudes to Awareness questionnaire. Endorsement of 'Asymptomatic Hypoglycemia Normalization' was significantly lower in Cluster 1 than both Cluster 2 ( $p < .05$ ) and Cluster 3 ( $p < .01$ ), and was significantly lower in Cluster 2 than Cluster 3 ( $p < .05$ ). Further, endorsement of 'Hypoglycemia Concern Minimization' was significantly lower in Cluster 1 than both Cluster 2 ( $p < .05$ ) and Cluster 3 ( $p < .05$ ).

Significant between-cluster differences were identified in the social determinants of health risk tally scores amongst the clusters. Social determinants of health risk tally scores were significantly higher in Cluster 3 than Cluster 1 ( $p < .001$ ) or Cluster 2 ( $p < .001$ ).

**Table 3. Characteristics and Survey Scores of Participants by Self-Care Cluster (n=200)**

	Cluster 1 (n=70)	Cluster 2 (n=112)	Cluster 3 (n=18)	p-Value
<b>Awareness Status</b> Categorical variables as Counts (%) and Continuous variables as Mean (SD)				
<b>Intact Awareness (%)</b>	56 (80.0%)	78 (69.6%)	13 (72.2%)	.303
<b>Demographics</b>				
<b>Female (%)</b>	39 (55.7%)	73 (65.8%)	10 (55.6%)	.349
<b>Race</b>				<b>&lt; .05</b>
<i>Black</i>	17 (24.3%)	22 (19.6%)	9 (50.0%)	
<i>White</i>	47 (67.1%)	81 (72.3)	7 (38.9%)	
<i>Asian</i>	1 (1.4%)	4 (3.6%)	2 (11.1%)	
<i>Other (i.e., More than 1 race, Unknown)</i>	5 (7.1%)	5 (4.5%)	0 (0.0%)	
<b>Hispanic/Latino</b>	4 (5.7%)	5 (4.5%)	2 (11.1%)	.802
<b>Age</b>	44.79 (17.02)	37.38 (14.00)	27.44 (7.12)	<b>&lt;.001</b>
<b>Disease Duration</b>	24.49 (15.90)	20.84 (13.18)	16.28 (8.23)	.052
<b>Hemoglobin A1C %</b>	7.36 (1.67)	7.26 (1.16)	8.97 (2.80)	<b>&lt;.001</b>
<b>Body Mass Index**</b>	28.63 (7.21)	27.66 (6.88)	24.41 (3.25)	.211
<b>Recurrent Severe Hypoglycemia (%)</b>	7 (10.0%)	17 (15.2%)	4 (22.2%)	.355
<b>Insulin Pump Use (%)</b>	44 (62.9%)	84 (75.0%)	8 (44.4%)	<b>&lt;.05</b>
<i>Insulin Suspend*</i>	34 (77.3%)	56 (66.7%)	5 (62.5%)	.697
<i>Hybrid Closed Loop*</i>	32 (72.7%)	54 (64.3%)	5 (62.5%)	.807
<b>CGM Use (%)</b>	62 (88.6)	104 (93.9)	14 (77.8)	.125
<b>Self-Care of Diabetes Inventory Scales</b>				
<b>Self-Care Confidence (0-100)</b>	92.73 (7.47)	85.23 (11.59)	69.44 (19.69)	<b>&lt;.001</b>
<b>Self-Care Maintenance (0-100)</b>	84.92 (8.82)	78.64 (8.92)	51.85 (7.66)	<b>&lt;.001</b>
<b>Self-Care Monitoring (0-100)</b>	85.09 (8.81)	65.61 (9.77)	56.86 (12.88)	<b>&lt;.001</b>
<b>Self-Care Management (0-100)</b>	72.54 (10.01)	56.76 (10.14)	44.54 (6.25)	<b>&lt;.001</b>

<b>Attitudes to Awareness Scales</b>				
<b>Asymptomatic Hypoglycemia Normalization (0-12)</b>	2.00 (2.30)	2.60 (2.12)	4.11 (2.47)	<b>&lt;.01</b>
<b>Hypoglycemia Concern Minimization (0-12)</b>	2.71 (2.25)	3.74 (2.44)	4.17 (2.36)	<b>&lt;.01</b>
<b>Hyperglycemia Avoidance Prioritization (0-12)</b>	5.73 (2.34)	6.03 (2.38)	6.39 (2.50)	.494
<b>Social Determinants of Health Risk Scores</b>				
<b>SDOH Risk Tally Score (0-22)</b>	2.90 (1.70)	3.09 (1.76)	6.83 (4.08)	<b>&lt;.001</b>
Key: CGM = Continuous Glucose Monitor; SDOH = Social Determinants of Health *Percentages reflect percentage of those with a pump. ** (Body Mass Index Centers for Disease Control and Prevention Parameters: Healthy = 18.5 – 24.9 kg/m <sup>2</sup> , overweight = 25 kg/m <sup>2</sup> – 29.9 kg/ m <sup>2</sup> ; obese = 30+ kg/ m <sup>2</sup> ) Full range of possible scores shown for each scale.				

**Sub-Aim 1: Describe the relationship between attitudes and self-care in adults with T1D.**

Models of self-care maintenance, monitoring, and management were constructed with Attitudes to Awareness scales as determinants of each self-care domain while adjusting for hypoglycemia awareness status and social determinants of health risk as covariates.

‘Asymptomatic Hypoglycemia Normalization’ ( $t = -2.55, p < .05$ ), ‘Hypoglycemia Concern Minimization’ ( $t = -2.02, p < .05$ ), and social determinants of health risk tally score ( $t = -6.13, p < .001$ ) were significant determinants of self-care maintenance ( $r^2 = .23, p < .001$ ). Every 1 unit increase in ‘Asymptomatic Hypoglycemia Normalization’, ‘Hypoglycemia Concern Minimization’, and ‘social determinants of health risk tally score’ was associated with a decrease of 0.95, 0.70, and 2.13 units in estimated self-care maintenance scores, respectively.

‘Asymptomatic Hypoglycemia Normalization’ ( $t = -1.97, p = .05$ ), and ‘Hyperglycemia Avoidance Prioritization’ ( $t = 1.89, p = .06$ ) trended towards significance as determinants of self-care monitoring, while hypoglycemia awareness status ( $t = -2.81, p < .01$ ) and social determinants of health risk tally score ( $t = -3.18, p < .001$ ) were significant determinants of self-care monitoring ( $r^2 = .12, p < .001$ ). In this model, every 1-unit increase in ‘Asymptomatic

Hypoglycemia Normalization', 'Hyperglycemia Avoidance Prioritization', and social determinants of health risk tally score was associated with a change in estimated self-care monitoring scores -0.88, 0.81, and -1.33 units, respectively. Additionally, screening positive for IAH was associated with a decrease in estimated self-care monitoring scores of 6.04 units.

'Asymptomatic Hypoglycemia Normalization' ( $t = -2.86, p < .01$ ), 'Hyperglycemia Avoidance Prioritization' ( $t = 2.07, p < .05$ ), and social determinants of health risk tally scores ( $t = -2.67, p < .01$ ) were significant determinants of self-care management ( $r^2 = .09, p < .01$ ). Specifically, every 1 unit increase in 'Asymptomatic Hypoglycemia Normalization', 'Hyperglycemia Avoidance Prioritization', and social determinants of health risk tally scores was associated with a change in estimated self-care management scores of -1.22, 0.85, and -1.07 units, respectively.

Sub-Aim 2: Describe the relationship between self-care and hypoglycemia awareness status in adults with T1DM.

A model of hypoglycemia awareness status was developed with Self-Care of Diabetes Inventory scales as determinants of hypoglycemia awareness alongside known covariates including age, disease duration, and recurrent severe hypoglycemia. In the resulting model ( $r^2 = .24, p < .001$ ), recurrent severe hypoglycemia ( $t = 4.60, p < .001$ ), disease duration ( $t = 3.01, p < .01$ ), self-care monitoring ( $t = -4.29, p < .001$ ), and self-care management ( $t = 2.00, p < .05$ ) were significant determinants of awareness status. Participants with recurrent severe hypoglycemia had a 46% greater relative risk of having IAH compared to those without recurrent severe hypoglycemia. Further, every 1-year increase in disease duration was associated with a 1% greater relative risk of having IAH. Additionally, every 1 unit increase in self-care monitoring was associated with a 1% reduction in relative risk of having IAH, whereas every 1 unit increase in self-care management was associated with a 0.5% increase in relative risk of having IAH.

## Aim 2: Qualitative Phase

### Subjects

Twenty individuals participated in follow-up semi-structured interviews. Half of the interviews came from Cluster 1 ( $n = 5$ ) and Cluster 3 ( $n = 5$ ), as these two groups together represented approximately half of the total sample. The remaining ten interviews came from Cluster 2. Saturation (no new emergent themes) occurred prior to interview 20. Those interviewed ( $n = 20$ ) were majority Black-identifying (65%), female (65%) adults with long-standing type-1 diabetes (Median [IQR] age (years): 34 [25.00, 44.75], Median [IQR] disease duration (years): 21.50 [12.75, 33.00]). Individuals interviewed all screened positive for IAH (100%), demonstrated varying levels of glycemic control (Median [IQR] A1C (%): 7.7 [6.6, 8.9], and many reported high prevalence of recurrent severe hypoglycemia (45%). The vast majority used continuous glucose monitoring (95%) and insulin pump delivery (70%). Among those with insulin pumps, the majority reported using insulin suspension (71.4%) and/or hybrid closed loop (85.7%) features.

<b>Table 4. Characteristics of Participants Interviewed by Cluster (n=20)</b>				
	<b>Cluster 1 (n=5)</b>	<b>Cluster 2 (n=10)</b>	<b>Cluster 3 (n=5)</b>	<b>p-Value</b>
<b>Demographics</b> Categorical variables as Counts (%) and Continuous variables as Median [IQR]				
<b>Female (%)</b>	2 (40%)	8 (80%)	3 (60%)	.151
<b>Race</b>				.719
<i>Black</i>	3 (60.0%)	6 (60.0%)	4 (80.0%)	
<i>White</i>	2 (40.0%)	2 (20.0%)	0 (0.0%)	
<i>Asian</i>	0 (0.0%)	1 (10.0%)	0 (0.0%)	
<i>Other (i.e., More than 1 race, Unknown)</i>	0 (0.0%)	1 (10.0%)	1 (20.0%)	
<b>Hispanic/Latino</b>	0 (0.0%)	1 (10.0%)	1 (20.0%)	.578
<b>Age</b>	47.00 [41.00, 47.00]	34.00 [29.00, 43.75]	25.00 [23.00, 25.00]	<b>.053</b>

<b>Disease Duration</b>	37.00 [28.00, 43.00]	20.00 [10.00, 30.25]	20.00 [13.00, 21.00]	.106
<b>Hemoglobin A1C %</b>	6.8 [6.4, 7.4]	7.4 [6.4, 8.0]	9.9 [8.5, 12.2]	<b>.049</b>
<b>Body Mass Index**</b>	26.41 [25.34, 27.48]	25.73 [25.30, 26.88]	22.11 [22.11, 22.11]	.283
<b>Recurrent Severe Hypoglycemia (%)</b>	1 (20.0%)	5 (50.0%)	3 (60.0%)	.403
<b>Insulin Pump Use (%)</b>	5 (100.0%)	7 (70.0%)	2 (40.0%)	.117
<i>Insulin Suspend*</i>	3 (60.0%)	5 (75.0%)	1 (50.0%)	.971
<i>Hybrid Closed Loop*</i>	4 (80.0%)	6 (75.0%)	2 (100.0%)	.417
<b>CGM (%)</b>	5 (100.0%)	10 (100.0%)	4 (80.0%)	.206
<b>Self-Care of Diabetes</b>				
<b>Self-Care Confidence (0-100)</b>	100.00 [95.45, 100.00]	89.77 [82.39, 93.18]	63.64 [63.64, 65.91]	<b>.006</b>
<b>Self-Care Maintenance (0-100)</b>	89.58 [85.42, 100.00]	79.17 [75.52, 83.33]	47.92 [47.92, 56.25]	<b>.002</b>
<b>Self-Care Monitoring (0-100)</b>	91.18 [82.35, 94.12]	64.71 [61.76, 67.65]	47.06 [41.18, 47.06]	<b>.001</b>
<b>Self-Care Management (0-100)</b>	69.44 [66.67, 77.78]	58.33 [51.39, 65.97]	47.22 [44.44, 53.12]	<b>.009</b>
<b>Attitudes to Awareness</b>				
<b>Asymptomatic Hypoglycemia Normalization (0-12)</b>	0.00 [0.00, 0.00]	1.00 [0.25, 3.00]	5.00 [3.00, 5.00]	<b>.012</b>
<b>Hypoglycemia Concern Minimization (0-12)</b>	4.00 [3.00, 4.00]	3.00 [2.00, 3.75]	4.00 [2.00, 6.00]	.720
<b>Hyperglycemia Avoidance Prioritization (0-12)</b>	5.00 [5.00, 8.00]	6.50 [5.00, 7.00]	5.00 [3.00, 6.00]	.625
<b>Social Determinants of Health</b>				
<b>SDOH Risk Tally Score (0-22)</b>	3.00 [2.00, 4.00]	5.00 [4.00, 5.00]	6.00 [5.00, 6.00]	.091
Key: CGM = Continuous Glucose Monitor; SDOH = Social Determinants of Health				
*Percentages reflect percentage of those with a pump.				
** (Body Mass Index Centers for Disease Control and Prevention Parameters: Healthy = 18.5 – 24.9 kg/m <sup>2</sup> , overweight = 25 kg/m <sup>2</sup> – 29.9 kg/ m <sup>2</sup> ; obese = 30+ kg/ m <sup>2</sup> ). Full range of possible scores shown for each scale.				

Thematic analysis of the interview data unveiled 12 themes. Three of these themes

characterized antecedents of self-care across two clusters. The remaining nine themes characterized each of the three domains of self-care (maintenance, monitoring, and management) for each of the three identified clusters (Table 5).

## Themes

### Cluster 1

#### Acceptance and Resilience Supporting Confidence

Cluster 1 participants consistently expressed a high level of confidence in their ability to engage in self-care. Their confidence was described by some as "sky high" (Black male, 41 years old) or "the best it's been." (White male, 47 years old) The confidence of participants in Cluster 1 remained high even when faced with challenges. For example, one participant stated that, despite the circumstances, they were always confident in their ability to detect and manage changes in glycemia effectively because of their knowledge of their diabetes and somatic awareness. This participant explained, "I'm confident in my abilities and my knowledge of my type one diabetes and how my body reacts to any and everything." (White male, 47 years old)

Acceptance and resilience emerged as facilitators of confidence in Cluster 1. Participants in this cluster reported accepting diabetes and its challenges as an integral part of their lives. As one participant stated, "Diabetes is just a part of life. We just get up and do what you have to do." (Black female, 47 years old) Further, individuals in this cluster generally accepted the challenges that come along with diabetes and a willingness to do whatever was necessary to overcome those challenges, highlighting their resilience. For example, one participant stated, "every day there's a new obstacle to get over. But I'm willing to jump, climb, crawl, whatever, over any obstacle that comes my way." (Black male, 41 years old) Overall, acceptance and resilience were present together, manifesting in a confidence that made successful diabetes self-care seem more like a choice than a challenge. Demonstrating this,



one participant stated, "Diabetes is either going to control your life or you're going to control the diabetes, and I just give myself the option to live my life as normal as possible." (Black female, 28 years old)

Overall, participants' expressions of confidence, acceptance, and resilience demonstrated how these interconnected qualities play a pivotal role in supporting their self-care practices. They showcased a firm belief in their abilities, embraced the challenges posed by their condition, and persisted in their efforts to ensure optimal self-care outcomes. Their confidence, acceptance, and resilience permeated their discussions of self-care.

### Holistic Self-Care Maintenance

Individuals in Cluster 1 exhibited a comprehensive approach to self-care maintenance. Their self-care maintenance encompassed behaviors to uphold both physical health and emotional well-being. Further, their reported behaviors reflected a proactive attitude towards maintaining a healthy lifestyle with diabetes. In terms of physical health, they reported engagement in regular physical activity, prioritizing nutrition, and diligently adhering to treatment regimens. For instance, one participant mentioned their commitment to staying active, adapting their workout routine based on their body's capabilities, making conscious dietary choices, and engaging in carb counting for medication adherence. Further, participants in Cluster 1 reported engaging in activities to support emotional well-being such as connecting with friends and family, nurturing their spiritual faith, and practicing mindfulness techniques. For instance, one participant mentioned the importance of maintaining a strong spiritual foundation and incorporating meditation and yoga practices into their life for emotional support. In general, these individuals prioritized their self-care above all other things, and therefore reported that it would not be sacrificed in challenging circumstances. A participant attributed their ability to persist in self-care to their mindset, stating "I don't give myself an option not to." (Black female,

28 years old) Participants in Cluster 1 demonstrated self-care maintenance that addresses the promotion and preservation of both physical health and emotional wellbeing and persists despite challenges.

### Comprehensive Self-Care Monitoring

Individuals in Cluster 1 reported a comprehensive approach to self-care monitoring that integrated somatic awareness with technology-based information to alert them to changes in condition. They placed particular emphasis on detecting changes in their diabetes via symptom detection and interpretation. One participant emphasized the importance of listening to bodily sensations for self-care monitoring, reporting it as critical to informing corrective action. They stated, “It is really important that... you're able to... feel, feel what's going on in your body and being able to listen to your body, to make the right... correction.” (White male, 47 years old)

Individuals in Cluster 1 showcased the synergy between endogenous (internal) and exogenous (external) monitoring behaviors in effective diabetes self-care monitoring. They reported maintaining a heightened awareness of bodily sensations to detect and interpret symptoms, which they then confirmed via technology such as glucometers, CGMs, and insulin pumps. This combined approach enabled them to identify acute changes in their disease state and make informed management decisions. For instance, one participant explained that they relied on detection and interpretation of somatic sensations to cue checking their blood sugar with a monitor. They reported that the findings of this monitoring process then positioned them to take appropriate actions such as consuming sugar or administering insulin. They explained,

*It all depends on how my body feels first. And then, if my body is telling me that I'm slowing down, or I'm kind of like bottoming out or anything like that, or if my body starts to cramp, then I'll check my blood sugar, and I'll say, 'Hey, listen all right. I need to eat some sugar. I need to eat a snack, or I need to give myself about 3 or 4 units of insulin.'*

(Black male, 41 years old)

In addition to immediate health concerns, participants in this cluster also prioritized self-care monitoring to detect progressive changes in their diabetes. They reported regularly performing lab work, attending appointments with specialists to monitor for complications, and conducting foot exams to detect subtle, chronic changes associated with diabetes. For example, one participant described the importance of their foot examination, noting sensations, skin conditions, and physical changes that could indicate a shift in their disease state. They explained,

*How does your foot feel? Does it hurt? Does it ache when you feel the skin? Is [sic] there any open cuts, sores, any changes to how your foot looks? Is it swollen? Is it red? Is it hot? You know, things like that that you try to zero in on.* (Black female, 47 years old)

The comprehensive approach to self-care monitoring adopted by these participants, which employed both endogenous and exogenous resources, provided them with a heightened awareness of changes in their disease state. This awareness positioned them well to engage in self-care management behaviors when changes were identified.

### Proactive Self-Care Management

Individuals in Cluster 1 demonstrated a well-informed approach to self-care management, integrating information from self-care monitoring with situational awareness to cue and evaluate corrective treatment. This approach allowed them to promptly engage in management behaviors when changes in their bodies occurred and accurately evaluate treatment effectiveness based on signs and symptoms. Their comprehensive monitoring behaviors enabled proactive responses to glycemic changes. For instance, one participant stated "as soon as I start to see that number trending up, you know. I try and be proactive, and making sure it doesn't get too bad." (White male, 47 years old) In relation to hypoglycemia, the

same participant described a proactive response to impending hypoglycemia, even if their blood sugar was still within normal range. They explained that if they notice a significant downward trend via glucometer or symptoms of hypoglycemia, they immediately take corrective measures, such as consuming 15 grams of carbohydrates to stabilize their blood sugar.

However, while individuals in this cluster ubiquitously reported quick action when managing hyperglycemia, multiple participants reported delayed treatment of hypoglycemia. For example, one participant noted, "I knew it [hypoglycemia] was happening... I wasn't quick enough to pull the, you know, dump all the carbs in to get it back up fast enough." (White male, 76 years old) Potentially underlying this behavior, these individuals revealed hyperglycemia avoidance prioritization and minimization of hypoglycemia concerns. For example, one participant reported "more times than I like to remember that I can't catch [hypoglycemia], and I have to wait for someone to get to me." Despite this, they stated, "I would rather have a low than a high because it's harder to fix highs." (Black male, 41 years old)

Regarding treatment evaluation, another participant highlighted the role of situation awareness. This individual stated that if they engage in corrective action for a high blood sugar reported on their CGM, but symptoms persist, then they can recognize that they may still have hyperglycemia. Then, they can engage in further corrective action.

Overall, individuals in Cluster 1 engaged in self-care management that was well-informed by both self-care monitoring and situational awareness. This allowed them to promptly address changes in glycemia and assess treatment effectiveness.

Table 5. Themes and Exemplar Quotes for Cluster 1	
Theme	Exemplar Quote
Acceptance and Resilience supporting Confidence	<p><i>Confidence</i></p> <ul style="list-style-type: none"> <li>• "My confidence is at an all-time high... I've mastered my own diabetes, and every day I learn something new about what I can do." (Black male, 41 years old)</li> <li>• "My confidence is probably the best it's been recently, and confirmation from all my doctors that all my numbers are where they need to be makes me feel like I'm doing the right thing." (White male, 47 years old)</li> <li>• "Me just being responsible for its not a hard task to accomplish." (Black female, 28 years old)</li> </ul> <p>Acceptance and Resilience</p> <ul style="list-style-type: none"> <li>• "Diabetes is either going to control your life or you're going to control the diabetes, and I just give myself the option to live my life as normal as possible." (Black female, 28 years old)</li> <li>• "Diabetes is just a part of life. We just get up and do what you have to do." (Black female, 47 years old)</li> <li>• "If I don't take care of myself, then I die. That's how I go about looking at my diabetes, because if I don't take care of myself and I eat whatever I want, and don't, you know, dose for it, or correct for it, or, you know, count my carbs the right way, I'm not going to be around to do any of that. I'm not going to be around for my family. So, for that, I don't think self-care is difficult for me per se, because I feel as though every day there's a new obstacle to get over. But I'm willing to jump, climb, crawl, whatever, over any obstacle that comes my way with this, because I have to. I don't have a choice." (Black male, 41 years old)</li> <li>• "I don't think that if... a person is diabetic, that they can forget that they're ever diabetic, they can pretend that they're not diabetic, but you can't forget it... and the pretending only lasts so long." (White male, 76 years old)</li> </ul>
Holistic Self-Care Maintenance	<p>Maintain Physical Health</p> <ul style="list-style-type: none"> <li>• "Work out as much as I can. Go for a run every now and again, when I, when my body allows it. Just making sure I'm eating the right foods. I drink a ton of water. It's just basically doing everything. Make sure I'm counting carbs the right way." (Black male, 41 years old)</li> </ul> <p>Maintain Emotional Health</p> <ul style="list-style-type: none"> <li>• "I just like to keep a good spiritual base, in addition to just doing meditation and yoga, for emotional support of myself." (Black female, 28 years old)</li> </ul> <p><i>Negative Cases: Neglecting an Aspect of Health Maintenance</i></p>
Comprehensive Self-Care Monitoring	<p>Value of Somatic Awareness</p> <ul style="list-style-type: none"> <li>• "It is really important that, you know, you're able to, you know, feel, feel what's going on in your body and being able to listen to your body, to make the right, to you know, make that correction." (White male, 47 years old)</li> </ul> <p>Integration of Endogenous and Exogenous modes of Monitoring</p> <ul style="list-style-type: none"> <li>• "It all depends on how my body feels first. And then, if my body is telling me that I'm slowing down, or I'm kind of like bottoming out or anything like that, or if my body starts to cramp, then I'll check my blood sugar, and I'll say, 'Hey, listen all right. I need to eat some sugar. I need to eat a snack, or I need to give myself about 3 or 4 units of insulin.'" (Black male, 41 years old)</li> </ul> <p>Monitoring for Long-term Changes in Disease</p> <ul style="list-style-type: none"> <li>• "How does your foot feel? Does it hurt? Does it ache when you feel the skin? Is there any open cuts, sores, any changes to how your foot looks? Is it swollen? Is it red? Is it hot? You</li> </ul>

	<p>know, things like that that you try to zero in on.” (Black female, 47 years old)</p> <p><i>Negative Cases: Reliance on Technology to Detect Changes when Asleep</i></p> <ul style="list-style-type: none"> <li>• “I would wake up because of my alarm. That was the only reason I knew that I was like going low in my sleep.” (Black female, 28 years old)</li> </ul>
Proactive Self-Care Management	<p>Proactive Self-Care Management</p> <ul style="list-style-type: none"> <li>• "As soon as I start to see that number trending up, you know. I try and be proactive, and making sure it doesn't get too bad." (White male, 47 years old)</li> <li>• "If I see it trending down, and you know it's dropping quickly, you know, I will start to address it, you know, as it is-- that's happening, even if it's, you know still like, maybe like 80 or 90. But I see that the trend is happening quickly, and it's dropping, you know. I'll make a correction, you know. Just eat something, you know. Just maybe like 15 carbs to, to kind of get stabilized." (White male, 47 years old)</li> <li>• “When the alarm went off...and I looked at it. I thought about it for a second. I said, ‘Well, I guess I got to eat a chocolate chip cookie.’ That's exactly what I did.” (White male, 76 years old)</li> </ul> <p>Evaluation of Treatment</p> <ul style="list-style-type: none"> <li>• "I usually can tell [if a treatment worked] by the pump, and also how you feel. If you have the same feeling that you had at maybe 200, and it doesn't feel too much better, then you know, maybe it's still kinda high. Maybe you need to bring it down a little bit more and get rid of the headache." (Black female, 47 years old)</li> </ul> <p><i>Negative example: Delayed self-care management</i></p> <ul style="list-style-type: none"> <li>• “Sometimes I can catch it before it gets too low where I can't do anything but there are more times than I like to remember that I can't catch it, and I I I have to wait for someone to get to me.” (Black male, 41 years old)</li> <li>• “I knew it (hypoglycemia) was happening... I wasn't quick enough to pull the, you know, dump all the carbs in to get it back up fast enough.” (White male, 76 years old)</li> </ul>

## Cluster 2

### Holistic Self-Care Maintenance Except When Difficult

Individuals in Cluster 2 reported regular and intentional efforts to promote and preserve physical functioning and emotional well-being through self-care maintenance behaviors. To preserve and promote physical health, individuals in this cluster reported efforts to maintain adherence to medication and care plans, perform exercise, take precautions, eat well, and stay hydrated. In addition to these behaviors to maintain physical health, participants in Cluster 2 also reported efforts to promote and preserve mental health, including engagement in mindfulness activities, professional therapy, speaking with social supporters, and leisure activities.

However, this group reported that their self-care maintenance behaviors suffer when adverse circumstances arise, often prioritizing other things over their self-care maintenance. For example, some individuals reported that high demands of work, distraction, and difficulties navigating the health system sometimes resulted in poorer self-care maintenance than they would like. For example, one participant stated, “I have a great job. But it takes a lot of my attention, and so I’m spending less time exercising, and maybe being mindful of diabetes control.” (White female, 44 years old) Therefore, while these individuals under normal or optimal circumstances were able to engage in self-care that addressed both physical and emotional health, their self-care was hindered when challenges arose.

### Diverse Approaches to Self-Care Monitoring

Individuals in Cluster 2 reported a wide variety of approaches to self-care monitoring. Some individuals in Cluster 2 reported self-care monitoring that combined endogenous with exogenous monitoring methods, whereas others reported monitoring that was solely reliant on technology. The first group of individuals in Cluster 2 employed a combination of endogenous and exogenous modes of self-care monitoring to detect acute changes. These individuals described symptom detection and interpretation coupled with employing glucometers, CGM and insulin pumps. For example, one individual (Black male, 24 years old) stated that moodiness, slowness, or difficulty getting up may alert them to abnormal blood sugars and cue them to check their blood sugar with a device.

On the contrary, the second group of individuals in this cluster relied heavily on technology alone for monitoring acute changes. One individual from this group reported that they exclusively rely on technology to alert them to changes in their blood sugar, stating “Honestly, the only thing that I do to monitor is look at my Dexcom on my phone.” (Black female, 29 years old) Underlying this, that same individual admitted difficulty detecting signs and

symptoms of hypoglycemia because their symptoms of hypoglycemia were not what they once were. Therefore, these individuals reported difficulty detecting nuanced signs or symptoms of changes in glycemia. Some individuals in Cluster 2 reported difficulty detecting lows while asleep and a general reliance on technology during this time. In contrast, others report an ability to detect lows while asleep and then awaken.

Regarding self-care monitoring of long-term complications, these participants demonstrated a range of perspectives and approaches. Some individuals reported regular engagement in monitoring activities such as attending eye doctor appointments twice annually, keeping logs to identify food-glycemia trends, and tracking changes in weight. However, other individuals did not endorse engagement in such activities. For example, one participant stated, “I don't do like the foot exams, or anything like that... It kind of just seems like it would be not a great use of time.” (White female, 35 years old)

Thus, the self-care monitoring strategies reported by participants within Cluster 2 demonstrated a range of approaches, with some individuals combining endogenous and exogenous methods while others heavily relied on technology alone. The ability to detect specific signs and symptoms, such as hypoglycemia, varied among individuals within this cluster. Additionally, the ability to detect lows, and reliance on technology during sleep, was varied within this cluster. Further, there was a large variety of approaches to monitoring of long-term changes in diabetes, with some individuals reporting many activities while others did not feel they were valuable.

### Inconsistent Self-Care Management

Individuals in this cluster exhibited inconsistent self-care management behaviors that were either uninformed by self-care monitoring or inconsistent with a structured treatment plan. Rather than relying on systematic approaches, individuals in Cluster 2 tended to make decisions



based on personal intuition in the moment. Their process may be understood as naturalistic decision-making.

Individuals in Cluster 2 reported management behaviors that were inconsistent with monitoring information. For instance, one participant mentioned administering a "magic number" of 2 units of insulin to treat hyperglycemia regardless of their actual blood sugar level (Black female, 60 years old). Another individual reported administering corrective insulin without knowing their blood sugar level at all. Moreover, when managing changes in glycemia, participants in Cluster 2 reported instances of "overdoing it" in treating hyperglycemia (Black female, 19 years old) and disregarding pump recommendations for corrections. Underlying some of these behaviors were expression of hypoglycemia concern minimization. For example, one participant expressed a lack of concern about the potential risks of insulin stacking. They stated, "I'm not quite as concerned about stacking, meaning like, I'm not concerned about taking multiple injections like within an hour." (White female, 35 years old)

Treatment of low blood sugar levels also varied within this cluster. Some individuals described it as a "guessing game" (Black female, 29 years old), while others considered it simpler than managing high blood sugar levels. Consequently, participants in this cluster exhibited both overtreatment of hypoglycemia as well as undertreatment and delayed treatment. For example, one participant characterized their treatment of hypoglycemia as "not very aggressive." (White female, 35 years old) Reasons for delaying treatment included normalization of asymptomatic hypoglycemia, minimization of hypoglycemia, and failure to prioritize prompt treatment. For example, one individual (Black male, 29 years old) reported that they only treat hypoglycemia if they feel hypoglycemic, suggesting that they do not treat asymptomatic episodes. Another individual reported that there have "been plenty of situations where I have failed to make [treatment] a priority." (White female, 44 years old)

Table 6. Themes and Exemplar Quotes for Cluster 2	
Theme	Exemplar Quote
Holistic Self-Care Maintenance Except When Difficult	<p>Maintain Physical Health</p> <ul style="list-style-type: none"> <li>• “Not eat too much carbs. That’s one goal not to eat too many carbs. Another goal is to get 30 minutes exercise in daily, which I do. I walk my dog every day except for today. But I do indoor activities as well. Another one is drinking enough fluids. Keep your blood sugar intact. I do follow a meal plan. I count carbs. I count proteins. I even count calcium and fats because I have osteopenia. I have to calculate how much calcium I’m getting a day.” (Black female, 60 years old)</li> <li>• “I exercise. I try to. I try this, for now I’m starting to try to eat better portions, kind of eat more fruits and vegetables.” (Black male, 29 years old)</li> <li>• “Be sure you’re always wearing your mask. Make sure You always have hand sanitizer around, always have your medicine.” (Black male, 24 years old)</li> <li>• “I take my insulin every day. I wear the Dexcom. That’s huge for maintenance.” (White female, 44 years old)</li> </ul> <p>Maintain Emotional Health</p> <ul style="list-style-type: none"> <li>• “Yoga helps me with my emotions.” (Black female, 43 years old)</li> <li>• “I am in therapy, so I do use my therapist as outlet for that.” (Black female, 25 years old).</li> <li>• “It really helps to talk about it. It really helps to talk about it with somebody that actually does understand what you’re going through.” (Asian female, 47 years old)</li> <li>• “I tend to like try to watch movies or watch Netflix or anything or read a book just to keep myself on a calmer side.” (Asian female, 33 years old)</li> </ul> <p>Challenges to Holistic Self-Care Maintenance</p> <ul style="list-style-type: none"> <li>• “I have a great job. But it takes a lot of my attention, and so I’m spending less time exercising, and maybe being mindful of diabetes control.” (White female, 44 years old)</li> <li>• “I guess just time sometimes, like if you know that your blood sugar would be better if you were able to take a walk and bring a high blood sugar down, or something like that. But you’re just not able to do it, because of you know constraints with their job, or with time.” (White female, 35 years old)</li> <li>• “I might do a lot of things and be active and constantly moving around, I might forget to get my medicine.” (Black male, 24 years old)</li> <li>• “There are times where you need supplies, and it’s kind of hard to get that, because you have to go through so many different obstacles, such as like doctors and forms, or whatever.” (Black female, 19 years old)</li> </ul>
Diverse Approaches to Self-Care Monitoring	<p>Technologically Reliant</p> <ul style="list-style-type: none"> <li>• “Honestly, the only thing that I do to monitor is look at my Dexcom on my phone.” (Black female, 29 years old)</li> <li>• “I have to look at my pump, and sometimes I don’t feel that I’m having a hypo until my blood sugar is in the fifties. So, I have to constantly look at the pump. (Black female, 60 years old)</li> </ul> <p>Integration of Endogenous and Exogenous modes of Monitoring</p> <ul style="list-style-type: none"> <li>• “If I get up, and like real slow getting up. Or if I have an attitude right away, or I’m like, or I don’t feel like, right, or I’m feeling down right away. That kind of give me like “Oh, you… probably haven’t took your medicine [sic], or …you need to check your sugar.” (Black male, 24 years old)</li> </ul> <p>Monitoring for Long-term Changes in Diabetes</p> <ul style="list-style-type: none"> <li>• “I go make sure I go to the eye doctor every 6 months.” (Black female, 60 years old)</li> <li>• “Keeping a log of different things, and what times I eat, or the things I eat, if I keep a log it helps you notice different patterns, how the body react to certain things.” (Black male, 29 years old)</li> </ul>

	<p>old)</p> <ul style="list-style-type: none"> <li>• “If my weight fluctuates the meaning...is that if I’m losing weight, I know that I’m off my blood sugar... They’re higher a lot.” (Black female, 29 years old)</li> </ul> <p>Challenges to Self-Care Monitoring</p> <ul style="list-style-type: none"> <li>• “The simple fact is that I can’t I’m not getting the same symptoms or the symptoms that I was getting before.” (Black female, 29 years old)</li> <li>• “When you're sleeping, you can't really tell because you know, you're tired, you're sleeping, and most time you're like, you know, passed out. But you don't even know what's going on sometimes.” (Asian female, 33 years old)</li> </ul> <p>Monitoring when Asleep</p> <ul style="list-style-type: none"> <li>• “If I’m sleeping, it is usually a Dexcom that is alerting me unless it's one of those times when it gets really really low.” (Black female, 43 years old)</li> <li>• “When I’m sleep, I can feel a low sugar, and I wake up instantly.” (Black male, 29 years old)</li> </ul>
<p>Inconsistent Self-Care Management</p>	<p>Self-Care Management Inconsistent with Monitoring information</p> <ul style="list-style-type: none"> <li>• "The CGM is like “Oh your sugars high”. Like okay, I already took some medicine. I'm just waiting to see what the actual number was.” (Black male, 29 years old)</li> <li>• “I test my blood sugar and if it's too high, I will take a manual dose. 2 units. The magic number is 2 units.” (Black female, 60 years old)</li> </ul> <p>Overtreating Hyperglycemia</p> <ul style="list-style-type: none"> <li>• “There are times where I do like to overdo it, just because, like I said, I don't really like how high blood sugar feels. Sometimes I could definitely say, I probably overdo it.” (Black female, 19 years old)</li> <li>• “I just go in the correction ratios that I have programmed in my pump for highs. Sometimes I will kind of override them, and correct more aggressively than my pump says.” (White female, 35 years old)</li> </ul> <p>Overtreating Hypoglycemia</p> <ul style="list-style-type: none"> <li>• “There are times that sometimes I might overdo it with the carbs. So, you know, even though I know what I needed to do. I might have overdone it with the carbs because low blood sugar, because of that--this is my chance that I can eat snacks that I don't usually eat, so you know I might-- I might overdo it. And of course, you know, it--- of course it's going to get rid of the low, but it also elevated my blood. We're at that point [where I need] the insulin now.” (Black female, 43 years old)</li> <li>• “I would keep eating, and then by the time... you test in two hours. It's like 350 [mg/dL].” (Asian female, 47 years old)</li> </ul> <p>Delayed Treatment of Hypoglycemia</p> <ul style="list-style-type: none"> <li>• “If its low, If I feel like it's being low like I said, I'll check and make sure it is, and I'll get some orange juice.” (Black male, 29 years old)</li> <li>• “I’m a person that can notice it, and, like I said, I can persevere... in my symptoms for a good, a surprisingly good amount of time. But if you're not a person like that, and your body can’t take it, you can pass out.” (Black male, 29 years old)</li> <li>• “I try not to have anything that’s like too much, just because I know that it’ll bring it up way too high. I don’t need that. But I try to stay like the first smallest limit before I have too much to bring it up.” (Black female, 19 years old)</li> <li>• “For lows, generally pretty- uh, not very aggressive and treating like I'll take maybe one glucose tablet.” (White female, 35 years old)</li> <li>• “If my Dexcom beeps at, you know, like 59 and I’ve been kind of just sitting between 60 and</li> </ul>

	<p>65 for hours, and I don't have any insulin on board-- in that case I might just eat something, not even necessarily glucose, but just some something very small to kind of just bump up a tiny bit.” (White female, 35 years old)</p> <ul style="list-style-type: none"> <li>• “I have been in... cases where I've said, hey, like, can I just order an orange juice, maybe you know. but there have been plenty of situations where I have failed to make that a priority.” (White female, 44 years old)</li> </ul>
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### Cluster 3

#### Economic Constraints on Self-Care

Individuals in Cluster 3 encountered barriers to self-care stemming from factors outside of their control such as finances and insurance. These barriers generally centered on economic constraints and issues with access to therapeutics, significantly impacting their ability to engage in self-care. Participants in Cluster 3 reported facing barriers to self-care because of financial limitations. Economic constraints prevented these participants from accessing better resources and therapies to best manage diabetes. For example, despite healthcare providers recommending an insulin pump as the best option for insulin delivery, a participant revealed that they could not afford it. They expressed the impact of financial constraints on their self-care, explaining,

*When you have to ration because of cost, self-care really isn't a viable thing for you at the time. You know, self-care kind of goes out the window. Because now you're thinking about other things, you know, 'If I don't have been anywhere to live [sic],' you know, 'how am I taking care of myself? If I don't have anything to eat, how am I taking care of myself?'* (Black female, 41 years old).

Another participant shared an experience of being unable to access therapeutic technology due to economic constraints, which ultimately led to hospitalization. They described how issues with insurance prevented them from having a CGM sensor, resulting in a severe episode of hypoglycemia. The participant explained, “That's how I ended up in the hospital when I was hypoglycemic. Because I didn't have my sensor, so I didn't know I was low.” (Black

female, 25 years old)

### Psychosocial Barriers to Self-Care

Individuals in Cluster 3 reported psychosocial barriers to engagement in self-care, originating from both internal and external factors. Internally, these barriers were primarily rooted in difficulties accepting their diabetes diagnosis. Externally, barriers arose from managing perceptions of others regarding diabetes. The interplay of these barriers influenced their mental health, consequently impacting their self-care.

Individuals in this cluster reported struggles to accept diabetes. Participants reported moments where they denied their responsibilities in caring for their diabetes, feeling as though they were not actually someone with diabetes. One participant expressed this sentiment by stating, "It'd be times where I feel as though I'm not a diabetic and I shouldn't have to take the medicine." (Black male, 25 years old) This difficulty with acceptance resulted in externalization of their disease, viewing it as something that they must struggle against. Illustrating this, another participant likened diabetes to the Greek myth of Sisyphus. She stated, "It's a constant fight. It's like-- What's that Greek mythology, where the guy has to like fight forever, or something? -- It's kind of like that." (Latino female, 23 years old)

Further, participants in Cluster 3 reported that managing others' perceptions hindered their mental health and, consequently, their self-care. Individuals in this cluster stated that they faced stigmas associated with having T1D, particularly regarding limitations that T1D supposedly imposes. Reflecting on these stigmas, individuals reported feeling abnormal and incapable, which eroded their wellbeing. A participant explained, "You get into a bout of basically feeling like you can't do anything. Feeling of not being normal eats away at you." (Black female, 41 years old) As a result, individuals in Cluster 3 internalized themselves as "other" and often compared their lives to those of "normal" people. Participants explicitly

expressed frustration with having to manage T1D when others did not and reported that harboring this mindset took a toll on their mental and emotional health. One participant explained,

*I just look at people around me, and I'm like, 'It sucks that I have to like, pause my, uh, day so many times just to take care of myself and keep myself alive, or like these people just get to keep going and not worry about that stuff.' So, like, I think sometimes I get in my own head, and that kind of hinders myself [sic].* (Latino female, 23 years old)

The negative impact of T1D stigmatization, and its influence on mental health, was a concern for people in Cluster 3. Individuals in Cluster 3 stated that mental health challenges compromised their ability to engage in self-care. Participants reported that during periods of poor mental health, they were generally more careless and indifferent towards their self-care. A participant explained, "I was way more careless when I was depressed, so it was like it didn't...It affected my diabetes care negatively. I just I didn't care." (Black female, 25 years old)

### Inconsistent Self-Care Maintenance

Individuals in Cluster 3 reported inconsistent self-care maintenance often interrupted or forgotten due to competing responsibilities or mental barriers. As a result, individuals in Cluster 3 did not feel that they were adequately maintaining their health. For example, one participant reflected on their physical health stating, "I really don't see me as maintaining it." (Black female, 25 years old)

Participants described external demands such as work and family responsibilities as obstacles to consistent self-care maintenance. For example, a participant explained that their work schedule and childcare responsibilities made it difficult to prioritize self-care. They admitted that they sometimes injected insulin early, late, or even forgot to entirely due to preoccupation with competing responsibilities. Another participant likened the additional

responsibilities of living with T1D to having a second job, which as a result, led to lapses in self-care when added to responsibilities of daily living. They explained, “Being diabetic is like having a second full time job sometimes, so sometimes I can be forgetful.” (Latino female, 23 years old)

Mental barriers were also identified as factors leading to self-care maintenance neglect. One participant described experiencing periods where they simply didn’t care about self-care for weeks at a time. Participants noted that neglecting self-care maintenance could escalate into even greater neglect. A participant reflected on this escalation, explaining, “when you're not taking any steps to take care of yourself, and you allow that feeling to always bring you down with saying, ‘Okay, I'm just going to eat whatever. I'm not going to check my blood sugars. I'm not going to take the insulin.’” (Black female, 41 years old).

However, it is worth noting that individuals in Cluster 3 did report engagement in self-care maintenance at times. Despite moments of neglect, a participant reported trying to remain active at work, hydrate throughout the day, address dental maintenance, and attend regular checkups.

### Dependence on Technology for Self-Care Monitoring

Individuals in Cluster 3 perceived exogenous monitoring devices like CGMs and glucometers as complete substitutes for somatic awareness of hypoglycemia. As a result, they relied heavily on technology to detect changes in glycemia. For example, when one participant discussed how they detect hypoglycemia, they explained, “it’s mostly the monitor. I've gotten to a point where I've become numb to lows, and I’m generally not aware until I’m almost kinda like at rock bottom.” (Black female, 41 years old) Another participant shared a similar sentiment, explaining that their CGM alerts them to hypoglycemia, often catching them by surprise.

Underlying this reliance on technology, participants in Cluster 3 generally harbored an attitude toward self-care monitoring that they no longer needed to actively monitor themselves

because devices were already doing so. In fact, one participant stated that technology assumes the responsibility of self-care monitoring, relieving them of the need to consciously do so. They remarked, “it’s always happening in the background. So, I don’t have to necessarily think about it.” (Latino female, 23 years old) In fact, participants in this cluster even referred to these devices as a “safety net” (Black female, 25 years old).

However, some individuals in this cluster recognized the potential drawbacks of relying solely on technology for monitoring. One participant acknowledged that a CGM’s glycemic estimate may lag behind the actual glycemic value, potentially providing the user a “false sense of security” (Black female, 41 years old). Another participant expressed uneasiness about relying on technology to detect hypoglycemia, fearing instances where it may not be functional or available. Despite this knowledge, individuals in Cluster 3 still endorsed reliance on technology for monitoring.

### Poorly Informed and Unevaluated Self-Care Management

Participants reported inadequate self-care management that was poorly informed and ineffectively evaluated, leading to inconsistency. Self-care management of individuals in Cluster 3 was characterized by either failing to perform management behaviors or performing inappropriate management due to inaccurate monitoring information. Illustrating this, individuals in Cluster 3 reported forgetting to engage in monitoring behaviors leading to failure to engage in corrective actions. For example, one participant explained, “sometimes I kind of do forget to check my sugar and take my insulin so that kind of can be challenging for me sometimes.” (Black male, 23 years old)

Further, participants engaged in management behaviors based on inaccurate information and, as a result, experienced undesired outcomes. Participants reported that technology such as CGM often produced inaccurate glycemic estimates when blood sugar was



quickly changing, and therefore prompted inappropriate management behaviors. Illustrating this, a participant explained, “The sensor doesn’t catch up as quick as my body is catching up. So sometimes I’ll see myself constantly trying to cover [hypoglycemia] with sugar, and then next thing I know I’m going high.” (Black female, 41 years old) Because self-care management frequently resulted in glycemic lability for individuals in Cluster 3, they generally reported feeling a lack of control. For example, a participant explained, “If I’m low and I correct it, I might still spike over 150. So, it's just like...It's kind of like chasing something that's going way faster than you all day, so it just feels like constantly having to manage something all day like it can never just be stable.” (Black female, 25 years old)

Individuals in Cluster 3 demonstrated deficits in self-care management regarding treatment evaluation, citing knowledge deficits as a key challenge to accurate treatment evaluation. For example, a participant described how not knowing their insulin’s duration and peak time hindered their ability to recognize that they were taking too much insulin. This participant reported, “I was having that issue with like my carb-ratio or my correction factor, like it was giving me too much insulin when it was correcting me. But I wouldn't even notice, because I'll be high, and I wouldn't come down until like an hour later, and I didn't notice like, ‘Oh, maybe it's because it was too much insulin.’” (Black female, 25 years old) Other participants demonstrated unawareness that they were supposed to evaluate their treatment altogether. One participant stated, “Once I cover, I don't really think about it whether I’m high or low. I don't think about it. I know I did what I was supposed to do. The confidence is basically like, ‘Okay, I did what I supposed to do. I don't have to worry.’” (Black female, 41 years old)

However, some participants in Cluster 3 demonstrated the ability to evaluate the effectiveness of a treatment, whether it be noticing that overtreating hypoglycemia resulted in hyperglycemia or that their blood sugar is remaining elevated despite administering insulin. One participant mentioned, “If my insulin don't work [sic] like, if I take it, and my sugar is still high. I'll

call the doctor and ask the doctor and tell her like my insulin is not working.” (Black male, 23 years old)

<b>Table 7. Themes and Exemplar Quotes for Cluster 3</b>	
<b>Theme</b>	<b>Exemplar Quote</b>
Economic Constraints on Self-Care	<p>Social Determinants of Health</p> <ul style="list-style-type: none"> <li>• "If the insurance company only wants to pay this and then I have to go to a higher cost with coming out of pocket. You know it's kind of like a debate between me, and how much self-care I'm trying to put in at the time, because now there's a strain on the pockets." (Black female, 41 years old)</li> </ul>
Psychosocial Barriers to Self-care	<p>Denial</p> <ul style="list-style-type: none"> <li>• "I get in these like mindsets for a couple of weeks where I just don't really care." (Latino female, 23 years old)</li> </ul> <p>Externalizing Diabetes</p> <ul style="list-style-type: none"> <li>• "I would define it as like a job. It's hard work." (Black female, 25 years old)</li> </ul> <p>Managing Perceptions of Others</p> <ul style="list-style-type: none"> <li>• "You get into a bout of basically feeling like you can't do anything. Feeling of not being normal eats away at you." (Black female, 41 years old).</li> </ul> <p>Mental Health</p> <ul style="list-style-type: none"> <li>• "When I wasn't taking care of my mental health, my diabetes wasn't getting taken care of as well." (Black female, 25 years old)</li> </ul> <p>Negative Examples:</p> <ul style="list-style-type: none"> <li>• "Take my health serious, because this is something I got to live with for the rest of my life." (Black male, 23 years old)</li> <li>• "This is severe to my life. I need medicine." (Black male, 25 years old)</li> </ul>
Inconsistent Self-Care Maintenance	<p>External Responsibilities</p> <ul style="list-style-type: none"> <li>• "I work a lot, and I have a kid. So it's like I gotta deal with both of that. And sometimes I may just not have time to stay on myself schedule [sic] to take insulin and stuff, so I may take it a little late, or I may take it a little early, so it can be kind of challenging for me when I'm trying to, you know, take care of my diabetes. (Black male, 23 years old)</li> <li>• "Sometimes I just may forget to take my insulin or check my sugar, and it kind of gets hard, because, you know, have a lot of stuff to do in my life. So sometimes I kind of do forget to check my sugar and take my insulin." (Black male, 23 years old)</li> </ul> <p>Mental Barriers Leading to Inconsistency</p> <ul style="list-style-type: none"> <li>• "When you're not taking any steps to take care of yourself, and you allow that feeling to always bring you down with saying, okay, I'm just going to eat whatever. I'm not going to check my blood sugars. I'm not going to take the insulin." (Black female, 41 years old)</li> </ul> <p>Negative Cases</p> <ul style="list-style-type: none"> <li>• "I don't get a whole lot of exercise these days. but I do try to stay active while I'm at work making sure I drink enough water, making sure that I'm, you know, addressing any issues with dental, addressing any issues when it comes to like personal care as far as cuts, bruises. Make sure I see the doctor on a regular basis. Any questions that I have. That's one of the biggest things." (Black female, 41 years old)</li> </ul>
Dependence of Technology for Self-Care	<p>Reliance on technology to detect hypoglycemia</p> <ul style="list-style-type: none"> <li>• "I didn't have my sensor so I didn't know I was low." (Black female, 25 years old)</li> </ul> <p>Passive Monitoring</p>

Monitoring	<ul style="list-style-type: none"> <li>• “It's always happening in the background. So I don't have to necessarily think about it.” (Latino female, 23 years old)</li> </ul> <p>Negative Findings</p> <ul style="list-style-type: none"> <li>• “It makes me feel uneasy when I can't catch my low blood sugar before the Dexcom does, because I'm like, you know what if my Dexcom is not working and stuff?” (Black female, 25 years old).</li> </ul>
Poorly Informed and Unevaluated Self-Care Management	<p>Failure to Evaluate Treatments</p> <ul style="list-style-type: none"> <li>• “If I was low. I would eat something, and I would go to sleep ... I should have waited to see if it came up or something.” (Black female, 25 years old)</li> </ul>

**Aim 3: Integration Phase**

Identification of clusters and qualitative exploration of attitudes and self-care within these clusters revealed three self-care typologies in individuals with T1D. These typologies were labeled as expert, novice, and inconsistent. Integration of quantitative and qualitative data to develop meta-inferences is displayed below in a joint display table (Creswell, 2023; Guetterman et al., 2015) (Table 8).

**Table 8. Integration of Quantitative and Qualitative Data**

Cluster	Quantitative Scores Mean (SD)	Qualitative Themes	Metainferences
<i>Antecedents to Self-Care</i>			
<b>Cluster 1</b> Excellent Self-Care Confidence	<b>Self-Care Confidence (0-100)</b> 92.73 (7.47)	Acceptance and Resilience supporting Confidence	<ul style="list-style-type: none"> <li>Those in Cluster 1 were best positioned to accept challenges and persist in self-care due to their confidence and resilience.</li> <li>Those in Cluster 3 faced unique challenges due to SDOH and failed to prioritize self-care when facing these challenges due to cognitive barriers such as disease denial.</li> </ul>
<b>Cluster 3</b> High SDOH Risks	<b>SDOH Risk Tally (0-22)</b> 6.83 (4.08)	<ol style="list-style-type: none"> <li>Economic Constraints on Self-Care</li> <li>Psychosocial Barriers to Self-care</li> </ol>	
<i>Self-Care Maintenance (0-100)</i>			
<b>Cluster 1</b> Excellent Maintenance	84.92 (8.82)	Holistic Self-Care Maintenance	<ul style="list-style-type: none"> <li>Consistency appears to be what separates the three clusters at this level.</li> <li>Those with the best self-care maintenance reported engagement in a holistic approach to self-care despite challenges.</li> </ul>
<b>Cluster 2</b> Adequate Maintenance	78.64 (8.92)	Holistic Self-Care Maintenance Except When Difficult	<ul style="list-style-type: none"> <li>Self-care maintenance of Cluster 2 suffered when challenging but was generally consistent and holistic.</li> <li>Cluster 3 was generally inconsistent.</li> </ul>
<b>Cluster 3</b> Poor Maintenance	51.85 (7.66)	Inconsistent Self-Care Maintenance	
<i>Self-Care Monitoring (0-100)</i>			
<b>Cluster 1</b> Excellent Monitoring	85.09 (8.81)	Comprehensive Self-Care Monitoring	<ul style="list-style-type: none"> <li>Cluster 1 (high scores) differentiated itself from Clusters 2 and 3 (inadequate scores) by engaging in monitoring behaviors that integrated endogenous and exogenous information. They valued somatic awareness and paid attention to changes in their bodily sensations and complemented this with technology.</li> </ul>
<b>Cluster 2</b> Inadequate Monitoring	65.61 (9.77)	Diverse Approaches to Self-Care Monitoring	<ul style="list-style-type: none"> <li>The other clusters relied more exclusively on technological approaches to detecting changes resulting in poorer self-care monitoring overall.</li> </ul>
<b>Cluster 3</b> Poor Monitoring	56.86 (12.88)	Dependence of Technology for Self-Care Monitoring	
<i>Self-Care Management (0-100)</i>			
<b>Cluster 1</b> Adequate Management	72.54 (10.01)	Proactive Self-Care Management	<ul style="list-style-type: none"> <li>Cluster 1 maintained adequate self-care management, likely due to their strong self-care monitoring, while the other clusters reported poorer self-care monitoring and management.</li> </ul>
<b>Cluster 2</b> Poor Management	56.76 (10.14)	Inconsistent Self-Care Management	<ul style="list-style-type: none"> <li>As a result, those in Cluster 1 were able to engage in proactive behaviors to manage changes before becoming severe and had the somatic and situational awareness to evaluate treatments sooner than technologies alone may have allowed.</li> </ul>
<b>Cluster 3</b> Poor Management	44.54 (6.25)	Poorly Informed and Unevaluated Self-Care Management	
<p><b>Key:</b> SDOH = Social Determinants of Health            Full range of possible scores shown for each scale.</p>			

## Cluster 1: Expert

Self-care of individuals in this cluster can best be categorized as *expert*. Quantitative results suggested adequate self-care maintenance, monitoring, and management along with high confidence and low endorsement of problematic attitudes toward hypoglycemia. Interviews expanded on findings to provide context and detail to the observed scores. Interviews first revealed that these individuals supported their self-care and confidence with disease acceptance and resiliency. These qualities empowered them to engage in self-care that addressed physical health and mental wellbeing despite challenges. Further, these individuals reported engagement in comprehensive monitoring to detect both acute and chronic bodily changes via a synergy of endogenous and exogenous monitoring behaviors. Ultimately, these individuals interpreted their comprehensive monitoring information to engage in proactive corrective action of both hypo- and hyperglycemia. Their consistent monitoring paired with accurate situational awareness allowed them to evaluate treatment effectiveness and adjust management as appropriate. Their proactive approach to treatment of hypoglycemia aligned well with low endorsement of 'asymptomatic hypoglycemia normalization' and 'hypoglycemia concern minimization'. Their proactive approach to treatment of hyperglycemia provided greater context to the positive association between "Hyperglycemia Avoidance Prioritization" and self-care management.

## Cluster 2: Inconsistent

Self-care of individuals in Cluster 2 can best be categorized as *inconsistent*. Interviews of participants in Cluster 2 expanded on findings by highlighting the heterogeneity present within this cluster, which ultimately differentiated these individuals from those in Clusters 1 and 3. Individuals in Cluster 2 demonstrated adequate self-care maintenance and confidence, although both faltered when challenged, but inadequate monitoring and management overall. Individuals in Cluster 2 endorsed engagement in self-care maintenance that was holistic, identifying

behaviors to preserve physical function and mental wellbeing as well as prevent complications. However, their scores were not as high as participants in Cluster 1, likely because individuals in Cluster 2 endorsed difficulty performing their self-care maintenance when facing challenges. Further, individuals in Cluster 2 demonstrated a wide array of approaches to self-care monitoring in interviews. While some individuals reported employing both endogenous and exogenous resources to detect acute and chronic changes in their body due to T1D, others reported reliance on technology or outside sources alone to detect such changes. Differences in somatic awareness amongst individuals in Cluster 2 contributed to the diversity observed quantitatively and qualitatively, as some participants reported the ability to detect and interpret weak or non-specific symptoms, while others reported that they experienced no symptoms and therefore had to rely on technology. This diversity of approaches offered context to the observed heterogeneity of self-care monitoring scores of this cluster, as a portion of these participants did, in fact, perform adequate self-care monitoring per quantitative results. The self-care management described in interviews expanded upon the low self-care management scores observed. The interviews highlighted that, underlying these scores, individuals were engaging in management behaviors that were either inconsistent with monitoring or completely uninformed by monitoring information. Further, these individuals, who endorsed greater “Asymptomatic Hypoglycemia Normalization” and “Hypoglycemia Concern Minimization” than Cluster 1, endorsed delayed treatment of hypoglycemia, which was something not as frequently reported in Cluster 1.

### Cluster 3: Novice

Self-care of individuals in Cluster 3 can best be categorized as *novice*. Individuals in this cluster were the youngest with the shortest duration of disease and had the lowest self-care confidence. The interviews expanded upon the quantitative findings, providing insight into barriers to self-care uniquely reported by this cluster. Additionally, interviews offered

descriptions of self-care maintenance, monitoring, and management that were consistent with low scores on quantitative measures. These participants reported barriers to self-care that were reflective of both financial/material constraints and psychosocial challenges of individuals who may face greater social determinants of health risks with shorter disease duration (less experience). These individuals reported issues with accessibility to standard of care therapeutics as well as best practice recommendations due to insurance and financial constraints. Additionally, these individuals reported psychosocial barriers to engagement in self-care including disease denial, lack of social support, and mental health challenges. As a result of inexperience and external challenges, individuals in this cluster reported difficulty adjusting to life with diabetes. Regarding self-care maintenance, individuals in this cluster reported difficulty prioritizing self-care maintenance while also managing responsibilities of daily living. These challenges included competing demands on time and mental traps that encouraged ignoring maintenance responsibilities. Additionally, interviews revealed that these individuals relied greatly on technology or exogenous monitoring tools to detect changes in their body, as they had not developed more advanced monitoring skills. Without these devices, individuals reported not being able to monitor at all, particularly regarding hypoglycemia. The inconsistent self-care maintenance and dependence on technology for monitoring often led to self-care management that was poorly informed (due to limitations of technology) and, due to lack of knowledge or experience, often unevaluated.



# CHAPTER FIVE: DISCUSSION

## Introduction

We performed a mixed-methods study to examine how self-care clusters or groups among adults with type 1 diabetes (T1D) and to characterize the differences between individuals in each cluster. To contextualize cluster differences, we explored the interrelationships between self-care, impaired awareness of hypoglycemia (IAH), attitudes about glycemia, and social determinants of health (SDOH). In an explanatory qualitative phase, we interviewed a diverse subsample of individuals with IAH from each cluster to gain deeper insights into cluster-based differences in self-care and attitudes. Through data integration, we identified a typology with three distinct types of self-care in adults with T1D: expert, inconsistent, and novice. The individuals in this typology exhibited significant differences in self-care, glycemic attitudes, demographics, clinical presentation, and SDOH, but not IAH. Quantitative analyses clarified the interrelationships proposed in our conceptual model between glycemic attitudes, self-care, IAH, and SDOH. These analyses revealed that glycemic attitudes and SDOH significantly influenced self-care, while self-care monitoring and management influenced IAH. Qualitative analysis identified a novel attitude toward the implementation of assistive technologies that may underly differences observed in self-care monitoring and management across types. These findings contribute to our understanding of the interplay between attitudes, self-care, and IAH in adults with T1D, expanding upon our preliminary model of self-care in individuals with T1D and IAH.

## Self-Care Typology

A typology with three types of self-care was identified among adults with type 1 diabetes: Expert, Inconsistent, and Novice. Experts exemplified holistic and unwavering self-care maintenance, comprehensive monitoring, and proactive management. Experts were

characterized by experience, high confidence, disease acceptance, and resilience. The inconsistent type exhibited holistic self-care maintenance that wavered when difficult, self-care monitoring that sometimes relied on technology, and self-care management guided by convenience and intuition rather than rationale. Despite challenges with self-care monitoring and management, individuals reporting inconsistent self-care endorsed a high level of confidence in their self-care abilities. Novices displayed increasing levels of challenge in self-care maintenance, monitoring, and management. Novices were characterized by limited experience, low confidence, and feeling challenged by the need to adapt to life with diabetes. While the finding of this typology in T1D research is novel, the types align well with previous studies that suggested similar typologies of self-care in patients with heart failure (Dickson, Deatrack, & Riegel, 2008; Vellone et al., 2017)

Dickson et al. (2008) performed a cluster analysis to identify a typology of patients with heart failure. This study highlighted a typology with three types of heart failure self-care: Expert, Inconsistent, and Novice. Experts with heart failure were experienced in disease management and confident in their abilities, even when they experienced challenges. Generally, they reported the ability to detect and interpret symptoms (self-care monitoring), relate these symptoms back to a cause, and make informed, proactive self-care management decisions to avoid exacerbations. The inconsistent heart failure group was the largest type and presented the most heterogeneity of the three types. These individuals failed to engage in self-care consistently as it was often not a top priority compared to other life events such as work. Despite challenges with self-care monitoring and management, individuals in the inconsistent type reported confidence in their abilities. Novices with heart failure reported low confidence in their self-care due to inexperience and lack of skill development. These individuals reported difficulty monitoring for and managing symptoms, particularly if they had not experienced such symptoms prior.

However, our typology differs from this typology in that our clustering and interviews additionally considered self-care maintenance, while Dickson et al. (2008) did not.

Similarities in typologies of self-care across various chronic illnesses are supported by the conceptual underpinnings of our present study, specifically the Middle-Range Theory of Self-Care of Chronic Illness (Riegel et al., 2012). Our study reaffirms that self-care of chronic illness is influenced by a range of factors including access to care, experience, confidence, and skill. Individuals with more experience and confidence were better equipped to perform self-care, while those with limited experience and skill to overcome obstacles faced challenges in doing so. Among those who were well-adjusted to their condition, adequate self-care maintenance was observed, with the highest levels seen in those who demonstrated resilience and consistency in the face of challenges. Individuals with resilience were more likely to engage in proper monitoring and management, while those lacking consistency in monitoring struggled to perform effective self-care management due to inaccurate information. The typology that we identified represents a group that engages sufficiently in self-care without requiring additional support (Expert), as well as two types (Inconsistent, Novice) that could benefit from targeted interventions tailored to their unique characteristics, strengths, and barriers.

Similarly, Vellone et al. (2017) performed a cluster analysis of quantitative data to identify self-care profiles of patients with heart failure. They identified four self-care clusters of patients with heart failure based on the European Heart Failure Self-Care Behaviour Scale, which measures the theoretical dimensions of “adherence with the regimen” and “consulting behaviors” (Jaarsma, Årestedt, Mårtensson, Dracup, & Strömberg, 2009). Of the four clusters identified, one cluster represented those with consistent adherence and high consulting behaviors (34.2%), two represented those with inconsistent adherence and either low or high consulting behaviors (48.9%), and the final cluster reported low adherence and low consulting behaviors (16.9%). These clusters differed significantly in patient demographic and clinical

characteristics. As a cross-sectional quantitative study, the authors were unable to provide a more in-depth exploration of these clusters or clarify how patient characteristics may have been related to observed self-care clusters. Our finding of the Expert, Inconsistent, and Novice typology aligns well with these prior findings. In the Expert type we identified a subset of individuals (35%) who performed all measured aspects of self-care sufficiently. In the “Inconsistent” type, we identified a heterogeneous subset of individuals (56%) who performed some aspects of self-care well but faced challenges performing others. In the “Novice” type, we identified a subset of individuals (9%) who struggled to perform all aspects of self-care adequately.

However, another study by Fisher and colleagues (2000) identified a self-management typology that does not clearly map onto our findings. This study (Fisher et al., 2000) aimed to create a typology of disease management status for patients with type 2 diabetes. They based profiles of patient disease management behaviors on five domains (biologic, general health and functional status, emotional tone, quality of life, and behavioral). The authors identified 5 types: balanced (33%), problematic (11.6%), coasters (34%), discouraged (16%), and distressed (11%). The balanced type was characterized by good disease management across all measured domains. The problematic type represented those who experienced challenges with management across all domains. The coasters type represented patients who reported moderate scores for disease management across all domains, without any notable strengths or weaknesses. The coaster group had the highest level of educational attainment, was significantly more Euro-American than Latino, and was older with longer disease duration than the other types. Those in the discouraged type generally presented with good “biologic” control but lower emotional tone and lower quality of life. Finally, those in the distressed group reported lower positive emotional tone and negative affect along with dissatisfaction with their diabetes care and control, although they otherwise reported a moderate profile of scores. This group

faced the greatest social determinants of health challenges. While the balanced and problematic types align well with our Expert and Novice types, respectively, the remaining types identified by Fisher et al. (2000) each demonstrated characteristics that align somewhere between our three identified types. Differences in typology findings may be related to the differences in conceptualization of self-management (that they employed) and self-care (that we employed). As a result, their clustering criteria included factors that we considered either antecedents or consequences of self-care (e.g., biologic, general health and functional status, emotional tone, and quality of life), while our clustering was based entirely on behavior. This difference in criteria may have resulted in greater stratification and different clustering results. Additionally, their sample was significantly more Latino (39%) than ours, which could have had significant influence on reported self-care (Kleinman, Eisenberg, & Good, 1978). Finally, it is possible that typologies of self-care have changed considerably alongside advancements in technology and treatment options since the study by Fisher and Colleagues (2000) was published over two decades ago.

Given our conceptual model, we were surprised to see that none of the types had a significantly greater proportion of individuals with IAH. We hypothesized that self-care was related to IAH status, and that self-care may cluster in particular ways that may predispose individuals to greater hypoglycemia exposure and therefore IAH. Our results did not support this. It may be that current measures of diabetes self-care are not optimally tailored to differentiate the self-care behaviors of individuals with IAH from those without, as current measures sum and assess self-care maintenance, monitoring, and management relating to hypo- and hyperglycemia together. However, individuals with IAH may take vastly different approaches to monitoring and management of hypo- versus hyperglycemia due to largely different outlooks on both glycemic states (Cook et al., 2019; Rogers et al., 2012). Therefore, deficits in self-care monitoring pertaining to hypoglycemia (such as absent symptom detection

and delayed management) may be hidden by proactive and aggressive self-care pertaining to hyperglycemia (such as vigilant body monitoring for symptoms of hyperglycemia and aggressive management) (Rogers et al., 2012). Thus, while these types did not differ in IAH status, we still believe that self-care may differ between those with and without IAH, as well as amongst those with IAH. Development of tools that differentiate self-care monitoring and management of hypo- and hyperglycemia behaviors may be warranted to identify self-care profiles that correspond best with IAH. This would allow us to tease apart heterogeneity in treatment response amongst those with IAH (Sepúlveda et al., 2022).

### Interrelationships Between Glycemic Attitudes, Self-care, and IAH

Our conceptual model proposed that glycemic attitudes were associated with self-care, and self-care was associated with IAH status in adults with T1D. The relationships between glycemic attitudes and the self-care domains, as well as between the self-care domains and IAH had not been described previously. Our findings highlighted that each glycemic attitude had a significant and unique relationship with diabetes self-care. Those endorsing minimization of hypoglycemia concerns generally reported greater challenges with self-care maintenance, while those endorsing normalization of asymptomatic hypoglycemia generally reported greater challenges with self-care maintenance, monitoring, and management. Interestingly, those prioritizing hyperglycemia avoidance reported better self-care management. The relationships identified therefore support the propositions of prior literature that glycemic attitudes may impact self-care (Rogers et al., 2012; Sepúlveda et al., 2022).

Our findings build on assumptions made in previous IAH literature by exploring the relationships between self-care and IAH status. While others have assumed that attitudes influence behaviors, and that these behaviors result in hypoglycemia exposure and therefore IAH (Amiel et al., 2019), no previous study has quantified a relationship between self-care and

IAH. In our model of IAH, both self-care monitoring and management were identified as significant determinants of IAH. Interestingly, while increases in self-care monitoring scores were associated with reduced relative risk of IAH, increases in self-care management were associated with increased relative risk of IAH. While these findings are novel, they are consistent with previous literature. Each of the attitudes measured in our study were initially identified in qualitative interviews in adults with IAH and were believed to predispose one to IAH development (Rogers et al., 2012). Conceptually, minimization of hypoglycemia concerns and normalization of asymptomatic hypoglycemia were assumed to result in inaction toward monitoring and management of hypoglycemia due to low concern (Cook et al., 2019; Rogers et al., 2012; Sepúlveda et al., 2022). Conversely, prioritization of hyperglycemia avoidance was assumed to encourage hypervigilant management of hyperglycemia to such extremes as intentionally overdosing insulin (Rogers et al., 2012). A recent study by Sepulveda and colleagues (2022) supported this when the authors identified prioritizing hyperglycemia avoidance and minimizing hypoglycemia concerns as barriers to successful hypoglycemia avoidance in adults with IAH.

It was therefore surprising that our results appeared to reflect that normalizing asymptomatic hypoglycemia (e.g., only needing to treat hypoglycemia if an episode is symptomatic) and prioritizing hyperglycemia avoidance (e.g., It's more important to avoid having high blood glucose than going low) influenced self-care in a way that was meaningful to IAH, but that minimizing concerns regarding hypoglycemia (e.g., reporting no concern about hypoglycemia) did not. Minimizing concerns of hypoglycemia was significantly related to self-care maintenance; however, self-care maintenance was the only self-care domain unrelated to IAH. It is possible that minimization of hypoglycemia concerns manifests in those who already have IAH, so it is not a driver of the condition (through self-care) but rather a consequence of losing the unpleasant stimuli previously associated with hypoglycemia. The Middle-Range

Theory of Unpleasant Symptoms (Lenz et al., 1997) supports the idea that the diminished experience of unpleasant hypoglycemia symptoms characteristic of IAH may result in minimization of hypoglycemia concerns. Additionally, it is possible that minimizing concerns around hypoglycemia was more strongly associated with other aspects of self-care, such as monitoring and management, before the widespread use of continuous glucose monitoring (CGM). In previous studies, where hypoglycemia concern minimization was found to differ significantly between individuals with and without IAH, a smaller proportion of participants used CGM than those in our study (44.6% vs 90%). The ease of monitoring provided by CGM, along with alarms that persist until treatment, may have shifted the perceived value of engaging in monitoring and management behaviors for those minimizing hypoglycemia concerns so that it no longer has a significant negative influence on their monitoring and management behaviors. Finally, this result may be due to the relatively low internal consistency reliability of the Attitudes to Awareness scale that was reported in recent literature (Cook et al., 2019) and observed in our present study. As our sample was roughly 10% that of the previously noted study (Cook et al., 2019), they may have been more likely to detect true between-group differences despite the limitations of the tool.

### **A Novel Attitude: External Monitors Replace Somatic Awareness**

Some participants, particularly those with challenges with self-care monitoring (and belonging to the inconsistent or novice types) viewed assistive technologies such as CGM as a complete replacement for somatic awareness of hypoglycemia. This attitude emerged from the qualitative interviews. Many participants endorsed the notion that these devices were the only mode of monitoring that they employed, and some even stated that they did not monitor for signs or symptoms because the monitor was doing it for them in the background. Others reported difficulty identifying symptoms of hypoglycemia because their symptoms had changed.



Thus, these participants overall reported very little symptom detection and interpretation, relying on technology to alert them of changes. Many participants referred to these devices as a “safety net” against hypoglycemia. Participants noted that these devices provided a sense of security around situations such as sleep. While previous literature has similarly noted that these devices are associated with reduced worries during periods such as night or school (Karakuş et al., 2021), our participants also reported extreme fears around situations such as sleeping or leaving the house if not accompanied by their device. Interestingly, participants admitted that their comfort was generally a false sense of security due to the shortcomings of these devices.

This finding is novel and adds to the list of glycemetic attitudes identified by others as characteristic of individuals with IAH (Rogers et al., 2012). It is likely that this attitude had not been previously identified because the previous qualitative study was performed well before the widespread implementation of CGM. Understanding this attitude is crucial, as it may predispose individuals to experiencing severe hypoglycemia when these devices malfunction or are unavailable. Further, it may explain in part the heterogeneity in treatment response of individuals with IAH. Previous research has demonstrated that despite implementation of advanced diabetes technologies, many individuals with T1D still experience severe hypoglycemia (Yu Kuei Lin et al., 2022). Thus, identification of this attitude within the context of previous literature highlights the necessity to educate patients on the importance of maintaining somatic awareness and developing skills to monitor symptoms of hypoglycemia even if diminished (Daniel J. Cox et al., 2006; Stuart A. Little et al., 2014). Belief that external devices can fully replace somatic awareness of hypoglycemia may promote or support other problematic attitudes toward glycemia; therefore, investigation into how this attitude may relate to other attitudes, such as asymptomatic hypoglycemia normalization and minimization of hypoglycemia concerns is warranted as well.

## Limitations

This study had the following limitations. First, the cross-sectional design did not allow for causal inferences. Thus, while we were able to describe relationships between concepts of interest including self-care, glycemic attitudes, and IAH, we were unable to determine the directionality of these relationships. However, identification of significant relationships allows us to better specify our conceptual model moving forward, which positions us for future investigation of directionality between relationships of interest, such as self-care monitoring and IAH, and avenues for intervention. Next, our study was geographically homogenous, as patients were all recruited from the same outpatient diabetes center. However, the center is a referral practice so the sample came from diverse areas of the region. Our sample was otherwise heterogenous, representing individuals of different age, sex, race, ethnicity, and socioeconomic status, which enhances the generalizability of our findings.

## Implications

Three types of self-care were identified in this typology: expert, inconsistent, and novice. In practice, individuals belonging to each type may require different support to overcome challenges to optimal self-care maintenance, monitoring, and management. Those with expert self-care demonstrated proficiency in all three domains of self-care and likely would not need additional intervention or support unless changes in self-care were observed. Those with inconsistent self-care may benefit from an education-based intervention to develop awareness of and skill in the more complex self-care domains. The inconsistent self-care profile, which demonstrated strong self-care maintenance but challenges with monitoring and management, may have developed basic self-care skills but their skillset never evolved further. The high confidence reported by those with inconsistent self-care suggested that individuals with inconsistent self-care felt capable of performing self-care and believed that they were doing

everything necessary to manage their diabetes. Therefore, they may possess a self-care knowledge gap. Thus, an education program to raise awareness of more advanced self-care and skills training may facilitate transition of these individuals toward expert self-care. Individuals with novice self-care differed significantly across many domains from those with inconsistent self-care. Therefore, facilitating the transition of those with novice self-care toward expert self-care likely requires a very different approach than that which may be employed to facilitate those with inconsistent self-care. First, the challenges individuals in the novice type faced due to increased exposure to potentially harmful SDOH cannot be ignored. As some participants noted, even the most basic aspects of self-care can be challenging to perform when one cannot prioritize self-care due to resource constraints such as time, money, or social support. Thus, many individuals with novice self-care may not feel that the locus of control for their self-care lies within them, which may underlie their lower self-care confidence. Therefore, the first step toward assisting participants with novice self-care likely must be an open conversation to understand their unique challenges to engagement in self-care. Only from this point can providers then make suggestions or referral to resources to support self-care that are considerate of SDOH and relevant to the individual. Additionally, a motivational interviewing intervention may help individuals to identify personalized solutions to their identified barriers to self-care. Such an intervention may help identify individual motivations to engage in self-care and approaches to overcoming unique challenges to support confidence building (Olsen, 2014). For those with novice self-care demonstrating challenges with disease acceptance, Acceptance and Commitment Therapy may provide additional value to motivational interviewing (Dindo, Van Liew, & Arch, 2017). Further investigation into these clusters, the interrelationships between self-care, IAH, and attitudes is warranted to develop interventions best tailored to suit the needs of individuals with T1D. Additionally, development of a self-care instrument to identify and characterize self-care of individuals with IAH is warranted.

## Conclusions

We performed a cross-sectional, mixed methods study with an explanatory sequential design to explore self-care, glycemic attitudes, and IAH in a diverse sample of adults with T1D. We performed a cluster analysis to identify how self-care groups or clusters in individuals with T1D and to describe characteristics of these individuals. Then, we explored the interrelationships between self-care, glycemic attitudes, and IAH to better specify the propositions in our conceptual model. We then explored self-care and attitudes qualitatively amongst a subsample of individuals with IAH from each of our identified clusters. Through data integration, we were able to identify overarching patterns in the self-care clusters and the characteristics associated with each cluster to propose a typology of self-care in adults with T1D. These findings have provided us with a foundation to refine our conceptual model and guide future investigations into the complex relationships among self-care, glycemic attitudes, and IAH, as well as to better understand the variations among individuals with IAH.

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