8-1-2015

The Retrospective Evaluation of the Effectiveness of Implementing Standard of Care Best Practices on Fear of Hypoglycemia (FOH) in Insulin Requiring Diabetics

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THE RETROSPECTIVE EVALUATION OF THE EFFECTIVENESS OF IMPLEMENTING STANDARD OF CARE BEST PRACTICES ON FEAR OF HYPOGLYCEMIA (FOH) IN INSULIN REQUIRING DIABETICS

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Submitted In Partial Fulfillment of the Requirements

For the Degree of

Doctor of Nursing Practice

Misericordia University

August 2015

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Signature of the Faculty Reader	Date
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Signature of the Director of DNP Programs	Date

Acknowledgments

I would like to take this opportunity to formally profess my deepest gratitude to the various people who have contributed to this project and to my pursuit of knowledge. Thank you to: my faculty mentors, Dr. Brenda Hage and Dr. Cheryl Fuller, for their enduring patience, guidance, and valuable expertise, my professional mentor, Dr. Michael Adler, for his support, friendship, and wisdom, Lauren Kalinay, L.P.N., for her dedication to nursing and her exuberant attitude, Dr. Anarte-Ortiz and her colleagues from Spain for their research and permission to use their research, and my peers, Christine Gallagher, Jens Hansen, Carol Medura, Christina Shuker, Charlene Zablotney, and Carla Weidner, for all of their professional and emotional support during countless hours of consultation. My thanks are also extended to the courteous patients within my clinical practice who so thoughtfully and altruistically gave their time and allowed me to share in their lives. Finally, I would like to dedicate this project to my family and to my devoted husband as it symbolically depicts the love and commitment bestowed upon me which gave me the faith and conviction to pursue my goal.

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Abstract

The population of individuals with diabetes is expected to rise along with a rise in the use of insulin therapy to control hyperglycemia and prevent diabetic complications. Insulin therapy is implicated as one of the leading causes of hypoglycemia, a potentially life-threatening adverse drug event. Hypoglycemia is recognized by patients and clinicians as the greatest barrier to achieving adequate glycemic control and it causes physical, psychosocial, financial, and safety concerns for individuals, their families, communities and health care systems. Hypoglycemia often causes insulin requiring diabetics to develop a fear of hypoglycemia, a complex phenomenon that manifests as avoidance of hypoglycemia or near normal euglycemia thus triggering hyperglycemia and increasing risk. The fear and risk of hypoglycemia requires attention by clinicians in order to assist patients in self-management. The purpose of this evidence based project was to add to clinical knowledge and demonstrate how the application of best practice strategies can be translated into real world clinical practice to improve quality and safety. All insulin requiring adults evaluated by the advanced practice nurse were provided education in accordance to best practice standards. Sixty participants were queried pre-intervention and post-intervention with the FH-15 Survey and a hypoglycemia incidence survey. The data was comparatively analyzed. Outcomes demonstrated that self-management education effectively reduced fear of hypoglycemia and incidence of hypoglycemia; however, the intervention was statistically significant in reducing fear of hypoglycemia only. Additional scholarly inquiry regarding the topic is recommended.

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Chapter 1: Introduction and Overview

Hypoglycemia is a potentially life-altering adverse drug event (ADE) and the most frequently experienced complication associated with insulin use. This event strikes fear in the hearts of insulin requiring diabetics and serves as a major barrier to attaining near normal glycemic control (Amiel, 2009). Hypoglycemia is an obstacle for both individuals and healthcare providers (HCPs) alike and deters patients from obtaining the degree of glycemic control needed for the prevention of long term diabetic microvascular and macrovascular complications. The effects of hypoglycemia on the individual range from minimally disruptive to life threatening and can have accompanying physical, psychosocial, safety, and financial implications. Hypoglycemic poses a serious threat to the health and well-being of the diabetic insulin user. The reach of hypoglycemia's effects stretch beyond the individual to influence families, communities, and the healthcare system at large.

Numerous priorities in diabetes care have been identified that continue to require translational research including the development of programs in different clinical settings, the identification of barriers to management, the discovery of facilitators of effective translation, and the shift in the paradigm from an acute care perspective to that of a multifaceted chronic care model. It is of the utmost importance that clinicians and researchers utilize a population based and patient centered approach to diabetes care management and apply best practice standards to revolutionize interventions for individuals, organizations, and communities. Interventions must be evaluated for cost

effectiveness. Additional translational research investigating the impact of interventions on vulnerable populations is imperative to assist with the ethical allocation of valuable resources. Translational research in diabetes care also assists in guiding efforts that influence public health initiatives and healthcare policy decision making (Garfield et al., 2003). Regrettably, although tremendous advances have been made over recent decades in the field of diabetes research, there is evidence that the application of standards of care for the procurement of achieving optimal results in real-world diabetes management often falls short. These real world barriers must be tackled by using methods in translational research as the attempt is made to move from bench to bedside.

It is widely stated that the ability for an insulin requiring diabetic to completely eliminate iatrogenic hypoglycemia and maintain near normal blood glucose levels consistently over a lifetime cannot be safely accomplished with the treatment methods that are currently available. Therefore, until such a time exists, clinicians and patients must address the issue of hypoglycemia with what is currently known (Cryer, 2008). Hypoglycemia risk factor reduction must first include acknowledgement of the problem. The need to address the issue through autonomy supported education, patient empowerment, shared decision making and individualized goals is the impetus for this evidence based project (EBP). The EBP is intended to add to the knowledge base of translational diabetes research and demonstrate how the application of best practice strategies can be translated into real world clinical practice in an effort to improve quality of care and patient safety.

Background

Diabetes Mellitus (DM) is a complex and multifactorial metabolic disease hallmarked by an absolute or relative insulin deficiency and/or the inability of the body to utilize insulin effectively thus resulting in elevations of glucose in the bloodstream. According to the American Diabetes Association [ADA] (2014), it is estimated that approximately 18 million people in the United States have been diagnosed with DM and an additional 7 million people remain undiagnosed. A more startling statistic is that 79 million people are estimated to have blood glucose levels that are considered to be indicative of pre-diabetes or at risk for DM. This translates to over 100 million Americans potentially at risk for developing complications associated with DM. Most cases of DM can loosely be categorized into Type 1 DM and Type 2 DM. The distinction between the types is generally contingent upon the amount of endogenously produced insulin, the hormone secreted by the beta cells of the pancreas responsible for deposition of nutrients to the cell through the transport of glucose from the bloodstream to the cells. The deficiency of insulin production in Type 1 DM is essentially considered to be absolute despite recent studies that indicate that Type 1 diabetics may have some micro-secretion of insulin. The deficiency in Type 2 DM is considered to be relative and accompanied by a myriad of other physiologic metabolic factors. DM of either type is considered to be a disease with the progressive loss of insulin production due to beta cell failure over an individualized period of time. Oral medications may provide benefit; however, in Type 1 DM, as well as advanced Type 2 DM, exogenous insulin becomes a modality that is life-

sustaining in order to negate the absence of endogenous insulin production and control hyperglycemia.

It is essential to realize the importance of the need for insulin therapy in the treatment of diabetes. Chronic hyperglycemia associated with a diagnosis of DM can lead to the development of crippling complications. Microvascular complications, such as retinopathy, neuropathy and nephropathy, and macrovascular complications, such as cardiovascular disease, are prevented by the near normalization of blood glucose levels. The near normalization of blood glucose levels frequently requires the utilization of insulin therapy in the majority of Type 1 and advanced Type 2 diabetics. Thus, insulin is thus considered a life sustaining and life preserving necessity.

The Centers for Disease Control and Prevention [CDC](2013) estimated that approximately 2.2 million diabetics utilize insulin therapy alone as a treatment modality while approximately 1.7 million additional diabetics use insulin with oral diabetes agents. An estimated 12% of the diabetic population use insulin therapy to control their DM (United States Department of Health and Human Services [HHS], 2014). This defined population represents the number of individuals with DM on insulin in the United States who are at risk for the ADE of iatrogenic hypoglycemia. The threat of ADEs has prompted government regulatory agencies, such HHS (2014) to develop national action planning for the prevention of ADEs. According to this agency, ADEs are defined as injuries resulting from drug related medication interventions in any setting. ADEs provide the potential for harm and threaten patient safety. It is estimated that

ADEs account for an estimated one in three hospital adverse events, 3.5 million additional HCP office visits, one million additional emergency department (ED) visits, and approximately 825,000 hospital admissions. The three most common pharmacologic agents associated with ADEs prompting national action planning include opioids, anticoagulants, and diabetes agents, specifically sulfonylureas and insulin. Hypoglycemia is the most common ADE associated with insulin use (HHS, 2014).

Description of the Phenomena of Hypoglycemia. Hypoglycemia is a major limiting factor in the management of DM (Wild et al., 2007). The definition of hypoglycemia has been inconsistently cited in the literature. The most recent consensus definition of hypoglycemia is a blood glucose (BG) < 70 milligrams/deciliter (ADA, 2014) with severe hypoglycemia defined as a hypoglycemic event requiring the assistance of another. Hypoglycemia, as previously stated, is said to have physical, psychosocial, and financial implications for individuals, families, communities, and the healthcare system. Further exploration of the phenomena of hypoglycemia is relevant to this EBP.

Significance

Physical implications. Hypoglycemia results from a relative or absolute insulin excess and progressively compromises the body's defenses against falling blood glucose levels. (Cryer, 2009). The normal physiologic defense by the body during hypoglycemia is reduced pancreatic beta cell insulin release, increased hepatic and renal glucose production, increased pancreatic alpha cell glucagon release, and cessation of glucose utilization by non-neural tissues. These defenses are compromised in the setting of DM.

Symptoms of hypoglycemia can be categorized as neuroglycopenic, those resulting in brain glucose deprivation, or autonomic, those resulting from stimulation of the sympathetic nervous system. Neuroglycopenic symptoms manifest as: cognitive impairment, behavioral changes, psychomotor abnormalities, seizures and coma. Autonomic symptoms manifest as: palpitations, tremors, anxiety, diaphoresis, hunger, parathesias, and pallor.

A disturbing phenomenon associated with repeated hypoglycemia is the loss of counter-regulatory responses to hypoglycemia resulting in the delayed detection of symptoms or the absence of symptoms in the individual. Although the previously stated definition of hypoglycemia is <70mg. /dl, the threshold for detecting hypoglycemia is individualized dependent upon precedent exposure(s) to hypoglycemia and hyperglycemia. Ergo, hypoglycemia may also be categorized as any abnormally low glucose concentration that exposes the individual to harm (Cryer, 2008). This concept is analogous with a defective thermostat's inability to detect variations in the room temperatures to signal a change in the heating or cooling system as a response. The inability of an insulin requiring diabetic to detect hypoglycemia before the overt cessation of glucose to the brain occurs poses exceptionally high risks to the individual and to surrounding individuals. This form of autonomic dysfunction is classified as hypoglycemia unawareness and, despite this particular complication being beyond the depth and breadth of this EBP, this EBP has the ability to assist in the prevention of the development of hypoglycemia unawareness. Additionally, hypoglycemia is associated

with an increased risk of cardiovascular (CV) events and all-cause mortality in insulin treated diabetics. There is a relationship that exists between hypoglycemia and CV outcomes and mortality over a long period of time (Khunti et al., 2015). Hypoglycemia is noted to prolong QT intervals, increase catecholamine release, and promote inflammation and endothelial dysfunction. Although CV disease from chronic hyperglycemia remains the primary cause of death in insulin requiring diabetics, the role of hypoglycemia cannot be discounted (Khunti et al., 2015).

The statistics regarding the phenomenon of hypoglycemia demonstrate the magnitude of the problem. IoH increases with the duration of diabetes. There is also a higher risk of hypoglycemia with autonomic dysfunction, renal impairment, advanced age, cognitive impairment, hepatic disease, and psychosocial factors, including fear of hypoglycemia (FoH) (Robertson, 2012). The frequency of hypoglycemia is such that it is considered a fact of life for most insulin requiring diabetics with the average insulin user suffering one to two episodes of disrupting hypoglycemia per week and one or more severe events per year (Cryer, 2008). The IoH among Type 2 diabetics, who have previously been viewed as having less risk of hypoglycemia in comparison to Type 1 diabetics, rivals that of Type 1 diabetics after several years on insulin therapy (Cryer, 2008). Insulin therapy was implicated in an estimated 13.9% of emergent hospitalizations for ADEs (HHS, 2014). Hypoglycemia was cited as the cause for an estimated 14 per 1000 patients and 298,000 ED visits in 2009 in the population of adult insulin requiring diabetics (CDC, 2013). It is also indicated that 2-4% of diabetics die

each year from hypoglycemia; however, more recent estimates indicate that up to 10% of deaths of Type 1 diabetics are the result of hypoglycemia. It is surmised that, although profound hypoglycemia can cause brain death, most episodes of fatal hypoglycemia are the result of cardiac arrhythmias (Seaquist et al., 2013). An estimated one in five Type 1 diabetics and two in ten Type 2 diabetics suffer impaired awareness of hypoglycemia (Robertson, 2012). The statistics regarding the magnitude of hypoglycemia are likely underestimated as most hypoglycemic events are not reported. The incidence of severe hypoglycemia may be more reliable than hypoglycemic events in general due to need for intervention from an outside source; however, these estimates are also considered under-represented. Inconsistent application of definitions across healthcare systems and epidemiological studies make it difficult for surveillance and comparisons to take place. Diabetic patients afflicted by repeated hypoglycemia may also be less likely to report events due to fear of activity restrictions, such as employment or driving privileges, thus skewing actual data regarding the phenomena. (Wild et al., 2007). The phenomenon of hypoglycemia does not typically garner the attention that it deserves from an epidemiological viewpoint.

Psychosocial Implications. The experience of hypoglycemia produces anxiety in individuals with insulin requiring diabetes and their families. Repeated hypoglycemic events, or even one severe event, has the potential to inflict traumatic stress in an insulin requiring diabetic. Along with the physical manifestations of hypoglycemia and the anxiety associated with the fear of developing complications from hyperglycemia long

term, the insulin requiring diabetic with hypoglycemia often develops a loss of internal locus of control and begins to experience reliance on others, social stigma and isolation, marital discord and a deterioration in the concept of self (Wild et al., 2007). Hypoglycemia is known to negatively influence an insulin requiring diabetic's self-efficacy (Erol & Enc, 2011).

Safety implications. Iatrogenic hypoglycemia is a major obstacle for insulin requiring diabetics and poses distinct safety risks to the individual experiencing the event and the individual(s) that surround that person. Hypoglycemic events have been associated with injuries due to falls, while using equipment, and motor vehicle accidents, to name a few. Hence, not only does hypoglycemia risk the health and well-being of the individual, it can directly impact upon the health and well-being of those who come in contact with the individual in the community setting.

Financial Implications. Hypoglycemia places an additional financial burden on individuals, families, and the healthcare system. Estimating the financial burden has historically been difficult in the United States due to under-reported episodes and broad differences in payer systems across the continuum (Quilliam, Simeone, Ozbay, & Kogut, 2011). Financial burden can be experienced in the form of the need for additional durable medical equipment (DME), such as blood glucose testing strips, lost work days, reduction in productivity, and increased health care related expenditures. Hypoglycemia management accounts for up to 13% of all out of pocket costs related to DM. An estimated 30% of insulin treated diabetics experience hypoglycemia at work and up to

10% of diabetics leave work or stay home from work due to a hypoglycemic event. Hypoglycemia reduces productivity as the average loss of work time for a hypoglycemia event is 9.9 hours overall. Absenteeism and tardiness rates are higher in insulin requiring diabetics due to hypoglycemia. Employers lose an estimated $1939.06 to $2986.28 per patient yearly due to the impact of hypoglycemia. The average cost for hypoglycemia management in the United States for individuals is an estimated extra $35.36/ month due to the need for additional groceries, DME, and transportation (Brod, Christensen, Thomsen, & Bushnell, 2011).

Fear of Hypoglycemia (FoH). Hypoglycemia is common, unpredictable, and worrisome to the insulin requiring diabetic. Insulin requiring diabetics must constantly modify their habits in an effort to balance between the avoidance of hypoglycemia and the long term consequences of hyperglycemia. Paradoxically, the modality that is indicated as life sustaining, i.e. insulin, becomes a source fear (Erol & Enc, 2011). The immediate, significantly unpleasant, and sometimes life-altering effects of hypoglycemia are much more tangible to the insulin requiring individual than the risks of developing long term diabetic complications. Hence, insulin requiring diabetics tend to develop FoH and utilize maladaptive coping strategies to avoid ADEs. This avoidance frequently triggers behavioral changes that manifest in the form of hyperglycemia. FoH, accompanied by the hyperglycemia associated with the inappropriate avoidance of either euglycemia or hypoglycemia, compromises metabolic control and increases the risks of diabetic complications while at the same time inducing psychological distress (Wild et

al., 2007). This cyclical chain of events desensitizes the diabetic individual to more extreme glycemic variations, thus increasing the associated risks of both hypoglycemia and hyperglycemia. The FoH leads to chronic anxiety, mood disorders, depression, dependency, loss of control, reduced productivity, and disruption of personal relationships (Seaquist et al., 2013).

Interventions. The ADA (2014) emphasizes that the prevention of hypoglycemia is deemed a critical element in adequate diabetes management. Ongoing education and support are critical to the prevention of complications. Comprehensive diabetic management strategies involve inquiry regarding hypoglycemia, including the severity, frequency, and cause. There is evidence that interventions, such as blood glucose awareness training (BGAT), can reduce levels of fear and improve diabetes management. Diabetes education is considered one of the most useful and cost-effective methods to promote coping techniques and help insulin requiring diabetics to gain an increased sense of control over hypoglycemia (Wild et al., 2007). Diabetes education regarding hypoglycemia prevention, detection, and treatment is also noted to assist diabetics on insulin with making positive behavioral changes to adapt and improve self-care abilities (Erol & Enc, 2011). Shared decision making, collaborative goal setting, and education empower patients with insulin requiring diabetes and allows them to successfully engage in problem solving (HHS, 2014). There is currently less available research on the influence of self-management education on FoH, but there is clear evidence that diabetes education improves outcomes. Systems must determine new surveillance methods to

provide consistent manners of reporting hypoglycemia to assess the impact of interventions (Seaquist et al., 2013).

Problem Statement

Insulin therapy is a life sustaining or life preserving therapy for the treatment of DM. Insulin therapy commonly results in iatrogenic hypoglycemia of varying severity. Iatrogenic hypoglycemia triggers a FoH in adult insulin requiring individuals with DM thereby increasing the risk of repeated hypoglycemia, hyperglycemia, and suboptimal long term health outcomes. Strategies that reduce FoH and promote self-efficacy for the prevention, detection, and treatment of hypoglycemia are needed to illustrate how evidence based research can be translated to real world clinical settings successfully.

Question Guiding Inquiry (PICO-T)

The original prognosis PICO-T question guiding scholarly inquiry for the proposed EBP was, "Does individualized self-management education influence the FoH and IoH in adult patients diagnosed with insulin requiring diabetes mellitus within 4 weeks? The PICO-T was revised to a time span of four weeks due to the time constraints of the program. The PICO-T format was derived from direction from Melnyk & Fineout-Overholt (2011) and New York University (2014).

Population. The population of interest for the EBP included adult, insulin requiring diabetic patients evaluated in a single outpatient endocrinology office in Northeastern Pennsylvania. Inclusion criteria for participation in the project included: English speaking, adult over age 18 years, diagnosis of insulin requiring DM, able of

performing self-blood glucose monitoring (SBGM), an ability to read above a 6th grade level, and access and willingness to participate in telephone follow up. Exclusion criteria included: age under 18 years, gestational diabetes, non-insulin requiring DM, cognitive impairment, inability to provide informed consent, inability to read above a 6th grade reading level, inability to participate with telephone follow up, refusal or inability to perform SBGM, or reliance on another person for the administration and determination of insulin therapy.

Intervention. The intervention for the EBP entailed the review of a developed take-home hypoglycemia psychoeducational tool (Appendix A) by participants for application to daily life after the completion of the FH-15 Survey (Appendix B) and a brief survey question regarding self-reported IoH (Appendix C).

Comparison. The comparison between pre-education and post-education FH-15 surveys and question regarding the incidence of self-reported hypoglycemia was made. No control group was utilized for the project.

Outcome. The anticipated outcomes of the EBP were a reduction in FoH and self-reported IoH within the four weeks following the intervention. The FH-15 survey and IoH question were administered at baseline and four weeks post intervention.

Time. The time frame for the EBP implementation was anticipated to be 10 weeks. The final outcome measures were administered 4 weeks after the time of the intervention.

System and Population Impact

Iatrogenic hypoglycemia is a significant problem for insulin requiring diabetics. It serves as a major barrier to the achievement of adequate and consistent glycemic control thus increasing the risk of complications due to hypoglycemia and hyperglycemia. The ramifications of hypoglycemia are far reaching and impact upon individuals, families, communities, and healthcare systems. There are extensive risks to the health and well-being of the identified insulin requiring diabetic population from hypoglycemia. There are also significant psychosocial risks to the families of insulin requiring diabetics and safety risks to members of the diabetic's community from hypoglycemia. Furthermore, the financial impact associated with hypoglycemia is considerable in an era where resource dollars for allocation are scarce.

Purpose, Aims, and Objectives

The purpose of the EBP in addressing the fear of hypoglycemia in insulin users was to demonstrate how research can be translated and applied to a real world setting. It was the intention of the investigator that this EBP is the first in a series of quality improvement initiatives meant to impact upon individual patients and the investigators organization. The project was intended to promote and improve adequate self-management skills and internal locus of control in individual insulin requiring diabetics by reducing FoH and the incidence of hypoglycemia. It was also intended to make an impact at an organizational level through the dissemination of evidence based information throughout the organization to drive changes in documentation, practice

standards, and data collection for further evaluation. Insulin requiring diabetics that are armed with the knowledge of how to prevent, detect, and treat hypoglycemia appropriately are anticipated to achieve better long term outcomes. Interventions aimed at autonomy supported self-management of diabetes have the distinct potential of improving the health and well-being of the insulin requiring adult population and in reducing health care expenditures across the continuum.

Conclusion

The need to address the phenomenon of hypoglycemia and its related consequences is often overshadowed in the discussion of diabetes and considered secondarily to hyperglycemia; but clinicians must remain diligent in their efforts to combat this complication. Patient centered approaches in addressing the phenomena of hypoglycemia can aid in better quality of care for the insulin requiring diabetic population.

Chapter Two: Review of the Literature and Evidence

The critical analysis of the relevant literature assists in developing a framework as to how a body of evidence relates to the topic of interest. The synthesis of evidence is not merely intended to reiterate references or citations, but is meant for identifying evidence that provides a standard for best practices and stimulates future inquiry for translational research. The developed clinical question, "Does individualized self-management education influence the FoH and the IoH in adult patients diagnosed with insulin requiring diabetes mellitus within 4 weeks?" is the driving force behind the assessment of the literature. The purpose of this chapter is to provide a literary framework that illustrates the need for evidence based practice changes that support patient centered diabetes care. The results of the project were intended to add to the body of growing evidence that supports quality care improvement initiatives for diabetic patients, mitigate safety risks that are associated with iatrogenic hypoglycemia, and empower patients by minimizing FoH. The presented synthesis of the evidence within the literature supported the need for inquiry to narrow research gaps and illustrated the significance of devising interventions that address the phenomena of interest.

Methodology

The determination of a logical search strategy was imperative for data organization and defense of the interpretation of the results once the review of the literature and evidence was completed. (Moran, Burson, & Conrad, 2014). Hence, a comprehensive review of the relevant literature was performed by thoroughly searching

the following data bases: Academic Search Primer, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane, Education Resource Information Center (ERIC), Healthsource, MEDLINE, PubMed, and Science Direct. The GOOGLE search engine was also intermittently accessed to broaden search capabilities thus ensuring access to as much information on the subject as possible. Database searches were restricted to 2004-2015 in an attempt to yield the most recent available data. Cross referenced landmark studies outside of the aforementioned date range or data in support of the conceptual framework of the literature review were summarized as their inclusion was felt to be crucial for providing context to the phenomena of interest.

Keywords and Medical Subject Heading (MeSH) terminology used to procure relevant literature included: diabetes, insulin, insulin requiring, hypoglycemia, fear of hypoglycemia, prevention, detection, patient education, autonomy supported patient education, self-management, blood glucose awareness training, individualized education, and shared decision making, Boolean phrases such as "and", "or" and "not" were used in combination with keywords and literature involving adolescents, pediatrics, pregnant woman, or diabetics treated exclusively with oral pharmacological agents were excluded.

Data extraction used the aforementioned keywords and phrases yielded varying amounts of data at the times the searches were performed. An initial search for hypoglycemia yielded 49,408 results. The inclusion of self-management yielded 288, and variation of the date range led to the discovery of 237 results. The exclusion of adolescents and pediatrics reduced the results to 223. Inclusion of insulin yielded 97

results which made the topic exceptionally more manageable. A combined search with FoH offered 15 results and narrowed the topic of inquiry to blood glucose awareness training as a viable area of study and provided a randomized controlled trial regarding the topic of interest. A continued search of the literature regarding autonomy support procured 841 results. The combination of hypoglycemia with this phrase yielded no results, however, a combination with diabetes resulted in 10 articles. Shared decision making produced 227 results and was able to be focused to 6 articles when the term hypoglycemia was added. Individualized care was searched resulting in 185 articles; this was narrowed to 36 articles with the inclusion of the keywords patient education and the exclusion of pediatrics and adolescents. The GOOGLE search engine was utilized to access alternative sites that provided full text access of the discovered information and to access the most up to date clinical practice guidelines in order to augment the search of the relevant literature.

The most recent data evaluating the phenomena of interest was searched until no new recognizable data was noted of relevance within the date range and a saturation point of common evidence was reached. Levels of evidence included in the search for relevant literature included: systematic reviews, randomized controlled trials, cohort or case control studies, qualitative and descriptive studies, and expert opinion publications.

Findings

Diabetes and the need for insulin. The ADA (2014) defines diabetes as a group of metabolic disorders stemming from defects in insulin secretion, insulin action, or both. The disorder is characterized by chronic hyperglycemia. Chronic hyperglycemia in diabetes is associated with long-term damage to multiple organs, specifically including the eyes, kidneys, nerves, heart, and blood vessels. Complications of diabetes include: retinopathy and a potential for blindness, nephropathy with progressive renal failure, peripheral neuropathy and a risk of lower extremity ulceration and/or amputation, autonomic neuropathy with gastrointestinal, genitourinary, and cardiovascular (CV) symptomatology, and atherosclerosis of coronary, peripheral, and cerebrovascular vessels. The assessment of glycemic control is performed through two primary techniques: self-blood glucose monitoring (SBGM) and measurement of the glycosylated hemoglobin (HbgA1C). The results of SBGM performed by the patient using a glucometer provides assistance to patients in guiding decision making in self-management and assists HCPs in ensuring that ongoing instruction is provided and regular evaluation of the effectiveness of the treatment plan is completed (ADA, 2014). The HbgA1C measurement reflects average glycemia over several months, correlates with mean plasma glucose values, and is a strong predictor of risk associated with diabetic complications. The HbgA1C provides feedback to patients and providers as to the need for additional risk reduction and evaluates the effectiveness of the current treatment plan (ADA, 2014). Landmark clinical trials have demonstrated the importance of intensive

glycemic control in the prevention of diabetic complications related to chronic hyperglycemia; however, the application of intensive therapy comes with a cost. Glycemic control is fundamental to diabetes management (ADA, 2014). The most noteworthy trials that provided the evidence for current standards of care that guide clinical decision making on diabetes management include: the Diabetes Control and Complications Trial (DCCT), the Epidemiology of Diabetes Interventions and Complications (EDIC) trial, the United Kingdom Prospective Diabetes Study (UKPDS), and the Kumamoto study.

The DCCT was a large prospective randomized controlled trial (RCT) released in June of 1993 at the annual Scientific Sessions meeting of the ADA and was sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH). This landmark study proved conclusively that intensive control of blood glucose in individuals with Type 1 diabetes could significantly reduce the incidence of retinopathy, nephropathy, or neuropathy, otherwise known as diabetic microvascular disease. The study involved 1441 Type 1 diabetics between the ages of 13 and 39 years in 29 medical centers in the United States and Canada. The duration of diabetes was between 1 and 15 years and each participant was required to have early to no signs of diabetic eye disease. This study compared the effects of standard, HbgA1C 7-7.9%, versus intensive control, HbgA1C <6%, on the complications of diabetes. The study demonstrated that intensive glycemic control reduced the risk of retinopathy by 76%, nephropathy by 50%, and neuropathy by 60%. The most significant

side effect of intensive treatment was an increase in the risk for hypoglycemia and the recommendation to implement intensive therapy is meant to be exercised with caution with consideration to the risk-benefit ratio (The Diabetes Control and Complications Trial Research Group, 1993).

EDIC was a landmark observational follow-up study to DCCT which continued to study more than ninety percent of the DCCT participants, or 1394 individuals. EDIC evaluated the incidence and predictors of CV, or macrovascular, disease in addition to microvascular disease. It also examined the impact of intensive versus standard glycemic control on quality of life and on cost effectiveness. EDIC demonstrated intensive glycemic control reduced the risk of any CV disease event by 42% and non-fatal myocardial infarction, cerebrovascular accident, or death from CV causes by 57%. EDIC was also beneficial in determining that the difference in outcomes between the intensive and control groups is persistent for as long as ten years. The prolonged and beneficial effects of intensive therapy, or the negative effects of standard therapy, influence the development of future risks. The preceding trend was coined as *imprinting* or *metabolic memory* (The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group, 2005).

The UKPDS Study aimed to determine the effect of intensive versus conventional glycemic control on the incidence of diabetic complications with a secondary aim of assessing the differences between treatments. This RCT evaluated patients utilizing both oral agents and insulin for the treatment of diabetes. The study was the largest and

longest study ever undertaken in diabetes and involved participation from over 7600 patients in 23 centers across the United Kingdom. The UKPDS demonstrated that any improvement in glycemic control and blood pressure reduced diabetic related complications. An increased risk in hypoglycemia was also noted (King, Peacock, & Donnelly, 1999).

The Kumamoto Study, a RCT examining whether intensive glycemic control could decrease the frequency and severity of microvascular complications in Type 2 diabetics was released in 2000. This prospective study of 110 participants utilizing insulin therapy demonstrated that intensive glycemic control can delay the onset and progression of the early stages of diabetic microvascular complications in Japanese patients with Type 2 diabetes. This study also demonstrated an increased risk of hypoglycemia, but this was noted to be to a lesser degree and severity than previously noted in the DCCT trial (Shichiri, Kishikawa, Ohkubo, & Wake, 2000). It is obvious from the volume of evidence surrounding the treatment of diabetes that the reduction of long term risks associated with hyperglycemia are moderated through the attainment of intensive glycemic control. This reduction in risk, however, comes with the price of an increased risk of hypoglycemia as noted in the evidence.

Diabetes involves multiple pathogenic processes ranging from autoimmune destruction of the pancreatic β-cells and insulin deficiency to a diminished tissue response to insulin and insulin resistance. The etiology of diabetes predominantly falls into two broad categories; Type 1 diabetes, caused by absolute insulin deficiency, and

Type 2 diabetes, caused by a combination of insulin resistance and an inadequate compensatory insulin secretory response. The severity of the underlying metabolic abnormalities can remain dynamic through the course of the disease process, but it is the present degree of hyperglycemia at a specified period in time that reflects the severity of the underlying metabolic process and determines the treatment. This complex, chronic illness requires a multi-factorial approach to management in order to prevent the consequences of hyperglycemia. Although modalities such as education and improvement in lifestyle habits can positively influence outcomes, historically, insulin therapy is often times unavoidable. This is predominantly due to the acute nature of Type 1 diabetes or the progressive nature of Type 2 diabetes, despite adherence to lifestyle modification or other pharmacological agents. Insulin therapy thus becomes a life-preserving, and in many cases, a life-sustaining treatment.

The use of insulin therapy is associated with a higher risk of iatrogenic hypoglycemia. Although extrapolation of epidemiological evidence from DCCT and UKPDS validates a curvilinear relationship between Hemoglobin A1C and the development or progression of microvascular complications, on a population level, the greatest number of complications will be averted by taking the most uncontrolled patients to fair/good control. Additional lowering of Hemoglobin A1C below seven percent is associated with a continued risk reduction; however, the absolute risk reductions become much smaller as the Hemoglobin A1C decreases toward the intensive goal. It is of importance to note that the risks of lower glycemic targets used to avert

complications from hyperglycemia may outweigh the potential benefits on a population level due to the risk of iatrogenic hypoglycemia (ADA, 2014). Evidence from landmark studies, such as Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluations (ADVANCE), Action to Control Cardiovascular Risk in Diabetes (ACCORD), and the Veterans Affairs Diabetes Trial (VADT), indicate an increase in the rate of serious hypoglycemic events in the intensive control groups as compared to the standard control groups (ADA, 2014).

The ADVANCE trial was a factorial, multicenter, RCT with a recruited 11, 140 participants evaluating both blood pressure and glucose. This study took place from 2001-2008 and included adults with Type 2 diabetes aged 55 years or older, with an increased risk of CV disease. Participants in the glucose arm were randomized to either an intensive modified release gliclazide based glucose lowering regimen or a standard guidelines-based glucose lowering therapy with follow up estimated to be for an average five to six years. The primary outcomes of the study were major microvascular and macrovascular complications. The aim of ADVANCE was to see if treatment to lower glucose levels more tightly than usual would reduce the risk of all complications in adults with Type 2 diabetes. Severe hypoglycemia, hypoglycemia requiring outside assistance, was more frequent in the intensive control group than in the standard group with 150 patients, or 2.7%, having at least one episode of severe hypoglycemia compared to 81 patients, or 1.5%, in the standard group with a hazard ratio of 1.86 and $P < 0.001$. Minor hypoglycemia was also more frequent in the intensive control group with 120

events per 100 patients per year versus 90 events per 100 patients per year with standard control. This study also demonstrated that intensive therapy had no significant effect on reducing CV disease (The ADVANCE Collaborative Group, 2008).

The ACCORD trial was designed to determine the best ways to decrease the risk of macrovascular disease in Type 2 diabetics. The study was intended to last approximately eight years and recruit 10,000 participants. This randomized, multicenter, double 2 x 2 factorial study from two countries was funded by the National Heart, Lung, and Blood Institute in collaboration with the NIDDK, the National Eye Institute, and the CDC. Patients with a median Hemoglobin A1C of 8.1% were assigned to receive intensive therapy or standard therapy. The primary outcome was a composite of nonfatal myocardial infarction, nonfatal stroke, or death from CV causes. The trial was terminated after a mean of 3.5 years of follow up due to higher mortality in the intensively treated groups as compared with the standard treated groups. The primary outcome occurred in 352 patients in the intensive therapy group as compared to 371 in the standard therapy group. Concurrently, 257 patients in the intensive therapy group died as compared to 203 patients in the standard therapy group. Hypoglycemia requiring assistance was more frequent in the intensive therapy group with $P < 0.001$. This study concluded that the use of intensive therapy did not significantly reduce major CV events and actually identified a previously unrecognized harm associated with intensive therapy.

The limitations of this study included the unaddressed issues of the risks and benefits of various approaches to lowering HbgA1C levels and a design that was not well suited for determining whether certain subgroups may benefit from intensive therapy. Additionally, analyses to determine which aspects of the therapeutic strategy contributed to which outcome were not able to be identified or excluded and exploration of the data would require additional prospective testing (The Action to Control Cardiovascular Risk in Diabetes Study Group, 2008).

The goal of the VADT trial was to compare the effects of intensive and standard glucose control on CV events. This open label RCT targeted poorly controlled Type 2 diabetics or selected individuals with inadequate responses to oral agents and insulin. Participants were required to have had a HbgA1C >7.5%, and the lack of CV events during the past six months with a life expectancy of less than seven years. It included obese patients with nephropathy and hepatic disease. Patients were randomized according to study site, the previous occurrence of a macrovascular event, and current insulin use. The most common adverse event was hypoglycemia with significantly more episodes in the intensive therapy group than in the standard therapy group in every category with $P < 0.001$. This study concluded that intensive control did not decrease the rate of CV events in patients with advanced disease but did increase hypoglycemia risk (Duckworth et al, 2009).

Additionally, in conjunction with the aforementioned landmark trials, a recent retrospective cohort study (Khunti et al., 2015) that used data from the Clinical Practice

Research Datalink database including all insulin treated patients over 30 years of age with a diagnosis of diabetes was published in *Diabetes Care*. The objective of the study was to assess whether there was an association between hypoglycemia, the risk of CV events, and all-cause mortality among insulin treated diabetics. A cumulative 13,682 patients were included in the regression analyses which included 3260 Type 1 diabetics and 10,422 Type 2 diabetics. During the course of the study, the proportion of diabetics in each group experienced CV events or death at a statistically similar rate, 18% versus 14% respectively. Death rates were twofold higher in both cohorts for patients with a history of CV disease. Basic statistical analysis along with stratified univariate and multivariate Cox regression models to estimate the risk of vascular events and mortality associated with hypoglycemia and practice level deprivation score as the stratification factor were used. This study indicated that patients who experience hypoglycemia were at a greater risk of CV events. Patients without a history of CV disease experiencing at least one episode of hypoglycemia had a 92% and 50% significantly increased risk of composite CV events in both cohorts. The study concluded that, in a nationally representative contemporary population, hypoglycemia is associated with an increased risk of CV events and all-cause mortality in insulin treated patients and confirms the findings noted in the ACCORD trial. It also adds to the body of evidence that supports the link between hypoglycemia and CV events in people with Type 1 diabetes. The study summarizes the point that CVD remains the primary cause of death in insulin treated diabetics; this is largely due to hyperglycemia and pre-existing comorbidities, but the

role of hypoglycemia as a contributing factor is still of importance. The study was not intended to identify a causal relationship, but to explore the relationship between hypoglycemia and CVD. The limitations of the study included the lack of randomization, the inability to capture all relevant confounding factors in the database, the underreporting of the incidence and severity of hypoglycemia, selection criteria affecting the representative quality of the Type 2 diabetes cohort, and inclusion of patients with Read Codes in C10+. Identified strengths of the study included a large sample size, evaluation in the Quality of Outcomes Framework period, a high quality of a nationally representative sample, and a robust approach to multivariate analyses providing a broader statistical picture. The implications of the study have a high applicability to the phenomena of interest as it confirmed a relationship between hypoglycemia and an increased risk of CV outcomes over an extended time frame and indicates that hypoglycemia may be a surrogate marker of greater disease burden and thus an indirect marker of CV risk. It was the recommendation of the study investigators that HCPs pay special attention to insulin treated patients who experience a hypoglycemic event and focus their efforts on the reduction of the IoH.

The most recent statistics available to date from the CDC (2014) estimate the incidence of diabetes at 29.1 million people, or 9.3% of the population, in the United States as of 2012. Diabetes was ranked as the seventh leading cause of death in the United States in 2010, but estimates citing cause of death due to diabetes are considered to be underreported. The estimated total cost of diabetes in the United States in 2012

was $245 billion. Understanding the epidemiologic magnitude of the phenomena of interest requires conceptualizing the fact that an estimated 26% of the 21 million people with diagnosed diabetes in the United States are being treated with insulin therapy; this equates to over 5 million people on insulin therapy. It becomes a logical conclusion that as the population of people with diagnosed diabetes increases, so shall the population of patients requiring insulin therapy. HCPs armed with the knowledge of the impact of diabetes on the population as evidenced by the aforementioned statistics are better able to comprehend the need for real world practice strategies to improve quality of care for diabetic patients, their families, communities, and health care systems. Health care providers must also possess the realization that insulin therapy is a method of treatment that cannot be averted if sustaining life and preventing long term complications are the goals of therapy; but it also needs to be recognized that the implementation of intensive glycemic control for the purpose of controlling hyperglycemia cannot outweigh the potential risk for hypoglycemia. Hypoglycemia risk is an important consideration in the determination of individualized care, the mutual setting of glycemic targets, and is a critical determining factor in the management of diabetes to both the patient and the HCP.

The barrier of iatrogenic hypoglycemia. Iatrogenic, or treatment induced, hypoglycemia is considered the greatest limiting factor that precludes the achievement of a degree of glycemic control that is considered adequate enough to prevent the long-term consequences of diabetes due to hyperglycemia. Iatrogenic hypoglycemia causes

recurrent morbidity, has the potential for fatality, compromises physiological and behavioral defenses against future events thus resulting in the cyclical pattern of recurrent hypoglycemia, and does not allow for the continued long term maintenance of adequate glycemic control across a lifespan with diabetes thus leaving the benefits of adequate glycemic control unrealized (Cryer, 2008). Therefore, it is incumbent upon health care providers to individualize care for the treatment of hyperglycemia while keeping the risk for hypoglycemia in mind as each needs to be balanced for mitigation of both short and long term risks to health and well-being.

There are multiple sources within the literature that identify iatrogenic hypoglycemia as the major barrier to the attainment of adequate glycemic control. A systematic review (SR) by Seaquist et al. (2013) reviewed the available evidence about the impact of hypoglycemia on patients with diabetes. The report was formulated through a joint effort between the ADA and The Endocrine Society. It contained all available new data from recent clinical trials and other studies since the past review of information on the subject of hypoglycemia by the ADA and The Endocrine Society and was used to update the previous workgroup report. The reviewers did not utilize unpublished data but did use expert opinions to develop some conclusions. The review was achieved through consensus and served to provide guidance about how new information should be incorporated into clinical practice. This SR was instrumental in: reconfirming the previous definitions of hypoglycemia in diabetes, reviewing the implications of hypoglycemia on both short and long term outcomes, considering the

implications of hypoglycemia on treatment outcomes, presenting strategies to prevent hypoglycemia, and identifying knowledge gaps that need to be addressed by future research.

Additionally tools were presented for patient use to report hypoglycemia at each visit and for HCP use to guide documentation of the counseling provided. The workgroup determined hypoglycemia to be defined as a blood glucose <70 mg. /dl and to be classified and documented as severe, symptomatic, asymptomatic, probable symptomatic, and pseudo-hypoglycemia. The implications of hypoglycemia were concluded to be a potential cause of fatality, brain death, or ventricular arrhythmia with up to ten percent of all deaths in Type 1 and 2 diabetics caused by hypoglycemia. The workgroup also concluded that recurrent episodes of hypoglycemia trigger hypoglycemia unawareness and hypoglycemia associated autonomic failure, hypoglycemia impacts on cognitive function in Type 1 diabetics, and there is an increased risk of mortality and CV disease in diabetic patients. The review elucidated information on special populations, such as the elderly, hospitalized and pregnant diabetics, as well as assessed the impact of hypoglycemia on quality of life due to FoH and activities of daily living. The workgroup concluded that glycemic targets should depend on age, life expectancy, comorbidities, preferences, and the assessment how resultant hypoglycemia may impact the patient's life. An individualized treatment plan using a patient centered approach was advised. The workgroup stressed the following approaches to decrease the risk of iatrogenic hypoglycemia: patient education, dietary intervention, exercise management, medication

adjustment, glucose monitoring, and clinical surveillance. The current knowledge gaps identified by the SR include: the need for the development of new surveillance methods to provide consistent metric collection to determine the epidemiological impact of hypoglycemia, the need to investigate which patients are most at risk for hypoglycemia, the need to develop new educational strategies to reduce the incidence of hypoglycemia, and the need for development of new blood glucose monitoring technologies with improved accuracy, ease, reliability, and cost-effectiveness.

The SR was a review of all published data on the topic of hypoglycemia from 2005-2012 and the data was evaluated, discussed, and summarized in the consensus report. Its findings indicated the importance of hypoglycemia on morbidity and mortality, the significance of the prevention of hypoglycemia, and the need for additional research to explore the phenomena. The weaknesses of the SR were identified as: its inability to empirically define individualized glycemic targets from a public health standpoint, the inability to evidence the balance between strict targeting and the goal of hypoglycemia prevention, the lack of culturally specific evidence, and the lack of an evidence based table. However, despite its limitations, the SR was considered to be highly reliable, valid and applicable to the phenomena of interest as it went directly to the heart of subject matter and included an extensive review of all available literature in combination with the consensus of experts in the field.

There are two clinical practice guidelines that are worthy of mention in addressing the phenomena of hypoglycemia and substantiate the need for the project.

These guidelines were derived from available published data from the ADA and The Endocrine Society and are addressed individually. The ADA (2014) Standards of Medical Care in Diabetes is viewed as an important resource for the health care providers and it divulged key clinical practice recommendations based on extensive literature searches and updates that are done annually based on the quality of new evidence. The Endocrine Society (2009) set forth practice guidelines with the aim of assisting HCPs in evaluating and managing diabetes with a particular chapter devoted to hypoglycemia in persons with diabetes mellitus.

The ADA (2014) identified hypoglycemia as a leading factor limiting glycemic management of insulin requiring diabetics that was associated with acute harm and increased mortality. The ADA mirrored the conceptual approaches identified in Seaquist et al (2013) in addressing hypoglycemia prevention. Attention to the prevention of hypoglycemia was considered a critical component of diabetes management. The practice guideline strategically provided the instructions that individuals should be queried regarding hypoglycemia at each encounter, advised on proper treatment and SBGM, provided glucagon if at significant risk, have ongoing assessment of cognitive function to stratify risk, and should be provided individualized treatment goals based on risk of hypoglycemia.

The ADA clinical practice guidelines contained an executive summary that addressed aspects of medical care required for individuals with diabetes. An analysis of all relevant literature, both past and present, was analyzed to update the guidelines. The

ADA was instrumental in developing, analyzing, and disseminating care standards and its Professional Practice Committee was a panel of multidisciplinary experts charged with the routine review and revision of evidence based standards. ADA clinical practice guidelines provide sound evidence for decision making. Determination of the reliability and validity of the guideline was evaluated using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument (2001). The scope and purpose of the guideline provided clearly defined objectives, specifically covered clinical questions, and defined patient populations for application. Relevant professional groups and target users were identified as stakeholders and performance measures were indicated. The rigor of development was considered worthy as: systematic methods were identified to search for the evidence, the criteria for selecting evidence was clearly defined, the methods for formulating recommendations were clearly defined, risk/benefit/side effects were considered, recommendations were linked to evidence, external review was internally and externally performed and the procedure for continued revision was described. The guideline was specific and unambiguous. Management options and key recommendations were identified along with a description of criteria for monitoring. Cost was mentioned, but organizational barriers and cost implications were not specifically described. The editorial independence of the guideline was sound and conflicts of interest were identified. The guideline was considered to be highly reliable, valid and supported by the highest levels of evidence available. It was applicable to the

project as it addressed the issue of hypoglycemia and provided evidence based support for the provision of care and the selected clinical problem.

The Endocrine Society (2009) also set forth clinical practice guidelines regarding hypoglycemia in their publication *Evaluation and Management of Adult Hypoglycemic Disorders.* The practice guideline included the background for iatrogenic hypoglycemia and identified hypoglycemia as the limiting factor in achieving adequate glycemic management of diabetes. It was estimated that until the prevention and/or cure of diabetes is achieved, the problem of hypoglycemia cannot be solved. Insulin and secretagogues were identified as the primary offenders that trigger iatrogenic hypoglycemia. Hypoglycemia in the insulin requiring diabetic patient is often considered a fact of life with the average patient with Type 1 diabetes experiencing two episodes of symptomatic hypoglycemia weekly and thousands over a lifetime along with an estimated one episode of severe hypoglycemia, often with seizure or coma, per year. An estimated two to four percent of Type 1 diabetics are known to die from hypoglycemia. The United Kingdom Hypoglycemia Study, as cited in the guideline, reported that in patients treated with insulin for less than 2 years or more than 5 years, the prevalence of severe hypoglycemia was 7% and 25% with an incidence of 10 and 70 episodes per 100 patient years respectively. Thus the risk of hypoglycemia is much lower in the first years of insulin therapy and substantially increases later in the course of the disease. It is also estimated that hypoglycemia is grossly underreported. Hypoglycemia was not a primary outcome of landmark clinical trials and the extent of data collection regarding

hypoglycemia is highly variable. For example, hypoglycemia event rates in UKPDS were not known. Insulin trials in Type 2 diabetics are often undertaken immediately after transition to insulin from oral agents and earlier in the disease state. Additionally, therapeutic goals in clinical trials are often different than those agreed upon in real life clinical situations. These points demonstrate the need to consider the evidence from a prospective, population based focus. Donnelly et al, as cited in the clinical practice guideline, indicated that overall the hypoglycemia event rates in insulin treated Type 2 diabetes were approximately one third of those in patients with Type 1 diabetes. Population based studies from hospital regions with known Type 1 and Type 2 diabetes incidences demonstrated event rates for severe hypoglycemia requiring emergency treatment in insulin requiring Type 2 diabetics was 40% and approximately 100% of those in Type 1 diabetes. Interestingly, because the prevalence of Type 2 diabetes is approximately 20-fold greater than that of Type 1 diabetes, and because most patients with Type 2 diabetes eventually require insulin therapy, this data suggested that most episodes of hypoglycemia occur in Type 2 diabetics.

The Endocrine Society guidelines indicated the following recommendations: persons with diabetes should become concerned about the possibility of developing hypoglycemia when SBGM is falling rapidly or is no greater than 70mg. /dl. Therapeutic glycemic goals should be the lowest mean glycemia that can be achieved safely in a given patient at a given point in the progression of that individual's diabetes and the prevention of hypoglycemia in diabetes involves addressing the issue at each encounter.

Making adjustments based on review and application of the principles of intensive glycemic therapy and consideration of known hypoglycemia risk factors is needed if hypoglycemia is present. Conventional risk and those indicative of compromised defenses against hypoglycemia should be considered in patients with recurrent iatrogenic hypoglycemia and urgent treatment of hypoglycemia should be accomplished by ingestion of carbohydrates or by parenteral glucagon.

The guideline was evaluated using the AGREE instrument for critical appraisal. The guideline was inclusive of the aspects of medical care required for the treatment of adult insulin requiring diabetics and was a compilation of evidence derived from SRs, expert consensus, and RCTs. No significant weaknesses were evident and the guideline provided sound evidence for decision making. The guideline was felt to be reliable and valid. The scope, purpose, objectives, clinical questions, and patient populations were specifically covered, defined and described. Stakeholder involvement included relevant professional groups, target users were identified. Performance measures were indicated. The rigor of development was felt to be adequate based on: identification of systematic methods to search for the evidence, defined criteria for evidence selection, and defined methods for formulating recommendations. Rigor was also adequate due to the consideration of risks, benefits, and side effects. Internal and external review was performed and procedures for continued revision described. The clarity and presentation were satisfactory as the guideline was specific and unambiguous. Management options were clear and key recommendations and criteria for monitoring were described. Cost

was mentioned, but organizational barriers and implications of cost were not specifically described. The guideline was editorially independent with conflicts of interest identified. The guideline contained high levels of compiled evidence which lent credence to its reliability and validity. It had high applicability to the project as it dealt directly with developing the framework for the conceptualization of the project.

Although not defined traditionally as a SR or clinical practice guideline per se, HHS (2014) developed a National Action Plan for Hypoglycemic Safety. The plan indicated hypoglycemic agents were one of the drug classes most frequently associated with ADEs in both inpatient and outpatient settings with nearly all cases of hypoglycemia considered preventable. The plan called for more effective surveillance of hypoglycemic events and identification of insulin as a high alert medication to health care providers. It remains challenging to compare hypoglycemia event studies or to quantify the phenomenon of hypoglycemia as there is inconsistent application of minor and severe hypoglycemic event definitions across post-marketing and epidemiological studies. Data cited in the plan indicated that approximately one quarter of all patient safety incidents involving insulin resulted in patient harm and insulin may be implicated in 33% of all medication error related deaths. Action planning also called for HCPs to utilize best practice standards involving: individualized target setting, provision of patient education, order standardization and continuous risk assessment. HCPs must acknowledge patient risk factors associated with a higher risk for hypoglycemia including: Body Mass Index, cachexia, age, advanced CV disease, advanced malignancy,

renal disease, hepatic disease, compliance, and health literacy. The action plan identified a four pronged approach for use in reducing patient harm from ADEs involving: surveillance, prevention, incentives and oversight, and research. The plan utilized strong evidence based data and identified strategies and specific actions for policymakers, professionals, and organizations in addressing hypoglycemia risk. The action plan supported the American Association of Colleges of Nursing (AACN) Essentials of Doctoral Education for Advanced Nursing Practice (2006) by including: scientific underpinnings, leadership for quality improvement, evidence based practice, information technology, policy activism, collaboration, clinical prevention and population health, and advanced nursing practice. The amassed evidence supporting the recognition of iatrogenic hypoglycemia as a major limitation to the attainment of a degree of glycemic control substantial enough to prevent complications from hyperglycemia was well established in the literature.

The phenomena of the Fear of Hypoglycemia (FoH). The discussion of relevant evidence to this point has set the stage for the introduction of the focal phenomenon of interest that served as the stimulus for the project. It has been discussed that diabetes is a prevalent metabolic disorder in which attention to strict glycemic control reduces complications from hyperglycemia and that insulin therapy is often required due to the progressive nature of the disease. Insulin requiring patients are at higher risk for repeated hypoglycemia. The use of insulin therapy can be problematic for most patients as they try to actively manage their diabetes and balance the need to avoid

the acute effects of hypoglycemia with the long term complications of hyperglycemia. The immediate and tangible consequences of hypoglycemia produce more noticeable concerns to the patient than the potential poorly envisioned future health problems (Wild et al., 2007). FoH is a complex phenomenon that is still not yet fully understood.

The fear of hypoglycemia and its impacts. FoH can occur in varying degrees and a general consensus definition of the phenomenon has yet to be established. Nevertheless, FoH is viewed as the undesirable emotional response triggered by the belief that a low blood glucose is a threat. It is completely rational and justified to state that some degree of caution and concern regarding the development of hypoglycemia and its implications is both adaptive and protective considering the nature of diabetes and the previously discussed statistical evidence regarding hypoglycemia in general,. FoH is unlike other phobias as it not irrational given the likelihood of experiencing hypoglycemia. However, FoH for the contextual purposes of this literature review is determined to be a maladaptive, excessive fear that can become problematic and disruptive to the diabetic plan of care (Gonder-Frederick, 2013). The presence or absence of FoH has the potential to be a problem when encountered in clinical practice. Inappropriately heightened levels of FoH are maladaptive as compensatory avoidance of near normal euglycemia or overcompensation when treating hypoglycemia or low normal euglycemia occurs. Alternatively, inappropriately low levels of FoH in individuals deemed to be high risk for hypoglycemia can be just as maladaptive as denial or avoidance of the risk can occur. It has been previously noted in this literature review that

hypoglycemia frequently becomes a part of life for the diabetic requiring insulin therapy; but when the FoH develops, it further complicates the diabetic patient's self-management and plan of care.

Two individual systematic reviews of the relevant literature regarding the topic of FoH were analyzed for better comprehension of the subject. Wild et al. (2007) provided a critical review of the literature on FoH. The aim of the review was to integrate existing research on FoH and discuss its implications for diabetes management and patient education. The literature review utilized MEDLINE and EMBASE with studies limited to English, published from 1985-2007 and included the review of 301 abstracts with 273 exclusions due to non-relevance. Finally, twenty eight papers and six additional articles were reviewed regarding the FoH and the negative consequences associated with hypoglycemia. Selection and pooling strategies were identified and actual results reported. The findings of the review concluded that there was sufficient evidence that the FoH has a negative impact on diabetes management, glycemic control, and health outcomes. The SR also discussed strategies for reducing the FoH and gaps in the current research. It indicated that there was strong evidence that the FoH exists, but there was less available evidence as to how it directly affected management behaviors. The availability of the data was felt to be negatively influenced by the suspected underreporting of hypoglycemia by patients and poor recognition by health care providers. The SR was considered valid and reliable with the notation that missing data may be due to underreporting. The SR concluded that there is a need for further

investigation of the empiric evidence regarding FoH. This is directly applicable to the area of inquiry. Wild et al (2007) indicated that FoH is particularly prevalent in patients who have been exposed to severe hypoglycemia. There was also an issue with consistent measurements of FoH and the need to determine why fear is greater in some individuals than in others. The authors signified that FoH triggering compensatory maladaptive strategies was an area of interest that has not received the scientific attention that it deserves. The evidence presented in the SR provided the basis for the conclusion that FoH may motivate some diabetic individuals to inappropriately prevent hypoglycemia and thus compromise metabolic control; however, the complexity of the interacting variables that comprise the issue make determination of causality very difficult. Undoubtedly, this was an area of concern based on the current recommendations regarding the management of hyperglycemia and the need for strict glycemic control.

Gonder-Frederick (2013) provided a comprehensive review of the available data on the topic of FoH. The purpose of the SR was to review the current literature on FoH and its impact on quality of life and clinical outcomes in people with diabetes and their families. Overall, the level of evidence provided in the narrative of the SR was considered to be reliable and valid upon evaluation of the 75 references associated with the SR. However, the author did not specifically identify selection criteria or pooling strategies. The objective of the review, interventions to address the issue, and strategies to address future research due to gaps in knowledge were addressed. It was implied that all relevant data on the topic of FoH was reviewed, but this was not implicitly stated. Data

extraction was inconsistently defined and the use of tables to illustrate data collection strategies was underdeveloped. There was no use of tables illustrating compiled study results despite summarized results. Gonder-Frederick did compellingly point out that the clinical factors associated with the risk of severe hypoglycemia correlated with higher levels of FoH and FoH tended to be higher in women versus men, single versus married, and in individuals with depression, anxiety, and neurosis. The author identified that psychiatric symptoms and FoH have a bidirectional association as FoH can contribute to the psychiatric symptoms and, conversely, psychiatric symptoms can contribute to FoH. One particular study cited by the author determined that spouses and partners of individuals who experience severe hypoglycemia exhibit not only a FoH, but also experience sleep disturbances and marital conflicts. An individual case study was referenced illustrating an increase in the FoH after a severe hypoglycemic event thus resulting in a rapid deterioration in glycemic control due to the patient's intentional attempts to avoid additional hypoglycemia. Additional studies cited by Gonder-Frederick demonstrated that in one survey study, 19% of the population of surveyed Chinese diabetics on insulin therapy reported keeping their blood glucose too high in order to prevent hypoglycemia. Another international survey performed discovered 14% of the surveyed insulin requiring diabetics reportedly kept their blood glucose elevated at bedtime to prevent nocturnal hypoglycemia. An additional survey study of over 300 Canadians with diabetes that found a large majority of patients modified insulin dosing, refused to adjust insulin dosages upon recommendation, or consumed more food to

prevent hypoglycemia due to FoH. This unwanted FoH was also said to limit engagement in physical activity thus negating this strategy for risk reduction.

Gonder-Frederick (2013) identified the commonality of physical and psychological burdens from hypoglycemia leading to the development of FoH. A myriad of manifestations were attributed to FoH including: reduction in energy, helplessness, anger, anxiety, depression, affective disorder, panic attacks, social isolation, treatment dissatisfaction, poor motivation for treatment adherence, poor sleep, and poor quality of life. Moreover, HCPs are more attentive to the minimization of hyperglycemia but do not address hypoglycemia routinely. Patients are not inclined to address hypoglycemia with providers due to stigmatization and fear of imposed restriction of privileges (Gonder-Frederick, 2013). Although the SR required cross-referencing to better guarantee reliability, it was highly valid and applicable to the phenomenon of interest.

Reach, Zerrouki, Leclercq, and d'Ivernois (2005) contributed research regarding the phenomenon of interest in their correlational study in one setting evaluating 28 participants with an elevated HbgA1C >8.5% for over 6 months. The aim of the investigation was to analyze the absence of adjustment of insulin doses in Type 1 diabetic patients with poorly controlled diabetes. Therapeutic education, health beliefs, FoH, and motivation were major variables and questionnaires evaluating cognitive and behavioral items in conjunction with objective data from glucose logs were evaluated. Data analysis was performed using E correlation coefficient of Spearman. The findings of the study demonstrated patients reported: adjusting insulin when they actually did not, not

adjusting insulin when they actually did, and experiencing time constraints which influenced decision making. The study also showed that patients: did not adjust insulin due to FoH or weight gain, held beliefs that contextually influenced decision making, expressed belief without action, did not express belief but demonstrated action, and demonstrated actions that were not based on reasoning. The theoretical foundation for the study, Causal Theory of Action, strengthened the study, but the small sample size, limited setting, and lack of cultural diversity were perceived as weaknesses. The validity of the study was adequate and findings were supported by statistical evidence, but the reliability must be interpreted with caution. It is applicable to the problem of FoH as it contributes to the exploration of the influence of FoH on behavioral management. This study offered the conclusion that patients claim and think in opposition to their actions. HCPS must realize this important factor when addressing the underreported problem of FoH.

Erol and Enc (2011) interjected research from a descriptive correlational study of 345 diabetic patients in two outpatient clinics in Istanbul. Hypoglycemia, FoH, and self-efficacy were noted to be major variables. Measurements of management behaviors, including avoidance of hypoglycemia and its negative consequences and the perceived ability to perform work tasks, were evaluated. Data was analyzed using Mann-Whitney U and Kruskal-Wallis with Spearman's correlation. The findings of the study revealed that FoH was affected by: age, gender, marital status, occupation, classification of diabetes, insulin usage, treatment with oral agents, and the presence of chronic

complications. It also indicated self-efficacy involved multiple social factors and patient education improved self-efficacy scores. The descriptive study was not able to establish causality and generalizability was limited due to self-reported patient data. The study did evaluate patient perceptions and cultural components of care. The validity of the study was sound and it supported existing evidence that education improves FoH, but the data must be interpreted with caution as reliability is less than optimal.

Anderbro et al. (2014) released a study with the objective of examining the association between FoH in adults with Type 1 diabetes with demographic, psychological, and disease specific clinical factors and differences in subgroups categorized by level of FoH and risk of severe hypoglycemia. Questionnaires were sent to 764 patients with 469 respondents and measurements included the Hypoglycemia Fear Survey and other psychological measures. Variables included FoH, severe hypoglycemia, and psychological factors. The instrumentation for measurement was determined to be reliable and valid. Statistical analysis of this descriptive correlational study included univariate approaches, multiple stepwise linear regressions, Chi-square t tests, and ANOVAs. The study showed that several clinical factors including hypoglycemia history, self-monitoring, and nocturnal hypoglycemia, were significantly associated with FoH and were made worse with underlying anxiety. Subgroups demonstrated significant differences when categorized by level of FoH and severe hypoglycemia risk. The study concluded that there is a strong link between FoH and non-diabetes related anxiety and the complexity of FoH and differences in psychological and clinical variables have

implications for clinical practice. The study was felt to have high validity and applicability to the phenomena of interest, but no causal conclusions could be drawn and the source of the bidirectional association between FoH and anxiety could not be determined. The reliability of the study was limited due to methodological limitations, sampling issues with patients in the study considered to be low risk for severe hypoglycemia, and the fact that definitions and measures of hypoglycemia may not have captured all of the aspects of hypoglycemia risk that contribute to the FoH. The results did suggest that a variety of interventions are needed to approach the complex interactions that exist between FoH, well-being, management, and diabetic control.

Interventions for FoH. There is no dispute that the FoH is a complex entity that represents only one variable in the prevention of hypoglycemia and the management of hyperglycemia. It was been previously stated in the evidence that experiencing hypoglycemia often triggers a fear of hypoglycemia. The FoH triggers a cyclical pattern of events in insulin requiring diabetics where the rational thought used for decision making is clouded resulting in undesired results. An unrecognized event or pattern of hypoglycemia can leave an insulin requiring diabetic with a sense of foreboding and trepidation regarding the use of insulin therapy. It is a logical hypothesis that empowerment of the patient with the education needed to address the prevention of hypoglycemia will lead to reduction in FoH and ultimately allow patients and providers alike the ability to more effectively manage both hypoglycemia and hyperglycemia.

Strategies to address the incidence of hypoglycemia and the FoH include medical, surgical, educational, and behavioral interventions (Gonder-Frederick, 2013). Patient education has long been recognized as an accepted and established method in the management of chronic disease. The economic and clinical benefits of educational interventions have been shown to positively influence patients for a minimum of at least twelve months following the intervention (Dalal, Robinson, & Sullivan, 2014). This is largely because the daily management of most chronic diseases is done by the patients themselves. Attempting to change patients' perception and modify their behavior using an autonomy supportive approach and shared decision making is no small undertaking. It is vital to identify patients with FoH as a significant clinical problem and to then provide the underpinnings for behavioral changes. Interventions involving patient education should not be entirely focused on saturating patients with knowledge; it should involve targeting the patient's beliefs and attitudes toward their self-management capabilities. Knowledge transfer is not the only answer to reducing risk. The transfer of knowledge must be accompanied by the support of the provider to the patient as to how to autonomously utilize knowledge for individual circumstances (Kubiak, Hermanns, Schreckling, Kulzer, & Haak, 2006).

Advanced practice nursing involves the ability to effectively engage in teaching and coaching strategies geared toward optimizing individual and population health. Provided patient education is less effective when motivational strategies are not included. Autonomy supportive patient education entails acknowledgement of the

patient's individualized situation and autonomous choice. Advanced Practice Nurses (APNs) are obligated to establish therapeutic nurse/patient relationships that consider patient perceptions, facilitate alternative choices, and allow patients to responsibly engage in the natural process of self-discovery. This also involves setting limits that do not compromise the legitimacy or honesty of the relationship (Johnson, 2007).

Pedagogical interventions with a psychoeducational foundation using autonomy support as a foundation can promote patient motivation and patient confidence in self-management skills. Autonomy support is indicative of the extent to which providers actively listen, provide support and education, and minimize external control (Williams, McGregor, King, Nelson and Glasgow, 2005). This was specifically illustrated by Williams, McGregor, Zeldman, Freedman, and Deci (2004) in a longitudinal study. The study tested a process model of health behavior change for glycemic control within a randomized trial. Patient activation versus passive education based on the educational Self-Determination Theory was evaluated. One hundred and fifty nine out of 232 patients from a university affiliated community hospital were selected for evaluation based on eligibility criteria. HbgA1C, autonomous motivation and perceived confidence were assessed at baseline, 6 month and 12 month intervals. The Modified Health Care Climate Questionnaire, the Treatment Self-Regulation Questionnaire, The Perceived Competence for Diabetes Scale, and a Summary of Diabetes Self-Care Activities, along with HbgA1C, were evaluated during the study. Participants were subject to activation or passive education from a multidisciplinary standpoint. This study concluded that autonomous

motivation and change in perceived competence were found to predict improvement in glycemic control over a twelve month period and indirectly improved HbgA1C. A direct relationship between HbgA1C lowering from autonomy supportive measures could not be concluded, but the information discovered supported interventions that promoted patient's autonomy in chronic disease self-management. It also validated prior research that has demonstrated that self-management education improves glycemic control and patients who experience autonomous motivation are more competent to attain relevant outcomes.

Schachinger et al. (2005) reintroduced the concept of Blood Glucose Awareness Training (BGAT) in the diabetes literature. BGAT is a psychoeducational program for patients with Type 1 diabetes that focuses on improving the recognition and management of extreme blood glucose levels and is the best documented American psychoeducational program for this intent. BGAT is typically an 8 week outpatient program in a group format that: teaches patients to identify internal cues of glucose fluctuations, anticipate fluctuations, apply personally relevant data and engage in strategic homework assignments. There have been three versions of BGAT to date and the efficacy of BGAT has been well documented in the United States. However, initial European studies found that it reduced glycemic fluctuations but did not improve hypoglycemia detection thus raising generalizability and cultural issues. Therefore, a randomized controlled prospective study of BGAT III in European settings was performed. The RCT hypothesized that: BGAT III would lead to improved blood glucose

estimation, a reduction in the frequency of extreme blood glucose levels, decrease the frequency of severe hypoglycemia, and improve psychological functioning in terms of an improved internal locus of control and a reduction in FoH. BGATs effects on psychological variables were also examined.

Six settings in Switzerland and Germany participated in the multicenter study. Approximately 400 patients were made aware of the availability of the study. Exclusion criteria were uncontrolled physical and mental diseases. Somatic comorbidity was assessed prior to the study. Six patients were excluded due to this criteria. Substance dependency was also assessed by self-reported data. Inclusion criteria were: intensified insulin regimen, three to five glucose measurements daily, recent insulin adjustment and dosing schedule, and routine quarterly HbgA1C evaluation. A total of 138 participants were randomly assigned to receive either BGAT or participate in a physician guided self-help group. Subjects in each group were matched. Fourteen patients were excluded as they did not complete the training. Thirteen subjects were noted to be noncompliant and excluded from the study. Exclusion rates between groups were comparable. The intervention with BGAT focused on: internal cues, disruptions in cognitive and motor performance, mood changes, food consumption, insulin injections, and exercise. Personal data was reviewed in week eight. The self-help group guided by the physician allowed participants to determine the topics and no homework was assigned.

Dependent variables included blood glucose monitoring results, number of times SBGM per day, and self-reports of hypoglycemia. The Blood Glucose Accuracy Index,

standardized questionnaires assessing locus of control and quality of life were utilized with each known to have proven validity and reliability. The Well Being Questionnaire, Diabetes Quality of Life Questionnaire, a nineteen item mood questionnaire, and the Hypoglycemia Fear Survey were utilized. ANOVA was used to examine the impact of the intervention. The primary statistic of concern was a significant interaction term. *A priori* constructed contrasts for comparison between intervals and severe hypoglycemia in the previous two years as a covariate in the model did not have a significant effect on the results, so to preserve the statistical power, the covariate was not used. All tests were two tailed.

There was a marginal tendency for a higher rate of hypoglycemia in the previous two years in the BGAT group and other variables were comparable. BGAT led to a decrease in severe hypoglycemic events and increased recognition of both hyperglycemia and hypoglycemia. Extreme fluctuations and HbgA1C were not affected. Internal locus of control and unpredictability in glycemia improved. Worry and fear were also reduced in the BGAT group. These results are supportive of the findings from the American studies. BGAT has been shown to: reduce adverse clinical events without compromising metabolic control, improve recognition of high and low glucose, reduce external locus of control and reduce FoH. The positive effects of BGAT were also noted to have a long lasting effect on the participants.

The limitations of the study included the possibility that BGAT participants had attention from two group leaders instead of one physician. Treatments were not of equal

length and control participants did not participate in homework. Control group participants were not obliged to talk about hypoglycemia. Blinding was not possible due to the delivery of behavioral treatments. Behavioral treatments may also have been influenced by cultural factors.

Wild et al. (2007) proposed that BGAT, specific training designed to improve awareness of blood glucose symptoms and factors leading to glycemic variability, may reduce both the IoH and the FoH. This is, in turn, anticipated to improve the quality of life and patient safety in insulin requiring diabetics. A study by Weinger and Jacobson (2001) as cited by Wild et al. (2007) found that BGAT may be effective for reducing the FoH and increasing appropriate diabetes management behavior. Gonder-Frederick (2013) summarizes BGAT in the SR of the literature by citing the works of Cox et al. (2001) and Schachinger et al. (2005) with their work with BGAT focusing on the improvement of the patient's ability to accurately recognize symptoms of hypoglycemia and better predict glycemic patterns. BGAT improved detection of hypoglycemia, reduced the frequency of severe hypoglycemia, and reduced FoH.

There is direct applicability of BGAT to the clinical question as it addressed the frequency and fear of hypoglycemia. BGAT's reproducibility in a real world practice setting is a major barrier and thus, the intervention requires a translational approach. The adaptation of BGAT to delivery in a real world setting can be achieved by extracting the specific components of BGAT that are directly related to hypoglycemic prevention, recognition, and treatment in a self-study module with assigned homework and

individualized instruction. The entire BGAT program need not be reproduced to reap the benefits of its inception. A real world practical educational intervention is anticipated to achieve positive results while preserving the spirit of BGAT.

The real world of clinical practice often presents financial, time, and patient imposed barriers. Intervention strategies based on a sense of realism are more apt to be implemented than complex idealistic approaches. Translational research occurs in two continuous phases: from bench to bedside and from clinical research settings to real world practice. It is not acceptable to investigate relationships between factors and outcomes in a research setting without testing interventions and documenting outcomes in real world settings. Intervention research is desperately needed and is one of the highest priorities in diabetes translational research (Garfield et al., 2003).

Limitations

There are definitive limitations to the review of the relevant literature. The major limitation perceived is the lack of a standardized definition of hypoglycemia and FoH in the literature. Hypoglycemia cannot simply be defined by a numeric value; it must also be conceptualized as the degree of glycemia that is noted to induce behavioral, cognitive, or motor disruptions in a diabetic individual. The FoH phenomenon has not been specifically defined and its variables have not been explicitly stated. There is a lack of strong empirical evidence as to how the FoH impacts on long term outcomes. There is a considerable lack of data defining strategies to increase awareness among health care providers. The topic of hypoglycemia and its impact on diabetes management is sadly

unrecognized and considered secondary to hyperglycemia. Poor metric collection strategies do not allow for the light to shine on this clinically important aspect of diabetes care. The lack of causality when discussing the phenomenon of interest clearly indicates the need for more research to be done on both an observational and interventional front. There is a lack of data involving culturally diverse diabetic patients as well as a lack of attention to practical strategies that may be employed to address this common, yet complex, clinical dilemma. The BGAT strategy has been applied to Type 1 diabetics; however, severely insulin deficient Type 2 diabetics demonstrate many of the same physiological problems as their Type 1 counterparts and data supporting BGAT in insulin requiring Type 2 diabetics is required. There is also currently no guidance for health care providers regarding how to utilize the limited available data in clinical practice (Ryan, 2013).

Conclusions

The incidence of diabetes is anticipated to increase over the next few decades at a time when the allocation of resources is dwindling. This rise in the incidence of diabetes and its complications is surely to have a significant clinical impact on the health and well-being of the population of the United States. The progressive nature of diabetes often necessitates the use of insulin therapy as a life preserving and life sustaining treatment. The need for insulin is absolute, but with this therapy comes an increased risk of iatrogenic hypoglycemia. Hypoglycemia is the greatest barrier to the achievement of good glycemic control and stands in the way of proper hyperglycemia treatment. The

unrecognized and unaddressed complication of iatrogenic hypoglycemia causes significant physical, psychosocial, and financial ramifications. Hypoglycemia that is left untreated begets more hypoglycemia. This cyclical process allows for the development of the FoH. This fear can trigger maladaptive coping strategies that interfere with diabetes management and serve as additional risk factor for poor long term outcomes. The prevention, recognition, and treatment of hypoglycemia and its associated psychological consequences needs to be a priority when addressing the care of the diabetic patient. Diabetes is a vastly self-managed disease requiring the application of learned knowledge and the support of health care providers through autonomy support. Education is a key to self-management, empowerment, and self-efficacy. Education specialized to the topic of hypoglycemia can reduce the incidence and fear of hypoglycemia. It is anticipated that these reductions will improve quality of life and reduce risk. The time for translational research in diabetes to address issues such as hypoglycemia and the fear it generates is now.

Chapter 3: Conceptual Model for Evidence Based Practice Change

The only constant in healthcare is that it is dynamic. Scientific evidence may sometimes be considered absolute, but the manner in which it is applied and how it is transformed into new evidence is an evolutionary process. Transformation of evidence is required to stay on par with the needs of the population in new eras and changing environments. A multidimensional approach is mandatory to address the transformation of healthcare. Evidence based practice is one of the dimensions that demands clinician attention. (Stevens, 2006). Evidence based practice is a problem solving approach to clinical decision making that couples the soundest research evidence with the best available clinical expertise to form a criterion to measure care and achieve more consistent patient outcomes (Hickey and Brosnan, 2012). It is frequently not a lack of evidentiary knowledge nor the desire for implementing a practice change that stalls clinicians; it is the manner of how to take the evidence and translate it into a useable format in a real world setting. Translating evidence into practice is explicated by the use of a conceptual model for evidence based practice change.

Conceptual Definitions

The definition and purpose of a conceptual model. A model, or conceptual framework, is a set of concepts and assumptions that are arranged into a useful configuration in order to describe the relationships that exists between them (Mensik, Martin, Scott, and Horton, 2011). It is imperative that concepts are defined for the

purposes of accurate communication. Models must be identified within research to contextually illustrate how information is interpreted for clinical decision making.

Models assist clinicians in the organization of thoughts regarding evidence based practice, guide design and implementation strategies, and strengthen decision making skills (Stevens, 2013). They steer evidence based practice changes to prevent deficiencies in program implementation and guarantee that time and resources are used to their greatest value. Models aid in moving evidence to practice by focusing efforts and providing a systematic approach to evaluation of the evidence thus resulting in the optimization of patient outcomes despite being less rigorously tested in comparison to theories (Gawlinski and Rutledge, 2008).

Choosing an appropriate model entails the consideration of: clarity, organization, comprehensiveness, ease of use, practicality, and versatility. Most models have commonalities, however, contextual differences may make some models more applicable to a situation than others (Gawinski and Rutledge, 2008). The implementation of a model requires the consideration of multiple factors. Patient preferences, clinical states, settings, contextual circumstances, and the availability of healthcare resources are used to weigh the decision. The quality of research evidence, available clinical expertise, and the amalgamation of the two, are also factored into the decision making process. The development of guidelines helps to focus on improvement strategies that are useful in real life settings when attempting to change practices (Melnyk and Fineout-Overholt, 2015).

The ACE Star Model of Knowledge Transformation.

Overview. Evidence based practice changes can occur with the transformation of knowledge. This involves the conversion of singular studies that are cumulatively evaluated for their impact on health outcomes. This transformation is necessitated before research can be useful in decision making. The translation of scientific evidence occurs within the context of clinical expertise and other information resulting in practice recommendations. These practice recommendations need attention at individual, organizational, and environmental levels (Stevens, 2006). Clinicians are hindered in making evidence based practice changes by the obstacles of complexity, volume of information, and the numerous forms in which the available evidence is bundled. These obstacles need to be overcome by the development of evidence summaries and the transformation of knowledge through systematic steps to increase their meaning and utility in real world practice (Stevens, 2004).

The goal of the ACE Star Model is to convert research findings through a series of steps in order to use evidence to impact upon health by using knowledge types as precursors to practice integration. (Gawlinski and Rutledge, 2008). The ACE Star Model explains how to cope with the volume of evidence, the inability to link the form of knowledge in its current state to a clinical situation, and the integration of expertise and patient preferences. Despite the fact that not all knowledge can be translated into clinical practice, this model makes an impact on health by way of evidence based action

and organization of key points to provide a basis for quality improvement initiatives in preparation for more advanced models (Melnyk and Fineout-Overholt, 2015). It builds upon the basic nursing process, yet places an emphasis on evidence based care. The model's simplicity is evident in the way it illustrates a sequential move from one step of transformation to the next allowing for the synthesis of amassed evidence to be funneled into a practical recommendation (Gawlinski and Rutledge, 2008), but it is comprehensive as it encompasses new knowledge for practice integration (Stevens, 2004).

Assumptions. The ACE Star Model identifies eight assumptions (Appendix D) which are detailed in this section. The first assumption is that knowledge transformation is necessary before it can be used in clinical decision making. The second assumption is that knowledge is obtained from multiple sources. The third assumption states that generalizable knowledge is discovered through the research process. The fourth assumption indicates that evidence is hierarchically categorized according to the strength of the evidence as determined by rigor. The fifth assumption states that knowledge is found in different forms. The sixth assumption identifies that knowledge is relative to its contextual use. The seventh assumption asserts that the form of the knowledge determines its utility. Finally, the eighth assumption avows that knowledge is transformed by the steps of summarization, translation, integration, and evaluation (Stevens, 2004).

Model and stages. The ACE Star Model is visually depicted as a five point star with each point of the star representative of a stage of knowledge transformation needed for evidence based practice change (Appendix E). Stevens (2004) described the schematic of the visual representation. The first point of the star represents the stage of discovery. This stage is considered the knowledge-generating stage and serves as the foundation for clinical action. The second point represents the evidence summary stage. This stage is known to include the synthesis of research into a singular statement regarding the phenomena of interest that continues knowledge generation by accumulating the most rigorously evaluated evidence through critical appraisal. This stage entails: the management of data, the generalizability of data, determination of the consistency of the data, identifying cause and effect within the data, reducing bias, synergy of old and new data, and the efficiency of the data. This second stage is considered ground zero for future evidence updates. The third point depicts the packaging of translated evidence. This is typically in the form of care standards, pathways, protocols, or algorithms used in clinical decision making. This is the stage where clinical research is combined with theoretical guides and clinical expertise for conceptualization to a specific population or setting to articulate the link between the recommendation and the evidence. The fourth point of the model represents practice integration. It is in this stage that change by the individual or organization through formal and informal channels is accomplished depending upon the rate of adoption of the change. Lastly, the fifth point symbolizes process outcome and evaluation. This is where

endpoints and outcomes are evaluated for the determination of impact on health outcomes, satisfaction, health status and efficacy. Efficacy notably includes ease of use and cost analysis.

Relationship of Model to the Project

The ACE Star model was applicable to the EBP and provided a very efficient template to pave the way for evidence based changes. The EBP required the research to be translated into a useable form for application in a real world setting to improve quality and patient satisfaction, as well as to enhance patient safety. It was also the intent of the researcher that this EBP would stimulate additional scholarly inquiry regarding ways to address the phenomena of hypoglycemia for incorporation into project investigator's (PIs) electronic medical record for use throughout an individual organization.

The first stage of knowledge translation was the identification of the clinical problem – the barrier of hypoglycemia on diabetes management. The project focused attention on FoH as the primary topic in diabetes management, the FoH. This stage called for the PI to collect evidence in the form of descriptive and correlational studies, as well as randomized controlled trials, to establish a data base of evidence. The PI discovered that BGAT was an effective approach in the reduction of FoH and improved patients self-management skills.

The second stage of knowledge translation continued the generation of knowledge through PI's evaluation of SRs and other relevant literature. The available

evidence was able to be narrowed in this stage. Evidence demonstrated that education positively impacts upon the phenomenon of hypoglycemia and reduces the FoH despite the fact that additional research is required to demonstrate an impact on long term health outcomes and prevention of complications. The FH-15 Scale determining FoH was ascertained to be a valuable tool in data collection regarding FoH pre and post intervention. The obstacle connected with BGAT was its limited feasibility in its current state for use in a busy individual practice setting with limited resources and available providers. BGAT required the selective extrapolation of specific components for the successful implementation in a real world clinical practice.

The third stage of knowledge translation was to evaluate the current clinical practice guidelines available for the prevention, detection, and treatment of hypoglycemia to impact upon FoH and IoH in insulin requiring adult patients. The evidence based guidelines articulated the link between the prevention of hypoglycemia and the development of FoH as a limiting factor to achieving adequate glycemic control. The packaging of relevant data in a single entity was more useful to the PI in determining how to apply the standards of care.

The fourth stage of the project involved the selection of one component of BGAT for implementation as BGAT in its original form was noted to be typically beyond the implementation of individual practices in a real world setting. The selected educational component dealing with the phenomenon of interest, hypoglycemia, was targeted for additional evaluation to determine the impact upon FoH and IoH. The EBP intervention

involved planning by the PI within an individual practice setting and collecting data regarding its efficacy.

The final stage of knowledge transformation included the evaluation of the EBP's endpoints and outcomes regarding FoH and IoH. Evidence regarding outcomes was compiled for dissemination to the organizational board of physicians and packaged for presentation to the policy and procedure group of the organization for incorporation into the electronic medical record for use in all individual sites caring for insulin requiring adult patients. Collaboration with information technology specialists within the organization for determination of methods for metric collection regarding the phenomenon of hypoglycemia is anticipated to be forthcoming. The widespread implementation of hypoglycemia education across the organization will improve quality, increase patient satisfaction, and safeguard the health and well-being of patients with insulin requiring diabetes.

Conclusion

The move to expand the use of evidence based approaches in clinical practice is crucial for the transformation of healthcare. The amount of information available and the form in which this information exists is not always conducive for translation into real world practice. The utilization of a conceptual model to organize the development of a project cannot be understated. The use of a logical framework by the clinician to undertake the task of clinical inquiry simplifies the process into measureable steps. The ACE Star Model for Knowledge Transformation is one model that is illustrative of how a

simplistic framework can incorporate complex ideologies and guide clinical inquiry for the purpose of quality improvement.

Chapter Four: Project Design

Project Design

Clinical research can either generate new evidence upon which practice should be based or it can evaluate the applicability and effectiveness of research findings for use in clinical practice on populations of interest. EBPs use a translational approach to research to bring about change in practice for the purpose of improving patient outcomes. Scrupulous attention to methodology that supports the project is a necessity for the project to be useful and ethical. Reliability of the project requires adherence to an evidence based process to ensure the project does not violate the principle of justice through the wasting of limited resources or violate the principle of beneficence through the result of ineffective outcomes (Melnyk and Fineout-Overholt, 2015). The purpose of this chapter is discuss the planning process for the EBP.

Project Purpose. The purpose of the project was to evaluate the effectiveness of implemented standard of care best practices, specifically an evidence based, psychoeducational tool extrapolated from BGAT, on FoH and IoH in insulin requiring adult diabetics. The reasons for the conceptualization of the EBP were two-fold: FoH is a major deterrent in the achievement of the degree of glycemic control required to prevent long term diabetic complications and insulin associated ADEs can significantly jeopardize patients' safety and psycho-social well-being. Scholarly inquiry and an extensive literature review regarding the topic of interest demonstrated that BGAT was an effective intervention for the reduction of FoH. However, BGAT was not deemed

practical for the purposes of the practice or the organization due to recognized barriers to implementation. Thusly, the prior evidence based implementation required a translational approach for adaptation to real life practice and subsequent evaluation to ensure its applicability and beneficence.

Project Management. An assessment of the feasibility in which an EBP is to be conducted must be performed prior to the implementation of change. Additionally, establishment of a thorough plan of action in preparation of the project must be considered during project planning. This EBP included: an organizational assessment, information technology assessment, Institutional Review Board (IRB) approval, data collection planning, and resource allocation planning.

Organizational topics. An organizational assessment included evaluation of the need for practice change, availability of collaboration, evaluation of potential barriers and a strategy in which to mitigate the identified barriers (Moran. Burson, and Conrad, 2014). The need for practice change was identified by the existing members of a single healthcare system owned Endocrinology practice. The existing members of the practice consisted of one board certified Endocrinologist, one Certified Registered Nurse Practitioner (CRNP), and one Certified Physician Assistant (PA-C). Consensus was achieved among the practice providers that there was an ongoing need to supportively educate patients on the recognition, prevention, and appropriate treatment of hypoglycemia. Interprofessional collaboration was utilized for the purposes of securing differing perspectives on the topic of interest. It was agreed that implementation of the

EBP would be initiated in the individual practice site with the potential for the results to be disseminated throughout the organization. It was theorized that successful implementation of the EBP could result in future widespread implementation and data collection used to improve the health of the identified population. Consultation with nursing and patient care staff was initiated by the CRNP to obtain other professional inputs to determine project worthiness. The individual practice site was deemed appropriate due to a desire to stimulate evidence based practice changes for the purpose of improving patient outcomes. Supporting organizational characteristics included: a high percentage of insulin requiring adult diabetic patients managed by the CRNP and the availability of resources to enact the practice change. Organizational approval to institute the project was granted by both the practice manager and the office manager. It was determined that all insulin requiring adult diabetics evaluated by the CRNP in a single practice site would be provided the availability of the same accepted evidence based practice guidelines for diabetes management. A survey measuring FoH and IoH was administered prior to the intervention and four weeks post intervention on participating patients for comparison. Informed consent (Appendix F) was obtained prior to patient participation to uphold ethical standards. The intended outcomes of the EBP intervention were to: reduce the FoH and IoH.

An analysis of the project using a strengths, challenges, opportunities, and threats (SCOT) analysis as defined by Melnyk and Fineout-Overholt (2015) was performed. The strengths of the project included the clinical need for practice change, organizational

support within the practice, and patient acceptance of receiving information. The challenges identified included: time management, securing patient enrollment, resource allocation and patient health literacy. Additionally, neither the practice nor the organization has a department dedicated to organizational research. The opportunities provided by the project included improved communication with patients, improvement in patient outcomes, and the ability for disseminated information retrieved from the project to stimulate an organizational change for improving population health and data collection for future research. The project also encouraged adherence to evidence based practice standards from the ADA (2015) and The Endocrine Society (2009) through the provision of ongoing provider supported patient education regarding diabetes self-management. Threats to the project were perceived to be time management, patient participation, and the future acceptance of disseminated information by the organization for stimulating changes in practice on a more widespread scale. These threats were mitigated by: modification of recruitment time for the project, ongoing preparation for impromptu meetings due to time constraints, adherence to informed consent, utilization of an LPN liaison, discussion of the project with the a physician member of the Board of Directors, and formation of a relationship with an IT and QI supervisor to incorporate education in the EMR.

Use of Information Technology. The utilization of IT in healthcare has become increasingly important in improving quality of care, supporting decision making, documenting adherence to standards of care, and improving patient safety. The EMR

serves as a tool to address each of these factors. The practice in which the intervention took place utilized an EMR and the password protected Centricity electronic database. The pedagogical tool utilized in the project was researched utilizing multiple databases accessed on the internet and was developed using Microsoft Word. Data collection was accrued in the EMR for retrospective evaluation of outcomes from implementation of best practice in diabetes management. Data analysis was performed using Microsoft programs. IT methods for dissemination of project results regarding diabetes management was done using the Microsoft Word and Power Point programs.

Institutional Review Board Approval. IRBs have been established for the purpose of reviewing and monitoring research involving the participation of human subjects to ensure the protection of their rights and welfare (United States Food and Drug Administration, 2014). The PI completed certification from the National Institute of Health on protection of human subjects in research in accordance with IRB policies prior to the project launch (Appendix G).

Interestingly, at the initiation of project planning, the organization in which the project took place did not have an established IRB; however, the parent healthcare system which owns the organization was noted to have an IRB. Organizational IRB requirements were investigated and preparation for review was done. One week prior to the submission of project information to the organization's IRB, it was discovered that the committee had been dissolved due to lack of participant interest and resignation of the IRB physician chair. Therefore, organizational IRB approval was not able to be

sought nor obtained. Project information was submitted to the Misericordia University's IRB in Dallas, Pennsylvania and the project was approved in May 2015 (Appendix H).

Data Collection Tools

The quality of a measuring tool that was used in data collection for translational research was based upon the instrument's reliability and validity. Reliability estimates measurement stability and internal consistency, whereas validity focuses on the extent to which interpretation of the results are warranted. Translational research in healthcare may also require the collection of data via self-reporting by patients but must be interpreted with caution due to the risk of bias (Kimberlin and Winterstein, 2008). This project used both an instrument for data collection in addition to self-reported data with each having distinct differences in reliability and validity but determined to be useful nonetheless in translational research.

FH-15. The FH-15 Scale was used in the EBP for practice improvement. Permission for use of the FH-15 Scale was granted by Professor Maria Teresa Anarte-Ortiz from the Department of Personality, Assessment, & Psychological Treatment Faculty of Psychology at the University of Malaga in Spain. This scale was determined to be applicable to the selected clinical problem and population as it provided an adequate instrument to specifically measure FoH and was directly linked to clinical inquiry. Its advantages were determined to be: use as a rapid assessment tool in determining hypoglycemia, assistance in the development of a patient centered individualized treatment plan for the prevention of ADEs, and improvement in the use of medical

resources for successful patient outcomes by addressing factors that contribute to treatment noncompliance. The scale was tested in a cohort study using the methodology of Factor Analysis with a principle components method and involved 229 voluntary participants recruited by a clinical psychologist in a diabetes unit in an endocrinology department. The study collected socio-demographic data and evaluated the subjective perception of FoH. Rigorous data analysis was performed concluding that the FH-15 scale had good test/re-test reliability with good sensitivity (0.736) and specificity (0.807) with a positive predictive value of 0.779 and a negative predictive value of 0.768. It was concluded that the instrument alone cannot comprehensively evaluate the complex phenomenon of FoH and requires additional research in various diabetic cohorts. However, it specifically measures FoH, has the potential for widespread use, and was useful in clinical practice as it demonstrated efficient use of time and helped to identify patients at risk that may require more intensive psychological intervention (Anarte-Ortiz, Caballero, Ruiz de Adana, Rondan,, Carreira, Dominguez-Lopez, … and Soriguer, 2011).

Demographic data collection included: ethnicity, gender, age, the use of insulin as monotherapy, and the presence of a significant other residing in the home. Additionally, the number of estimated incidents of hypoglycemia in the past four weeks was self-reported by the patient participants at baseline and four weeks post intervention. All data collected for the project were normally collected as part of standard of care for all insulin requiring patients in the practice evaluated by the CRNP.

Data Management

Information associated with the project was confidentially maintained on the password protected Centricity electronic database that was accessible only to the PI. Patient participants who agreed to receive the informational tool and in which informed consent was obtained were identified in the EMR upon retrospective chart review. Each patient was assigned a numeric code to be used in place of any identifying information in any and all retrospective data collection used for the EBP to protect the anonymity of the patient. Absolutely no patient identifiers were used in the documentation of the project findings or disclosed. No other information was used.

Data Evaluation

A non-experimental EBP for the purpose of stimulating practice change differs from traditional research despite overlapping characteristics (Melnyk and Fineout-Overholt, 2015). The cross-sectional design of the project entailed the collection of measurements at the same point in time. The FH-15 survey data was evaluated pre and post intervention in addition to the self-reported estimates of the number of hypoglycemic events experienced within the past four weeks pre and post intervention. Survey data were collected in person or via phone interview. The chart review involved the evaluation of a convenience sample and the use of descriptive statistics to explain demographics. Paired two-tailed *t* tests were used to determine the differences between the two sets of data.

Required Resources

Several resources were required for the EBP. A provided copy of the informed consent, printed pre and post FoH survey forms, and a copy of the written intervention tool was required for each voluntary participant. A laptop computer equipped with Centricity, copy paper, ink cartridges, pens, copy machine, and Microsoft Office software was deemed necessary. Facilities with an exam room were required. Glucometers and/or test strips were provided to patients who did not have one for home use. A privacy secured locked disposal system for discarded documents was marked for incineration and used in conjunction with other resources such as a telephone system and office support staff services for scanning information into the EMR. The services of an LPN trained in the protection of human subjects was employed for data collection in the event the project manager required assistance (Appendix I). There was no cost associated for obtaining permission to use the FH-15 Scale. Statistician services were not required.

Budget Justification

The EBP was considered to be low cost and affordable. The required resources were purchased by the practice for the quality improvement project in advance of the retrospective data collection. The bulk of the cost associated with the practice implementation was comprised of paper and ink for the printing and distribution of surveys and psychoeducational materials to patients accepting the interventional tool. The maximum amount allotted would be 100 copies of each for the period of recruitment.

Glucometers and test strips were earmarked for patients who did not have use of these items prior to retrospective data collection, were provided gratis by multiple pharmaceutical companies, and are routinely available in the office setting. The retrospective data collection associated with the project after implementation involved the use of existing equipment that was included in the day to day operations of the practice. These items included: a laptop equipped with Centricity, copy machine, Microsoft Office software, privacy ensured document disposal, a telephone system, facilities and personnel for scanning information. The additional allocation of financial resources required for the project included the employment of the LPN for assistance with data collection and time for training on protection of human subjects in research. The anticipated amount of LPN reimbursement time for the project was estimated at no more than $250.00. The utilization of the LPN to ensure the success of the project in the event of time management issues was determined to be imperative. There was no cost for obtaining permission to utilize the FH-15 Scale or for statistician services.

Conclusion

Undertaking an EBP for practice improvement is not necessarily a cut and dry process. Planning an implementation demands the creation of a step-by-step process to guide management, but it must also allow some flexibility as actual implementation is not as forthright. A well-formulated project plan ensures success and provides a better chance of reproducibility in the event the project is successful. Hypoglycemia is a major barrier to the achievement of adequate glycemic control and can wreak havoc on diabetic

patients and their loved ones. This EBP sought to practically incorporate psychoeducational information during routine follow up of diabetes care for the purpose of reducing FoH and IoH. It represented an initial step in practice and organizational change that has the potential to reduce health care costs and improve patient safety in accordance with national action planning.

Chapter 5: Project Implementation

Preparation

Problem Identification and Project Justification

Diabetes currently afflicts millions of people and the population of individuals with diabetes is expected to continue to rise (ADA, 2014). The progressive nature of the disease and the devastating consequences from chronic hyperglycemia frequently require the utilization of insulin therapy to prevent the onset or progression of diabetic complications. Treatment with insulin therapy, although often life-sustaining, is not without potential risks. Iatrogenic hypoglycemia is an ADE that can trigger patients to experience fear associated with the same therapy that is meant to protect their health. FoH can serve as a major barrier to the achievement of glycemic control adequate enough to prevent diabetic complications (Wild, et al., 2007). Iatrogenic hypoglycemia is the most commonly experienced ADE associated with insulin use (HHS, 2014) and has physical, psychosocial, financial, and safety implications that affect individuals, families, communities, and populations. Ongoing education regarding the recognition, prevention, and treatment of hypoglycemia has been evidenced to reduce FoH and improve self-management skills in diabetic patients (Wild, et al., 2007). National guidelines have suggested routinely addressing hypoglycemia in insulin requiring patients to improve patient safety (HHS, 2014) and experts concur that inquiry by clinicians regarding hypoglycemia in the insulin requiring patient should occur at every encounter. (The Endocrine Society, 2009).

Identification of the clinical problem, accompanied by an extensive review of the relevant literature, was performed prior to the implementation of the EBP. Furthermore, the EBP was foundationally supported by linkage to the ACE Star Model of Knowledge Transformation. The project design was formulated with the purpose of evaluating the effectiveness of implemented standard of care best practices on the improvement of FoH and IoH in insulin requiring adult diabetics. Interprofessional collaboration, stakeholder involvement, organizational issues, and the use of IT were examined in project management. Data management and evaluation were conceptualized. IRB approval was sought and obtained on May 13, 2015 and valid until August 16, 2015. Instruments for data collection were critically appraised and required resources were defined. Compiled information extrapolated from BGAT was used to compose an evidence based pedagogical tool aimed to improve the recognition, prevention, and treatment of hypoglycemia. The tool included BGAT derived strategies and patient homework assignments.

Incorporation of best practice standards into individualized care assists clinicians in the challenging task of caring for insulin requiring diabetics. Translational research bridges the gap from bench to bedside as it determines how best practice standards are applied. The EBP was planned and implemented to address the clinical problem of interest. The purpose of this chapter is to detail the implementation procedures and processes of the EBP.

Project Setting and Participants

The setting in which the EBP took place was a health care system owned Endocrinology practice in Luzerne County located in a region of northeastern Pennsylvania. Statistically, the majority of patients cared for in the practice were primarily insured by Blue Shield with Medicare as the second largest insurer of practice patients. Endocrine services within the setting were provided by a Board Certified Endocrinologist, a CRNP, and a PA-C. Cumulatively, an estimated 50 to 70 patients with a variety of endocrine disorders were evaluated in the practice on a daily basis. The EBP was implemented by the CRNP, otherwise known as the PI. The population selected for the EBP included all adult insulin requiring adult patients evaluated by the PI between June 2, 2015 and June 12, 2015 who met inclusion criteria.

Implementation Procedures and Processes

The EBP was implemented in four distinct phases as summarized in a visual timeline (Appendix J).

Phase One. Implementation of the EBP took place daily on the aforementioned dates during normal office hours to ensure the implementation could be successfully completed during an actual patient encounter in order to be considered translatable to real life clinical practice. The enrollment time frame for the EBP was initially estimated at four weeks; however, in the interest of time and to mitigate the risk to the project, the CRNP's patient encounter schedule was examined for a two week time period prior to implementation and considered by the PI to be sufficient for capturing patient

participants of an adequate number. The implementation phase of the EBP started on June 2, 2015 and continued through June 12, 2015. Each patient was counseled individually regarding hypoglycemia in accordance with the usual standard of care. Each patient agreeing to participate in the FH-15 survey was queried. Patients were provided with the created pedagogical tool extrapolated from BGAT when accepted. Each patient was encouraged to read the information, consider the homework assignments, and apply the learned information to daily management. All participants agreeing to retrospective data collection from their records were additionally provided with informed consent and a copy of the consent form. Participants were informed that a follow up phone interview by the PI or LPN assistant to the PI trained in the protection of human subjects would voluntarily occur in one month. Reiteration of the retrospective collection of de-identified information was provided to each patient. The time commitment required per patient for project implementation for phase one was approximately fifteen minutes with slight variations required depending on patient health literacy and the need for repetition or additional explanation.

Phase Two. The time frame between June 12, 2015 and July 2, 2015 included education of the assistant LPN in protection of human subjects and the maintenance of an open line of communication between the project manager and patient participants regarding any issues of concern or questions that arose.

Phase Three. The time frame between July 2, 2015 and July 12, 2015 was utilized for daily follow up telephone interviews of the EBP participants. This phase involved the

PI or the assistant LPN conducting a post-intervention FH-15 survey with the participants and having each participant estimate the IoH over the past four weeks as noted in their glucose log or by patient recollection. It was determined patients would be considered voluntarily withdrawn from the EBP if post project data indicated: the patient did not read the provided information, was deceased, hospitalized, voluntarily withdrew, or was unable to be contacted after three individual attempts on three separate days within one week starting the first day of the four week benchmark date.

Phase Four. The time frame between July 12, 2015 and August 12, 2015 was utilized for program evaluation. The FH-15 pre- and post-intervention were compared. The data were entered into the secured Excel spreadsheet for data analysis. Descriptive data analysis and paired two-tailed *t*-test were used to evaluate pre- and post-intervention data. The findings were analyzed to substantiate the original clinical question of "Does individualized self-management education influence the FoH and IoH in adult patients diagnosed with insulin requiring diabetes mellitus within 4 weeks?"

Data Collection

All patient interviews were conducted individually in a private office. Confidentiality was maintained and no personal identifiable information was retrospectively collected. Each patient was linked to an identifier code number on the FH-15 and incidence of hypoglycemia survey. An Excel spread sheet was used to enter the data from survey tools and for data computation. Data were secured by the use of de-identified code system, the use of a locked file in a private office, and electronic data

secured on a password protected computer. All paper data was destroyed by disposal into a locked professional disposal system of privacy protected documents marked for professional incineration. All electronic files were permanently deleted.

Conclusion

Ongoing education regarding the self-management of diabetes continues to be the cornerstone of disease management (Erol and Enc, 2011). This EBP was intended to investigate a method of improving the quality of care to insulin requiring adult diabetic patients. Project implementation processes and procedures were clearly delineated for the purpose of understanding what the EBP provided and how it was provided. Evaluation of an EBP was required to prove usefulness in clinical practice and worthiness of additional inquiry and for the dissemination of information. The results of the EBP were intended to stimulate additional changes in order to improve patient and population outcomes.

Chapter Six: Evaluation and Outcomes

Introduction

A population needs assessment and a thorough review of the relevant literature regarding the topic of FoH demonstrated that iatrogenic hypoglycemia is the most commonly experienced ADE associated with insulin use and is notably one of the biggest barriers to the attainment of glycemic control and stability (Amiel, 2009). The barrier of FoH develops through the construction of maladaptive behaviors; thus it becomes essential for insulin requiring patients and their HCPs to deconstruct this barrier and rebuild a solid foundation of knowledge in its place using a population based and patient centered approach to diabetes self-management. FoH is often overlooked or underestimated by providers and distressing to a large percentage of diabetic patients who must rely on insulin therapy as a life-sustaining measure for the prevention of diabetic complications associated with hyperglycemia (Seaquist, 2013). HHS (2014) has identified the need to address the risks associated with iatrogenic hypoglycemia through the use of multiple methodologies meant to mitigate the variables that lead to this ADE. Attention to hypoglycemia has been judged to be a high priority and has been included in HHS National Action Planning. (2014).

This EBP was intended to add to the knowledge base of translational diabetes research and demonstrate how the application of best practice strategies can be translated into real world clinical practice for improvement of quality care and patient safety. The supposition was made at the inception of the project that the practical

provision of self-management education derived from BGAT that addressed the topic of hypoglycemia in insulin requiring diabetics would influence FoH and IoH. It was hoped that the EBP would demonstrate an influence on the FoH and IoH in a positive manner in order to allow the PI to use the information gleaned from the project to: promote population health, improve patient safety, stimulate additional scholarly inquiry, and prompt organizational change in accordance with national action planning. The project objectives were congruent with HHS (2014) National Action Planning and the need for practice changes addressing hypoglycemia supported the need for the project. The purpose of this chapter is to discuss the project data results and analysis, establish a relationship to the project framework, and demonstrate the relationship of the results to the project's objectives.

Establishment of the Project Population

The EBP was conducted over a ten week time period. The PI evaluated a cumulative total of 89 insulin requiring adult patients in the endocrinology setting between 9a.m. on June 2, 2015 and 4:30p.m. June 12, 2015. All patients were provided with hypoglycemia education in accordance with best practice standards. A total of 14 patients were excluded from the cumulative 89 patients evaluated for potential enrollment in the project based on the following: 9 patients declined project participation, 3 patients were unable to provide informed consent due to dementia or mental illness, 1 patient was blind and therefore unable to read the provided information, and 1 patient was non English speaking. The remaining 75 patients provided informed

consent, completed the pre-intervention FH-15 Survey and Incidence of Hypoglycemia (IoH) question and were provided with the educational tool for their perusal and application to self-management. It was later discovered in Phase Three of the project that Participant 10 had not answered all of the questions on the pre-intervention FH-15 Survey and this was not immediately noted by the PI. Participant 10 was excluded to preserve the integrity of the project. The project population was recalculated to be 74 participants. The continuation of the project saw an additional 14 participants lost through attrition. Participants 21 and 45 were withdrawn due to hospitalization and Participant 26 was withdrawn due to an inability to continue participation due the acute illness and hospitalization of a spouse. Participants 15, 27, 41, 51, 54, and 63 were withdrawn from the project due to lack of participation as evidenced by admitted failure to read the provided educational information. Participants 20, 23, 31, 48, and 74 were withdrawn from the project due to an inability for the PI or assistant LPN trained in the protection of human participants to make contact with the patient to administer the Post-intervention FH-15 Survey and IoH question within the required time frame. Sixty of the initially enrolled 74 participants included in the Pre-Intervention data were able to be queried with the Post-intervention FH-15 Survey and IoH question four weeks after the intervention. The project was noted to have an attrition rate of 19% and a response rate of 81%. The project population was finally recalculated to have an N=60. This was considered adequate for survey research by the APN project investigator.

Data Results and Analysis

Data was collected on a convenience sample and identified as the project population (Appendix K). A mixed method analysis of the project data was performed using both observational and statistical methods. Observational data was recorded to investigate the topic and expand on the statistical analysis. Statistical analysis was utilized to assist in the interpretation of the observational data and to assist in establishing whether the influence of the intervention was significant allowing for the rejection of the null hypothesis. The null hypothesis in the project was assumed to be that the intervention had no influence on FoH or IoH.

Project population demographics

Participant demographics were compiled for descriptive analysis (Appendix L). Participants ranged in age between 18 and 80+ years with the 60-69 year old age group having the highest number of participants at 38%. Thirty-one participants, 52% of the project population, were male and 29 participants, 48% of the project population, were female. One participant was African-American and 59 participants were Caucasian. Thirty-five participants, or 58% of the project population, were maintained on insulin mono-therapy during the project while 25 participants, or 42% of the project population, were maintained on a combination of insulin along with other oral or non-insulin injectable agents used to treat diabetes. Forty-nine participants, 82% of the project population, were noted to reside with another person(s) while 11 participants, 18% of the project population, resided alone.

Descriptive Statistics.

The project data was descriptively expressed in order to summarize the characteristics of the project population.

Total project population.

The mean pre-intervention FH-15 score in the project population was 28 with FH-15 scores that ranged from 15 to 68. Thirty participants, representing 50% of the project population, were noted to have FoH pre-intervention as evidenced by FH-15 scores of ≥28. Thirty participants, or 50% of the project population, did not have FoH pre-intervention as evidenced by FH-15 scores of <28. The mean post-intervention FH-15 score in the project population was 25 with FH-15 scores that ranged from 15 to 65. Post-intervention FoH scores were reduced in 37 participants, or 62% of the project population, unchanged in six participants, or 10% of the project population, and increased in seventeen participants, or 28% of the population. Post-intervention FoH was noted in 19 participants, or 32% of the project population.

The mean pre-intervention IoH in the project population was 4.7 with a range of IoH between 0 to 35 events within the four weeks preceding the intervention. The mean post-intervention IoH score in the project population was 4.3 with a range of 0 to 30 events within the four weeks after the intervention. Post-intervention, IoH was reduced in 25 participants, 42% of the project population, unchanged in 20 participants, or 33% of the project population, and increased in 15 participants, or 25% of the project population (Appendix M).

FoH sub-populations.

The sub-population of participants with pre-intervention FoH was of particular interest to the PI. Post–intervention FH-15 scores in the 30 participants noted to have pre-intervention FoH demonstrated that 17 participants continued to demonstrate FoH post-intervention as evidenced by a FH-15 score ≥28. Characteristics of the sub-population are noted in Table 1.

Table 1

FoH Population Demographics

	Age	Gender	Ethnicity	Therapy	Living Situation
Pre-Intervention	Range: 30-80+ years	M=13 (43%) F=17 (57%)	C= 29 (97%) AA= 1 (3%)	I=23 (77%) I+=7 (23%)	W/O=23 (77%) A=7 (23%)
Post-Intervention	Range: 30-79 years	M=6 (20%) F=11 (37%)	C=16 (97%) AA=1 (3%)	I=13 (43%) I+=4 (13%)	W/O=14 (47%) A=3 (10%)

M= Male F= Female C=Caucasian AA=African American

I= Insulin Mono-therapy I+= Insulin with other agents W/O= With Another A= Alone

Comparative analysis of the pre-intervention participants with FoH (n= 30) versus that of the post-intervention participants with FoH (n=17) demonstrated a 57% reduction in FoH within the sub-group. Trends in the post-intervention FoH as they correlate with the trends of post-intervention IoH in participants who demonstrated pre-intervention FoH are noted in Table 2.

Table 2

Pre-intervention FoH population post-intervention trends

	IoH Increase	IoH Decrease	IoH without change
FoH Increase (n=4)	2 (7%)	1 (3%)	1 (3%)
FoH Decrease (n=24)	7 (23%)	12 (40%)	5 (17%)
FoH without change (n=2)	0 (0%)	1 (3%)	1 (3%)
*Percentages were rounded to the nearest whole number for reporting purposes			

Alternatively, an additional sub-population was identified in the QI project. It is noteworthy that two participants, Participant 35 and Participant 61, did not demonstrate FoH pre-intervention; however, both participants demonstrated a higher post-intervention FoH score and both participant's post-intervention scores were consistent with FoH. Interestingly, despite Participant 35 being male and Participant 61 being female, the two participants shared the age group of 70-79 years, Caucasian ethnicity, insulin mono-therapy, and a living situation of residing with another. The development of FoH in these two participants demonstrates a 7% rise in FoH post-intervention in a sub-population of participants that did not demonstrate pre-intervention FoH.

Statistical analysis.

Project outcomes were measured using the FH-15 Survey and patient self-reported IoH pre and post intervention. The FH-15 Survey measured 15 participant

responses ranked according to experienced frequency of hypoglycemia and its impact on daily life pre-intervention and four weeks post-intervention. The IoH question collected each participant's self-reported estimated incidence of the number of hypoglycemia events experienced within the four weeks prior to the intervention and four weeks post-intervention. The pre- and post-intervention data for both FoH and IoH was statistically analyzed.

A paired two-tailed *t*-test was performed to assess the differences between pre- and post-intervention FH-15 scores and IoH estimates from the 60 qualified participants which comprised the project population. Results were statistically significant (FoH- M=26.5, SD=10.7, t (59) =3.47, [p = 0.001] with a CI of 95%) for FoH. This supported that the intervention did influence the FoH with statistical significance in this particular EBP and the null hypothesis could be considered for rejection. Results were not statistically significant (IoH- M=3.58, SD=6.1, t (59) =0.65, [p = 0.5]) with a CI of 95%) for IoH. This supported that the intervention did not influence IoH with statistical significance in this particular EBP and the null hypothesis could not be rejected. A summary of the statistical analysis data is noted in Table 3.

Table 3

Population Statistical Analysis Summary

N		Pre-Intervention FH-15 Score	Post-Intervention FH-15 Score	Pre-Intervention IoH	Post-Intervention IoH
60	**Sample Mean**	27.95	25.03	3.80	3.40
	Population Mean	26.49		3.58	
	Sample SD	11.032	10.314	6.208	6.087
	Population SD	10.734		6.126	
	SE	1.4243	1.3315	0.80141118	0.7858087
	p Value	0.000965827		0.518400569	

Thematic Reports.

Participant commentary was solicited by the PI or LPN assistant trained in the protection of human subjects at the conclusion of the post-intervention query by asking participants if they had any additional information they would like to offer regarding the information that was provided. Nineteen participants offered no additional comments. Forty-one patients had brief remarks suggesting the provided information was valuable in assisting with self-management. Six participants provided brief remarks suggesting the information increased self-management behaviors along with assisting in self-management. Two themes arose surrounding participant's perceptions of the intervention: education assisted in self-management and increased self-management

behaviors. These thematic reports in the observational project were identified for potentially providing information that would stimulate future scholarly inquiry. These themes were reported during the collection of information while evaluating a different objective and could not infer any cause, effect, or change in practice. The themes did serve to observationally assist in the evaluation of the impact of the pedagogical tool.

Relationship of Results to Framework

The EBP was guided by the ACE Star Model. The ACE Star Model focused on the transformation of evidence for use in clinical practice. The use of this framework assisted the PI in the translation of knowledge from bench to bedside. The results of the project demonstrated the effectiveness of the ACE Star Model as an approach to scholarly inquiry. Evidentiary information regarding the topic of inquiry, along with critical appraisal of best practice standards, were investigated, contextually translated, and practically applied using clinical expertise in a specified population. The results of the project, made possible through the guidance of the ACE Star Model, were relevant to improving patient safety and quality care, stimulating practice change, and generating additional scholarly inquiry.

Relationship of Results to Objectives

The objective of the EBP was to add to nursing knowledge and translational diabetes research through the demonstration of the application of best practice strategies for improved quality of care and patient safety. This objective was realized through the completion of the project and dissemination of the data. The outcomes of the

EBP were an anticipated reduction in FoH as well as a reduction in IoH within the four weeks following the intervention as evidenced by comparative analysis of observational and statistical data collected during the project. The EBP utilized an observational approach to ascertaining whether education influences the FoH and the IoH in insulin requiring diabetics within a four week time frame. The PI made the initial assumption that the provision of self-management education derived from BGAT practically addressing the topic of hypoglycemia in insulin requiring diabetics would lead to a reduction in the FoH and IoH.

Conclusion

This project was devised in an attempt to validate that a relationship existed between the provision of diabetes self-management education and the fear and incidence of hypoglycemia. The extracted data that was analyzed for this project confirmed that a relationship existed between the project intervention and FoH, but no statistically significant relationship was evident between the intervention and IoH.

Chapter Seven: Implications

Introduction

The incidence of diabetes continues to rise and along with the population of patients requiring insulin therapy. Insulin is a necessary form of therapy that is often life-sustaining and remains a key to the prevention of diabetic complications associated with hyperglycemia. However, the use of insulin increases the risk of hypoglycemia and has been identified as one of the most common medications associated with ADEs. Insulin requiring diabetic patients are called upon to balance the threat of hyperglycemia with the risk of hypoglycemia on a daily basis. Insulin use frequently triggers a FoH as the risk of hypoglycemia is perceived by many patients to be an experience far worse than the any potential future threat posed by hyperglycemia. FoH serves as a major barrier in achieving the degree of glycemic control adequate enough to prevent complications from arising (Wild, 2007). Evidence has indicated that a multipronged approach to diabetes is needed and addressing self-management skills and the topic of hypoglycemia with patients is crucial (Seaquist, 2009). The purpose of the EBP was to add to the knowledge base of translational diabetes research and provide a demonstration as to how the application of best practice strategies can be translated into real world clinical practice in an effort to improve quality of care and patient safety. The EBP provided statistical and observational data supporting the fact that individualized education reduces FoH and IoH in insulin requiring adult diabetic patients.

The purpose of this chapter is to discuss the implications for nursing practice associated with the project, identify the strengths and limitations of the project, and detail how the project was guided by the eight *Essentials of Doctoral Education for Advanced Nursing Practice* developed by the American Association of Colleges of Nursing (AACN, 2006).

Implications for Nursing Practice

Insulin requiring diabetes mellitus is a chronic disease that continues to impose substantial risks to the health and well-being of individuals, families, communities, and the healthcare system at large. Nurses are obligated to use scientific evidence and nursing knowledge to provide healthcare with respect for human dignity regardless of a patient's socioeconomic status, personal attributes, or nature of their health diagnosis (ANA, 2006). This EBP was demonstrative in showing that a chronic disease can be influenced by self-management education. It validated that the CRNP can engage in scholarly inquiry with success. A more in-depth discussion regarding the strengths, limitations, and linkage to the AACN (2006) *Essentials of Doctoral Education for Advanced Nursing Practice* reveals more specific implications of the EBP as it related to nursing practice.

Strengths of the project. This EBP provided additional information that added to nursing knowledge and diabetes translational research for the purpose of improving quality care and patient safety. An analysis of the observational data generated by the project indicated that best practice standards involving education supporting self-

management positively influenced FoH in insulin requiring diabetics despite the inability to determine an influence on IoH. The project was backed by an exhaustive literature review that summarized key evidence supporting the need and methodology of the project. Statistical analysis indicated that the ability to reject the null hypothesis allowed for the conclusion that the intervention was most likely responsible for the influence on FoH rather than sheer happenstance. This reaffirmed previous diabetes translational research demonstrating the importance of self-management education in diabetic patients. The EBP was an example of how the CRNP can identify a clinical need and translate scientific evidence from the bench to the bedside by developing an intervention to improve population health and promote patient safety in a cost effective manner. The project clearly provided a basis for organizational change and stimulated the need for additional scholarly inquiry. The sample size was considered to be of an adequate nature considering a project of this type.

Limitations of the project. The results of the project must be interpreted with caution despite the generally positive results from the observational data and statistical analysis. This observational study used a convenience sample and could not infer causality. It was more valid than reliable as no control group was utilized. Other identified limitations included: conduction of the intervention by one HCP from one clinical discipline in one specialty setting, limited experience of the PI with translational research, and a short time frame used to demonstrate the effectiveness of the intervention. Thus, evaluation of long term effects, influence on glycemic control and

improvement of long term outcomes could not be performed. The levels of evidence used to support the intervention were not considered to be substantially high as there was a lack of clinical evidence on interventions addressing FoH and IoH that were noted to improve patient outcomes. The project demonstrated a lack of cultural diversity as the large majority of patients were located in one geographical area and were of Caucasian ethnicity. Some of the participants were long term patients of the PI with the prior establishment of a provider-patient relationship; an influence from an established relationship on the project could not be fully excluded. Recall bias was also considered a significant limitation to the project as survey information was based on patient's perceptions of hypoglycemia and recollection of hypoglycemia without actual documentation. Albeit that this is how true to life clinical practice operates, it was required to be factored into the evaluation of the project for determination of project reliability.

Linkage to DNP essentials. A practice oriented doctoral program is designed to provide nurses with the skill level needed to practice using innovation, evidence, and credible research findings. The *DNP Essentials* provided the framework for the doctoral program and addressed the foundational competencies that are core to the advanced practice nurse role. Incorporation of the *DNP Essentials* into the scholarly project assured its theoretical authenticity (AACN, 2006).

Essential I: scientific underpinning for practice. It was evident within the relevant literature that insulin induced hypoglycemia and the FoH required a

psychoeducational approach to aid patients in self-management for the prevention of diabetic complications. However, a practical approach that could be utilized in daily clinical practice eluded the PI and was identified as an area that required additional translational research. This project utilized the synthesis of knowledge from multiple disciplines, an evidence based approach using scientific information and theory, and the development of an intervention in the form of a patient-centered, pedagogical tool that assisted in the translation of research from bench to bedside.

Essential II: organization and systems leadership for quality improvement and systems thinking. Diabetes care may be initiated with the forging of a relationship between the provider and the diabetic patient, however effects of this relationship extend far beyond a singular partnership to include families, communities, and healthcare systems. Chronic care management exhausts resources and places a high burden on society. This EBP was performed after assessing: the needs of the diabetic patient, the impact iatrogenic hypoglycemia has on families, the risk associated to the community, and the need for organizational changes for the improvement of population health. It focused on the development and evaluation of a practical, evidence based care approach for improvement in patient safety in a cost effective manner and served as an initial step in organizational change.

Essential III: clinical scholarship and analytical methods for evidence-based practice. This project involved an exhaustive review of the relevant clinical literature, critical appraisal of the available evidence, the development of a clinical

question, and a needs assessment. It was deemed necessary to address FoH as it serves as a major barrier in the achievement of glycemic control and does not receive the attention that it clinically deserves. The project intervention was based on up to date clinical practice guidelines. Information technology and research methods were employed for the ethical collection of data, data organization, data analysis, and data interpretation. This project extracted relevant components of BGAT for translation into real life practice to influence the FoH and IoH. The results demonstrate that this EBP was also able to identify gaps in clinical research for additional query.

Essential IV: information systems/technology and patient care technology for the improvement and transformation of health care. The use of technology to augment care management and innovation is essential. Doctoral prepared CRNPs are educated to gather information, determine appropriate use of technology, and determine the ethical application of available tools to delivery care (McGonigle and Garver-Mastrian, 2015). This project used technology from its inception to conclusion. Technology was employed in the evaluation of relevant literature, the organization of data, the development of the pedagogical tool and the data analysis. The project was designed and planned using patient care technology, information technology, and available communication systems. Computer systems, computer software programs, electronic medical records, and telephone systems were all utilized ethically and in accordance with regulatory and legal guidelines.

Essential V: health care policy for advocacy in health care. The prevention or early detection of complications associated with chronic disease is essential at an organizational and population level for the preservation of health and the conservation of valuable resources. This project demonstrated that the intervention influenced the FoH in a positive manner. This EBP is a beginning step in organizational change; but, although performed on an organizational level, its reach extends beyond the organization. Dissemination of the project information on an organizational level can stimulate changes across multiple facilities for improved quality of care and for improved health care outcomes in the diabetic population. The organizational policy change can assist in cost savings and the equitable distribution of valuable resources. Innovative interventions that reduce cost and risk while improving quality of life are valuable and cumulatively impact upon the health of our nation physically, financially, and socially.

Essential VI: interprofessional collaboration for improving patient and population health outcomes. The complexity of health care delivery requires a team approach and the skill sets of multiple disciplines. Doctors of Nursing Practice (DNPs) are prepared to serve as effective leaders and facilitators of communication. A collaborative approach is required in chronic care management. DNPs are professionally prepared to act as conductors of health care delivery and to orchestrate the interdisciplinary management of care with the patient centered in the spotlight. DNPs are not required to be expert in every field; however, DNPs are expected to know how to get expert input for care management by tapping into the expertise and literature of

other disciplines. This project involved seeking commentary from medical, nursing, physician assistant, information technology, and non-clinical personnel. It also involved research from nursing, medicine, physical therapy, education, and psychology. The fusion of multidisciplinary input was utilized to conceptualize, design, implement, and evaluate the project despite the fundamental reliance on nursing knowledge.

Essential VII: clinical prevention and population health for improving the nation's health. Prevention is key to achieving the goal of improved health and well-being of our nation's population. Using evidence based best practice standards, the DNP impacts upon the reduction of incidence, severity and development of complications associated with chronic disease. This project demonstrated how education can influence the FoH in insulin requiring diabetics. It also illuminated additional avenues for future scholarly inquiry to further the cause of diabetes management. Direct attention to the recognition, prevention, and appropriate management of hypoglycemia is encouraged in National Action Planning (HHS, 2014). This project demonstrated a move toward that national goal.

Essential VIII: advanced nursing practice.

The DNP can design, implement, and evaluate interventions while accounting for the differences in patients in a culturally sensitive manner (AANC, 2006). The DNP can skillfully identify issues in clinical practice that require scholarly inquiry for the improvement of individual and population health. The expertise attained from terminal level education in nursing advances the nursing practice into a whole new dimension.

This project was based on evidence and grounded in theory. Most importantly, this project was motivated by the principle of caring. Advanced practice nurses are particularly prepared to address the needs of the whole person, not just their disease, as the basis for advanced practice nursing is rooted in justice and compassion. Advanced practice nursing allows for the expression of love for fellow man and recognition of the frailty of the human condition. The desire to improve patient health through advanced practice nursing was the impetus for this EBP.

Conclusion

The dynamic healthcare environment demands the application of high levels of evidence combined with practice expertise. Advanced practice nursing offers a distinct perspective to healthcare delivery that is unlike any other discipline. DNPs are equipped to design interventions based on scientific evidence using the art of nursing and clinical expertise to transform knowledge. This project: was influenced by concepts from multiple disciplines, transformed research using nursing knowledge into a more practical application that was utilized in daily practice, demonstrated a positive and statistically significant influence on patient care, and stimulated the need for additional research for the improvement of patient outcomes. Despite its limitations, it demonstrated devotion to quality improvement, use of a patient-centered approach based on scientific evidence, and a compassionate commitment to patient safety.

Chapter Eight: Project Conclusion

Summary and Conclusions

Iatrogenic hypoglycemia is a serious ADE that is predominantly associated with insulin therapy. It serves a major obstacle for patients and providers in attaining the degree of glycemic control adequate enough to prevent diabetic complications from hyperglycemia. Hypoglycemia has physical, financial, safety, and psychosocial ramifications to individuals, families, communities, and healthcare systems. The population of individuals with diabetes is expected to reach astronomical proportions in the coming years and it is anticipated that the population of patients requiring insulin therapy will continue to rise as well. Currently, up to 12% of patients with diabetes use insulin therapy translating into a population of over 4 million individuals nationwide (CDC, 2013). Diabetes is a chronic disease that is predominantly self-managed. Insulin is a life-preserving or life-sustaining form of therapy that cannot be avoided. There is a lack of clinical attention to the topic of hypoglycemia in the efforts to address hyperglycemia. It has been discovered that FoH is a frequently occurring problem for a large percentage of individuals on insulin therapy. FoH is notably a huge barrier in achieving glycemic goals as the tangible effects of hypoglycemia are often more distressing to patients than the future risk of complications from hyperglycemia (Wild, 2007). There is a definitive need to address the issue through autonomy supported education, patient empowerment, shared decision making, and individualization of goals to improve quality and patient safety. Reducing the impact of hypoglycemia has been identified as a

national priority by HHS (2014). However, there is less available evidence on how to accomplish this goal indicating gaps in research. The need to combat this complex problem served as the impetus for the EBP.

The clinical question that arose was "does individualized self-management education influence the FoH and the IoH in adult patients diagnosed with insulin requiring diabetes mellitus within 4 weeks?" In order to answer this question, a thorough review of the relevant literature ensued. Multiple educational strategies were identified to address hypoglycemia. BGAT, a psychoeducational intervention, was discovered to be effective in reducing FoH in randomized clinical trials. However, implementing BGAT programs is less practical in real life and in healthcare systems with limited resources despite the noted benefits on improving care. Thus, information from BGAT regarding hypoglycemia was extracted and a pedagogical tool was developed from the extrapolated data for use in daily clinical practice in an attempt to translate research from the bench to the bedside to address FoH and IoH. The focus of the pedagogical tool was the recognition, prevention, and treatment of hypoglycemia. Preparation for project implementation included training on the protection of human subjects and University IRB approval to ensure the project met with ethical standards. It was determined that an observational study of a convenience sample would take place with retrospective data collection from the EMR. The ACE Star Model for knowledge transformation guided the process. The APN project manager applied best practice standards to all adult, insulin requiring diabetics over an allotted time frame in a single endocrinology practice setting.

Sixty participants were included in the project with 30 participants noted to have pre-intervention FoH. FoH was measured pre- and four weeks post-intervention using the FH-15 Survey and IoH was measured through patients' self-reports pre- and four weeks post- intervention. Statistical analysis of the project results indicated that the intervention did statistically influence FoH but failed to achieve statistical significance in influencing IoH in the specified population. A comparative analysis of descriptive data indicated a favorable impact from the intervention on FoH and IoH overall. Interprofessional collaboration and the use of informational technology was included from the inception of the project to its completion. The EBP was linked to the AACN's *DNP Essentials* (2006). The implementation and the results of the project added to the nursing and translational research knowledge bases while being rooted in science and caring. This patient centered EBP takes quality of care and patient safety another step closer to meeting national goals.

Dissemination Plans

The dissemination of research findings is an important method used to share information to improve quality care, improve population health, identify mistakes or pitfalls, influence policy change, reduce cost and close the gaps in research. The research finding associated with the project that is worthy of dissemination is individualized self-management education does influence the FoH in adult patients diagnosed with insulin requiring diabetes mellitus within 4 weeks. The project results have the potential to be used in an interdisciplinary fashion to stimulate practice changes or for repetition to

demonstrate reliability. The primary end users of the information include HCPs, individuals with diabetes, or individuals associated with the provision of care to individuals with diabetes. Initially, the dissemination of data will be released during the oral defense of the DNP Capstone project to a small group of nursing peers for critique. It is the intention of the PI to summarize and distribute the results on an organizational level to the physician Board of Directors, the Director of Clinical Operations, and the Director of Information Technologies. It is hoped that the project will stimulate an organizational change in how data is collected in the EMR for future evaluation demonstrating quality of care initiatives and an improved ability to track population data. Additionally, it is the anticipation of the PI that Misericordia University will provide viewing of copyrighted Capstone projects for future reference by upcoming nursing students. The CRNP will continue to distribute information to patients and their family members in the PI's individual practice setting. The possibility of posting the information on the organization's patient teaching website will not be excluded from the realm of possibilities by the PI. The PI will communicate the results of the EBP to Professor Anarte-Ortiz at the University of Malaga in Spain to assist in the translation of the FH-15 Scale internationally. Widespread distribution of the results will only be considered after future collaboration with more experienced colleagues due to the limited expertise of the PI at this time. The adoption of information by patients, the organization, and collaborators for implementation into clinical practice or to stimulate additional translational research building on this project would be considered a

measurement of dissemination success. The PI will encourage feedback from end users to further improve quality of care. An additional measurement that will be used to monitor success of data dissemination for the project is the desire of other health care providers to engage in translational research or potentially participate in the development of a randomized controlled trial for improving input into clinical practice guidelines or participating in studies investigating the topic of interest.

Future Ideas

It is the distinct intention of the PI to continue to pursue organizational change using the project results. National Action Planning (HHS, 2014) calls for improved data collection regarding the topic of hypoglycemia for prevention of ADEs and to further investigate the implications of the phenomenon. Incorporation of EMR prompts to improve recognition, prevention, and treatment of hypoglycemia will be sought. Consultation with IT personnel for data collection using identified prompts will be requested for further evaluation of the subject matter and to advance translational research.

The PI hopes that there is continued investigation regarding: the development and influence of FoH, the relationship between FoH and IoH and HbgA1C, the relationship between severity of hypoglycemia and FoH, the relationship between FoH and restoration of hypoglycemia awareness, how FoH is viewed and addressed among different HCPs who vary in discipline and health care settings, the effect of FoH on significant others, or the effect of a low FoH paired with high risk for hypoglycemia.

Conclusion

Translational research should not be conceived as applicable only to academia. It is the comingling of translational research with other knowledge sources such as research utilization, quality improvement initiatives, population data analysis, patient perspectives, and clinical expertise that makes the DNP an expert in translational science and evidence based practice (McGonigle & Garver-Mastrian, 2015). Hence, the evolution of nursing knowledge and improvement of population health outcomes depends upon DNPs advancing the profession through clinical practice using the basic skills learned in academia.

Nurses have a distinct viewpoint with which to see events and capture information in the clinical setting differently than any other professional discipline. The participation in translational research is the initial step that nurses need to take to demonstrate the insurmountable effect that the profession has on healthcare delivery. Translational research provides an avenue for DNPs to contribute to nursing knowledge and realize self-worth. This is a crucial step in in the process of solidifying the external perception of the professional identity of nurses as evidence based advanced practitioners. Nursing research is irrefutably influential in healthcare and its impact demonstrates that nursing independently holds itself to the highest professional standards thus fortifying its position as a profession worthy to share governance through accountability (Flaugher, 2009). Nurses not only investigate the scientific and medical outcomes, but also take into consideration the broader determinants of health including

the humanistic and emotional outcomes of care. Additionally, nurses evaluate the importance of information noted by other members of the healthcare team (Brown, 2010). Nursing plays a unique role in health care delivery. The evolution of healthcare requires the intellect, leadership, and compassion of nurses to build partnerships in the service of others.

References

American Association of Colleges of Nursing, (2006). The essentials of doctoral education for advanced nursing practice. Retrieved from: http://www.aacn.nche.edu/publications/position/DNPEssentials.pdf

American Diabetes Association, (2014). Standards of medical care in diabetes-2014. *Diabetes Care*, *37*(S1), S14-S155.

American Nurses Association, (2006). Position statements: risk and responsibility. Retrieved from: http://www.nursingworld.org/MainMenuCategories/Policy-Advocacy/Positions-and-Resolutions/ANAPositionStatements/Position-Statements-Alphabetically/RiskandResponsibility.pdf

Amiel, S., (2009). Hypoglycemia: from the laboratory to the clinic. *Diabetes Care*, *32*(8), 1364-1371.

Anderbro, T., Gonder-Frederick, L., Bolinder, J., Lins, P., Wredling, R., Moberg, E. ... & Johansson, U., (2014). Fear of hypoglycemia: a relationship to hypoglycemia risk and psychological factors. *Acta Diabetologica.* Retrieved from: http://www.pubfacts.com/detail/25528005/Fear-of-hypoglycemia:-relationship-to-hypoglycemic-risk-and-psychological-factors

Anarte Ortiz, M., Caballero, F., Ruiz de Adana, M., Rondan, R., Carreira, M., Dominguez-Lopez, M. ... & Soriguer, F., (2011). Development of a new fear of hypoglycemia scale: FH-15. *Psychological Assessment*, *23*(2), 398-405.

Brod, M., Christensen, T., Thomsen, T., & Bushnell, D., (2011). The impact of non-severe hypoglycemic events on work productivity and diabetes management. *Value in Health, 14*(5), 665-671.

Brown, G., (2010). A curious mind. *John Hopkins Nursing, 8*(1), 25-27. Retrieved from: http://web.jhu.edu/jhnmagazine/spring2010/features/a_curious_mind

Centers for Disease Control and Prevention, (2013). Diabetes public health resources. Retrieved from: http://www.cdc.gov/diabetes/statistics/meduse/fig1.htm

Centers for Disease Control and Prevention, (2014). National diabetes statistics report, 2014. Retrieved from: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf

Cryer, P., (2008). The barrier of hypoglycemia in diabetes. *Diabetes, 57*, 3169-3176.

Cryer, P., Axelrod, L., Grossman, A., Heller, S., Montori, V. ... & Service, F., (2009). Evaluation and management of adult hypoglycemic disorders: an endocrine society clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism, 94*(3), 709-728. Retrieved from: https://678d687f-a-e1cc97f3-s-sites.googlegroups.com/a/nckuherjournal.co.cc/nckuherclub/jiao-xue-huo-dong-1/intern-guideline/20100323GuidelineReading.pdf?attachauth=ANoY7cqn14sXqpEZsiwc_qfguEcsR6D2WajaX-TBCtmicGcunMKIEVmZGXEtmQiGHW9JAZcVPpG9UN-9v_wvsqNSr_LXzT5nQiLnL_1Ed0fBaESlmOjLZ-FjIFvCdCeYTq3E1Xrx2-tepKQqvFt5Y0r5LQVtfgb-CWs5UwOY-A_vj8YP8tp7LlQ3-

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Dalal, M., Robinson, S., & Sullivan, S., (2014). Real-world evaluation of the effects of counseling and education in diabetes management. *Diabetes Spectrum, 27*(4), 235-243.

Duckworth, W., Abraira, C., Moritz, T., Reda, D., Emanuele, N., Reaven, P. ... & Huang, G., (2008). Glucose control and vascular complications in veterans with type 2 diabetes. *The New England Journal of Medicine, 360*, 129-139. Retrieved from: http://www.nejm.org/doi/full/10.1056/NEJMoa0808431

Erol, O., & Enc, N., (2011). Hypoglycemia fear and self-efficacy of Turkish patients receiving insulin therapy. *Asian Nursing Research, 5*, 222-228.

Flaugher, M., (December 4, 2009). Ask the expert: how important is it for nurses to do research? *Staff Development Weekly: Insight on Evidence Based Practice in Education.* Retrieved from: http://www.hcpro.com/NRS-242980-975/Ask-the-expert-How-important-is-it-for-nurses-to-do-research.html

Garfield, S., Malozowski, S., Chin, M., Narayan, K., Glasgow, R., Green, L. ... & Diabetes Mellitus Interagency Coordinating Committee (DMICC) Translation Conference Working Group, (2003). *Diabetes Care, 26*(9), 2670-2674.

Gawlinski, A., & Rutledge, D., (2008). Selecting a model for evidence-based practice changes: a practical approach. *AACN Advanced Critical Care, 19*(3), 291-300.

Retrieved from: https://bblearn.misericordia.edu/webapps/blackboard/execute/content/file?cmd=view&content_id=_312153_1&course_id=_3269539_1

Gonder-Frederick, L., (2013). Fear of hypoglycemia: a review. *Diabetic Hypoglycemia*, *5*(3), 3-11. Retrieved from: http://www.hypodiab.com/article.aspx?volumeID=15&issueID=24&articleID=131

Hickey, J., & Brosnan, C., (2012). *Evaluation of healthcare quality in advanced practice nursing.* New York, New York: Springer Publishing Company

Johnson, V., (2007). Promoting behavior change: making healthy choices in wellness and healing choices in illness-use of self-determination theory in nursing practice. *Nursing Clinics of North America*, *42*, 229-241.

Khunti, K., Davies, M., Majeed, A., Thorsted, L., Wolden, M., & Paul, S., (2015). Hypoglycemia and risk of cardiovascular disease and all-cause mortality in insulin-treated people with type 1 and type 2 diabetes: a cohort study. *Diabetes Care*, *38*, 316-322.

Kimberlin, C., & Winterstein, A., (2008). Validity and reliability of measurement instruments used in research. *American Journal of Health System Pharmacy*, *65*(23), 2276-2284. Retrieved from: http://www.ajhepworth.yolasite.com/resources/9817-Reliabillity%20and%20validity.pdf

King, P., Peacock, I., & Donnelly, R., (1999). The UK prospective diabetes study (UKPDS): clinical and therapeutic implications for type 2 diabetes. *British Journal of Clinical Pharmacology*, *48*(5), 643-648. Retrieved from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2014359/

Kubiak, T., Hermanns, N., Schreckling, H., Kulzer, B., & Haak, T., (2006). Evaluation of a self-management-based patient education program for the treatment and prevention of hypoglycemia-related problems in type 1 diabetes. *Patient Education and Counseling,* 60, 228-234.

McGonigle, D., & Garver-Mastrian, K. (2015). *Nursing Informatics and the foundation of knowledge. (*3rd ed.). Burlington, MA: Jones & Bartlett Learning

Melnyk, B., & Fineout-Overholt, E., (2011). *Evidence based practice in nursing and healthcare: a guide to best practice. (2nd edition)*. China: Wolters-Kluter, Lippincott, Williams & Wilkins.

Melnyk, B., & Fineout-Overholt, E., (2015). *Evidence based practice in nursing and healthcare: a guide to best practice (3rd edition)*. China: Wolters-Kluter. Lippincott, Williams & Wilkins.

Mensik, J., Martin, D., Scott, K., & Horton, K., (2011). Development of a professional nursing framework: the journey toward nursing excellence. *The Journal of Nursing Administration*, *41*(6), 239-264. Retrieved from:

http://www.nursingcenter.com/lnc/pdfjournal?AID=1172653&an=00005110-201106000-00007&Journal_ID=&Issue_ID=

Moran, K., Burson, R., & Conrad, D., (2014). *The doctor of nursing practice scholarly project: a framework for success.* Burlington, Massachusetts: Jones & Bartlett Learning.

New York University, (2014). NYU's guide to locating the evidence. Retrieved from: http://guides.nyu.edu/content.php?pid=27011&sid=551267#1733240

Quilliam, B, Simeone, J., Ozbay, B., & Kogut, S., (2011). The incidence and costs of hypoglycemia in type 2 diabetes. *The American Journal of Managed Care, 17*(10), 673-680.

Reach, G., Zerroucki, A., Leclercq, D., & d'Ivernois, J., (2005). Adjusting insulin doses: from knowledge to decision. *Patient Education and Counseling, 56*(1), 98-103. Retrieved from: http://www.pec-journal.com/article/S0738-3991%2804%2900031-X/abstract

Robertson, P., (2012). Hypoglycemia in diabetes update. *Translational Endocrinology & Metabolism, 3*(4), 1-136.

Ryan, C., (2013). Fear of hypoglycemia: does it have any clinical utility? *Diabetic Hypoglycemia, 5*(3), 1-2. http://www.hypodiab.com/article.aspx?volumeID=15&issueID=24&articleID=132

Seaquist, E., Anderson, J., Childs, B., Cryer, P. Dagogo-Jack, S., Fish, L. ... & Vigersky, R., (2013). Hypoglycemia and diabetes: a report of a workgroup of the American

Diabetes Association and the Endocrine Society. *Journal of Clinical Endocrinology & Metabolism, 98*(5), 1845-1859.

Schachinger, H., Hegar, K., Hermanns, N., Straumann, M., Keller, U., Fehm-Wolfsdorf, G. ... & Cox, D., (2005). Randomized controlled clinical trial of blood glucose awareness training (BGAT III) in Switzerland and Germany. *Journal of Behavioral Medicine, 28* (6), 587-594.

Shichiri, M., Kishikawa, H., Ohkubo, Y., & Wake, N., (2000). Long-term results of the Kumamoto study on optimal diabetes control in type 2 diabetic patients. *Diabetes Care, 23*(S2). Retrieved from: http://journal.diabetes.org/diabetescare/FullText/Supplements/DiabetesCare/Supplement400/B21.asp

Stevens, K., (2004). ACE star model of evidence EBP: knowledge transformation. *Academic Center for Evidence based Practice, the University of Texas Health Science Center at San Antonio.* Retrieved from: http://www.acestar.uthscas.edu

Stevens, K., (2006). National consensus: competencies for evidence-based practice in nursing. Retrieved from: http://www.acestar.uthscsa.edu/media/Competencies_Methods.swf

Stevens, K., (2013). The impact of evidence-based practice in nursing and the next big ideas. *Online Journal of Issues in Nursing, 18*(2). Retrieved from: http://www.medscape.com/viewarticle/813264

The Action to Control Cardiovascular Risk in Diabetes Study Group, (2008). Effects of intensive glucose lowering in type 2 diabetes. *The New England Journal of Medicine*, *358*, 2545-2559. Retrieved from: http://www.nejm.org/doi/full/10.1056/NEJMoa0802743

The ADVANCE Collaborative Group, (2008). Intensive blood glucose control vascular outcomes in patients with type 2 diabetes. *The New England Journal of Medicine*, *358*, 2560-2572. Retrieved from: http://www.nejm.org/doi/pdf/10.1056/NEJMoa0802987

The AGREE Collaboration, (2001). Appraisal of guidelines for research and evaluation instrument. Retrieved from: http://apps.who.int/rhl/agreeinstrumentfinal.pdf

The Diabetes Control and Complications Trial Research Group, (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine*, *329*(14), 977-986. Retrieved from: http://www.nejm.org/doi/pdf/10.1056/NEJM199309303291401

The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group, (2005). Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *New England Journal of Medicine*, *353*(25), 2643-2653. Retrieved from: http://www.nejm.org/doi/pdf/10.1056/NEJMoa052187

The Endocrine Society, (2009). Evaluation and management of adult hypoglycemia disorders: an endocrine society clinical practice guideline. *Journal of Clinical Endocrinology &Metabolism, 94*(3), 709-728. Retrieved from: https://www.endocrine.org/~/media/endosociety/Files/Publications/Clinical%20Practice%20Guidelines/FINAL-Standalone-Hypo-Guideline.pdf

United States Department of Health and Human Services, (2014). National action plan for adverse drug event prevention. Retrieved from: http://www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf

United States Food and Drug Administration, (2014). Regulatory information. Retrieved from: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

Williams, G., McGregor, H. Zeldman, A., Freedman, Z., & Deci, E., (2004). Testing a self-determination theory process model for promoting glycemic control through diabetes self-management. *Health Psychology, 23*(1), 58-66.

Williams, G., McGregor, H., King, D., Nelson, C. & Glasgow, R., (2005). Variation in perceived competence, glycemic control, and patient satisfaction: relationship to autonomy support from physicians. *Patient Education and Counseling, 57*, 39-45.

Wild, D., Maltzahn, R., Brohan, E., Christensen, T., Clauson, P., & Gonder-Frederick, L., (2007). A critical review of the literature on fear of hypoglycemia in diabetes: implications for diabetes management and patient education. *Patient Education and Counseling, 68*, 10-15.

Appendix A

A Practical Guide to Recognizing, Preventing and Treating Hypoglycemia While Using Insulin

Introduction

The information that is contained within this booklet is meant to provide you some basic tips and strategies about how to recognize, prevent, and treat hypoglycemia. It is meant to help you manage your diabetes and keep you safe.

> You have the power to control your diabetes- it does not have to control you!

Diabetes

Diabetes is a medical condition in which your body does not properly use food for energy. The food we eat is broken down, changed to sugar, and released into the blood.

The pancreas, an organ in the body that is located near the stomach, makes a hormone called insulin. Insulin is responsible for taking the sugar from the blood and carrying it to the cells of the body where it is turned into energy, or fuel. A person with diabetes either does not make enough insulin or cannot use insulin the way it should causing sugar to build up in the blood. Abnormally high levels of sugar in the blood can lead to some very serious health related problems. These problems are typically referred to a diabetic complications. They include: blindness, kidney failure, painful nerve endings to the feet and hands, amputations of limbs, heart disease, liver disease, and could mean premature death.

Insulin and Diabetes

Healthy eating, routine physical activity, and taking medications by mouth can help to control diabetes. However, when a person with diabetes cannot maintain a blood sugar adequate enough to prevent diabetic complications, insulin therapy becomes a necessity. The need for insulin does not mean that a person with diabetes has "end stage diabetes" or "failed as a diabetic". The need for insulin does not mean it is your fault. The amount of insulin that a person with diabetes needs is influenced by lifestyle habits, like dietary intake and exercise, but the need for insulin means that your pancreas does not work the way that it should. It is sometimes possible for a person with diabetes to stop using insulin by changing their lifestyle; but remember, it depends on your pancreas's ability to make insulin. It is the degree to which you keep your sugar controlled that determines your risk of developing complications, not the type of medication that you use to control it!

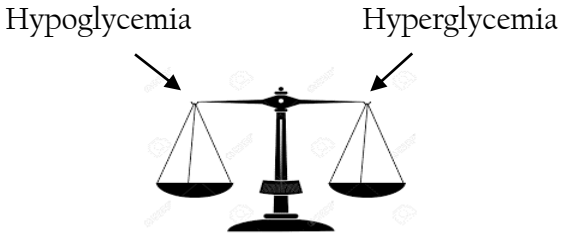
Hypoglycemia

You can ask almost any person with diabetes what one of their biggest concerns is with using insulin to control their disease and they will tell you that they worry about having a low blood sugar. A low blood sugar is called hypoglycemia. This occurs when the sugar in the blood drops below a normal level. Sugar is an important source of energy for the body. A low sugar is like a car that is running out of fuel. Hypoglycemia is a medical emergency and requires immediate attention. There is no need to panic, but treatment cannot wait!

Eating more food than the body can use at any given time causes the body to store extra sugar in the liver, the muscles, and in the fat where it can be used for energy in between meals. These stores of sugar can be used by the body initially when a low sugar

occurs. Unfortunately, however, when you are treated with insulin or other medications, it makes it much harder for the body to correct a low sugar as quickly.

It is not wrong that you are concerned about a low sugar because this is a potential risk of insulin use; but you have to come to terms that you cannot prevent a low sugar by keeping your sugar elevated either. It's all about balance!



What can a low sugar do to me?

- ✓ Weight gain
- ✓ Longer hospital stays
- ✓ Increased medical costs
- ✓ Reduction in quality of life
- ✓ Fear
- ✓ Depression
- ✓ Anxiety
- ✓ Struggle with personal relationships
- ✓ Fear of dependency
- ✓ Loss of control
- ✓ Reduction in work productivity
- ✓ Irregular heartbeat
- ✓ Seizures
- ✓ Inability to drive or operate machinery safely
- ✓ Coma
- ✓ Death
- ✓ Hypoglycemia unawareness (the absence of warning symptoms of a low sugar due to repeated exposures)

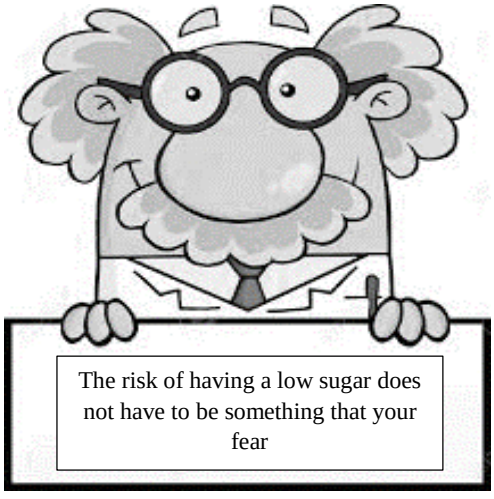
A blood sugar is usually considered to be too low if it is below 70 mg. /dl, however, not all people with diabetes feel the same with a low sugar. Some people with diabetes do not have any symptoms when their sugar is low while others may feel like their sugar is low when it is not. Therefore, a sugar may be considered too low for some when it is below 70 or when it is low enough to cause symptoms that represent a threat to safety in others. It is important that you communicate with your health care provider the range of sugars that you can physically tolerate so that they are aware of your experiences. This allows both you and your provider to come to a joint decision on a target range for your sugar that is individualized to you. This is important to protect you from diabetic complications as well as to protect you from low sugars. Knowing your personalized target sugar range will allow you to better track your progress.

My Glucose Target Range

Before meal: _____

2 Hours after Meal: _____

Bedtime: _____



Self-Blood Glucose Monitoring

Monitoring your glucose is a vital tool used by both you and your health care provider in managing your diabetes. Generally, glucose testing is done before you eat a meal and/or at bedtime. However, you should always test your sugar with any changes in your symptoms,

when starting new medication, with illness, or when changing your routine. This may involve you to test your sugar at varied times which may include 2 hours after eating or in the middle of your sleep cycle.

The importance of testing your sugar is simply to help you make better decisions. Monitoring your sugar:

- ✓ Tells you how you are responding to your individualized treatment plan
- ✓ Shows you what things in your routine influence your sugar
- ✓ Helps you adjust your treatment
- ✓ Helps you to predict high or low sugars
- ✓ Provides a useful tool to help you prevent diabetic complications
- ✓ Gives you the evidence you need to match your symptoms to your sugar

Keep in Mind

Your readings can be false if: you are using the wrong strip, you are using the wrong technique, the meter is dirty, the meter is very hot or cold, your hands are dirty or wet, or there is not enough blood on the strip.

Key Points:

- It is very easy to become frustrated with testing your sugar especially if the results are not the ones that you want to see. It is very common to sometimes feel like you are trying very hard, but your sugars do not fall within your target range. **Remember, your sugar reading is a reflection of how well your pancreas and your treatment plan are working. It is not a reflection of you as a person or the effort you are putting into your diabetes!**
- The information that you get from testing your sugar is very valuable because it is a way of giving you feedback. Feedback helps you to understand cause and effect. Using a sugar diary will help put the pieces of the puzzle together so you to make future improvements. The result of testing may not be what you wanted, but try not to get frustrated, angry, or defeated. Testing your sugar will keep you safe from harm, reinforce that you made the correct choice, or guide you to try a different way of handling a situation. Using your test results can show you areas that need improvement. The only results that will not help you are the ones you do not take!

- Invest your time in keeping a written log of your blood glucoses to help identify patterns. A repeated pattern of abnormal sugars that occur on a daily basis at the same time will alert you to the need to have your daily treatment adjusted. Sometimes there is no daily pattern when you look at your glucose log. However, labeling abnormal sugar readings in your log book with a

one word phrase will help you to remember what caused the abnormal sugar. You will start to see certain events (cause) trigger an abnormal sugar (effect) even though these events may not be happening on a daily basis. Identifying these patterns can allow you to discuss them with your health care provider to alter the treatment plan and will help you to predict future abnormal sugars. For example,

Breakfast	Lunch	Supper	Bed
114	Walk 68	Pizza 214	155
98	112	Walk 71	129
124	Walk 64	147	Pizza 231

Walking= low sugar Pizza = high sugar

Recognizing Hypoglycemia

You need to know the symptoms of hypoglycemia, or low sugars, so that you will not miss them if they happen. The longer you have diabetes, the easier it is to miss some of the symptoms of hypoglycemia. You are not to blame for that- here are some tips to help.

Keep in mind that the symptoms of a low sugar are not always related to a low sugar and the symptoms could be caused by other things; but if they are happening, it is important to test your sugar when possible to make sure you

Here is a list of the most common symptoms that occur in people who are having a low sugars.

Tremors/shaking	Argumentative	Nightmares
Sweating	Poor Coordination	Crying in sleep
Blurred Vision	Poor Concentration	Seizures
Dizziness	Anger/Irritable	Poor sleep
Weakness	Slurred speech	Damp pajamas
Fatigue	Fast Heartbeat	AM Confusion
Headache	Confusion	Unconsciousness
Hunger	Hunger	Slow reactions
Nausea/upset stomach	Anxiety	Numbness

Practice this exercise to help you become more aware of your symptoms.

Keep a daily log of your symptoms. When you believe your sugar may be starting to get too low, do a quick head to toe self-assessment of how you feel. Start with your head and end with your toes. Jot your symptoms down on your log in the appropriate column. Next, based on how you feel, guess where your sugar is at the time and write it down in the estimated column then test your sugar and write the blood sugar result in the actual column.

Sample Diary

Date	Time	Symptoms	Est.	Actual
6/1/15	5p	Headache, Nervous (this show you how to log the information)	49	41

Now, let's take a look at what you can do with the information you have collected:

1. Find every single actual low sugar in the log
2. List each individual symptom
3. List the blood sugar value that occurred with each symptom
4. Find the average by adding up all of the individual blood sugars that accompanied that particular symptom and then divide the total by the number of glucose readings.

Example after collecting information for a week.

Symptom	Average Blood Sugar
Headache	53+66+64+61+49=293 / 5= 58

In this example, headache occurred 5 times that was associated with a low sugar.

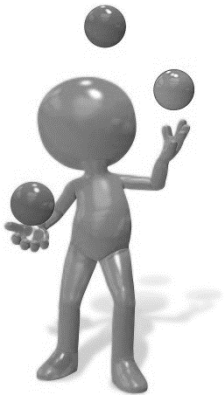
The average blood sugar associated with headache is 58.

Now:

5. List the number of times you felt that symptom when you were low under frequency
6. Find out how consistent the symptom is by dividing the frequency of the low blood sugar by the total number of low blood sugar entries on your log. This will help you to see which of your symptoms are the most reliable in helping you to recognize a low sugar.

Symptom/ Average Sugar/ Frequency/ Consistency

Headache 58 5 x 5/10= 50%



(This means that my log showed 10 low sugars in total with headache listed as a symptom 5 times out of 10; this means a headache happens 50% of the time when I am low)

Pause: Take a deep breath and look at the example below. Be patient- it will not take long to figure this out and soon enough you will be a pro! Learning to link symptoms to hypoglycemia can allow you to intervene earlier and respond to subtle clues before hypoglycemia becomes disabling.

Think Hypoglycemia!

A person experiencing hypoglycemia, or low blood sugar, commonly has difficulty in performing routine daily tasks. See if these clues will help you to identify a low sugar before it is too late.

Mental Clues

Are you having trouble?
Following directions
Making change with coins or converting money
Following a conversation
Thinking of a correct word
Reading
Concentrating
Doing simple arithmetic (count backwards from 100 by 3s)

Physical Clues

Are you having more difficulty-?
Walking quickly and turning?
Climbing stairs?
Standing up?
Bending over at the waist?
Dancing?

"I can't write a check!"	"I can't hammer a nail!"
"I can't tie my shoelace!"	"I can't flip a dime!"

Can you think of words that begin with a certain letter of the alphabet?
Can you say "Peter Piper Picked a Peck of Pickled Peppers"?

Keep your eyes open for subtle clues to a low sugar.

Am I having a hard time doing this simple task?

Am I doing this task more slowly than usual?

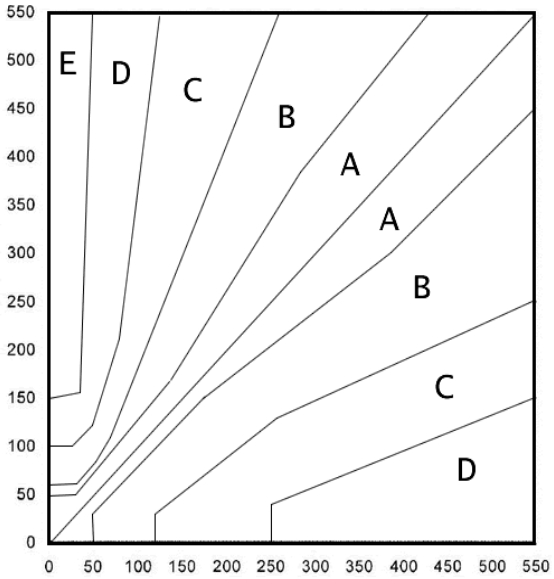
Am I making repeated mistakes?

If this is the case, you should test your sugar!

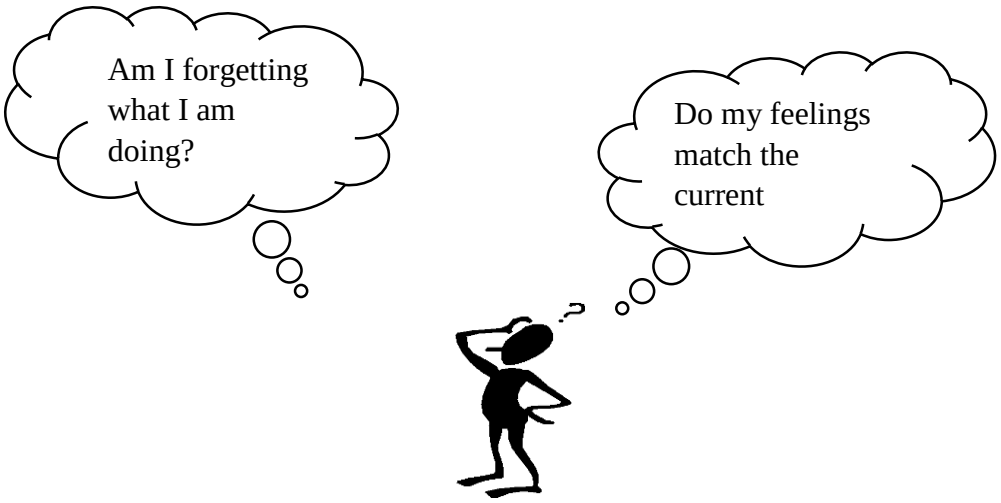
Listen to your body trying to warn you!

When feelings and emotions are stronger or weaker than usual or when family or friends tell you that you are acting or looking different-TEST.

Plot your actual sugar in one color on the left side of the grid and your estimated sugar in another color on bottom of the grid and connect the point where they intersect on the error grid



Sugars that are plotted in the C, D, or E ranges show a need to talk to your provider



Preventing Hypoglycemia

Risk Factors that trigger lows and how to deal with them

Visual problems

Know your limitations. If you have trouble seeing the dose on your insulin syringe, you need to bring this up to your provider. You may need a magnifier for your syringe, an insulin pen device, or prefilled syringes.

Memory Problems

You made need to ask for help from your provider, your family, or friends. Try an alarm on a clock or watch. Keep a written log of when you took your insulin. Try to keep a strict routine. Carry your supplies with you everywhere you go.

If you cannot remember if you already administered your insulin dose, it is advisable that you do not administer insulin so you do not take the insulin dose twice. Instead, you need to notify your provider and test your sugar more frequently over the next 4-24 hours. If you are noticing your sugar rapidly climbing, get instructions from your provider.

Taking Insulin at the Wrong Time

Taking insulin too early or too late is a common pitfall that causes low sugars. Do not fool yourself into thinking that just because you did this before you can repeatedly take a chance! Intermediate or long acting insulin does not need to be administered with a meal- but a rapid or short acting insulin meal dose must be timed around food. This ensures that your insulin will peak at the same time as your food reaches your system. If you are delaying a meal, you may need to have a small snack to prevent a low sugar and you should not take your short acting insulin until you eat. Carry your supplies- no shortcuts!

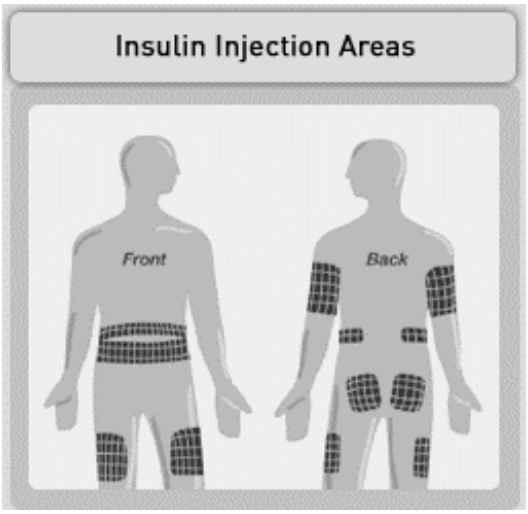
Taking the wrong insulin

This can happen to the best educated diabetics- do not panic. Immediately test your sugar so you know where you are starting from. If you took intermediate or long acting

insulin by mistake, you will need to test your sugar every 1-2 hours for the duration of the action of the insulin. If you took rapid or short acting insulin by mistake, eat a snack and test your sugar hourly for the duration of the insulin action and have another snack if the hourly sugar drops below 100. Wait to take any additional insulin until you are sure the incorrect insulin is beyond its duration of action time. Alert a loved one or friend to check on you and call your health care provider for more instruction if needed. Prevention is best- label your insulin clearly- make yourself a checklist- use different appearing devices for different insulin to tell them apart.

Scar Tissue (known as Lipohypertrophy)

The longer you have used insulin, the more likely it is that you have injected into the same general areas to administer your insulin. This can cause scar tissue underneath the skin that does not absorb insulin the right way. If you start using fresh injection sites, you might notice you have low sugars because the insulin is absorbing better. Try to make sure you do not inject into a muscle as this can trigger low sugars. Prevention is best-regularly rotate your injection sites and if you start using new injection sites, monitor more closely.



If there is any question in your mind that you are not using the right technique to monitor your sugar or take your insulin, please bring it up to your provider!

Reduction or miscalculation of food intake

This is a common trigger for low sugars. If you are starting a new diet, you may require changes in your insulin doses. Consider learning to carbohydrate count if you do not

already do so; it is important to know how carbohydrates and how the combination of carbohydrates with fats and proteins in your diet impact upon your sugar. Carbohydrates cause your sugar to rise rapidly and the effects do not last more than a couple hours; but when you combine carbohydrates with fats or proteins, your sugar may initially not spike up as high, but it may remain elevated for a longer period of time.

If you are sick to your stomach and feel like you may not be able to keep the food you are eating down without vomiting or you might not eat the amount of food that is customary for your typical insulin doses because of illness, dental problems, or scheduled tests for which you have to fast, you may need to consider waiting until immediately after the meal to take any short acting insulin to confirm you were able to consume the food; otherwise, your short acting mealtime insulin dose should be held. . You do not want your insulin peaking if you could not eat enough or vomit what you have just eaten. You should discuss a sick day plan with your health care provider as to how to adjust your insulin if this occurs.

Activity

Increased physical activity is also a common trigger for causing low sugars. The timing and type of your last meal, the timing and amount of your last insulin dose, you're blood sugar before exercise, and the intensity of the physical activity all play a role in determining your risk. The important thing is to be prepared, test before, during and after, and realize that sometimes activity can lower your sugar several hours after you have completed the exercise depending on how long or how vigorously you exercised. More prolonged activity is more likely to progressively lower your sugar than short bursts of activity, but this can be unpredictable and may be difficult to figure out.

You need to test your sugar before engaging in exercise because if you are below 100 or over 250, it is recommended that you delay your exercise. The optimal range for your sugar pre-exercise is 120-180. If you are too low prior to exercise, options include eating a carbohydrate containing snack for short duration activity or a combination of carbohydrate and protein for anticipated longer duration of activity. If you are scheduled to take short acting insulin within 2 hours of exercising, you may need to reduce the dose by 20-50% instead of consuming a larger quantity of food.

Alcohol

Alcohol use causes you to be more sensitive to insulin and it stops the liver's ability to release stored sugar into the bloodstream for up to 12-14 hours after you drink. Initially, you might say that drinking alcohol raises your sugar. This may be true for a brief period of time due to the amount of carbohydrates (sugars) that the drink

contains. However, the effects of carbohydrates only last for a 1-4 hours, but the impact of the alcohol contained within the drink lasts well after the effect of the carbohydrates. The American Diabetes Association recommends no more than 1-2 drinks in a 24 hour time period for an adult female and no more than 2-3 drinks in a 24 hour period for an adult male. It is also recommended that you eat food when you ingest alcohol, test your sugar periodically while drinking and have a small snack before you go to bed. You may need to consider a reduction in your long acting insulin if you have been drinking. Consider setting an alarm during sleep if needed to test your sugar to make sure it is not low and alerting someone you live with (if possible) to test your sugar in the middle of sleep. Try not to drink alcohol when you have been more active than usual or are eating less than usual. You must also be careful when drinking alcohol because it may mask the symptoms of a low sugar and you may not be able to tell if your sugar is low or it is the alcohol's effect you are feeling.

Delayed gastric emptying (Gastroparesis)

Years of having diabetes can sometimes result in a condition called gastroparesis. This condition slows the emptying of food from the stomach. When food leaves the stomach slower than the rate of speed that your insulin starts to peak, it can predispose you to low sugars. If you have this documented condition, you may want to talk to your health care provider about taking any short acting insulin immediately after eating rather than before to better match how food is being absorbed into the system more slowly.

Kidney or Liver Disease

The effects of insulin can last longer in people who also have kidney or liver disease. The kidneys and liver are responsible for clearing insulin out of your system; however, people with kidney or liver kidney disease have less of an ability to remove insulin from the system as quickly and the action of the insulin can last longer thus increasing the risk for a low sugar.

Weight Loss

Weight loss, whether intentional or unintentional, can increase your sensitivity to insulin and make you more prone to low sugars. If your weight has been dropping, this can trigger a need to reduce your intake of insulin.

Aging

The aging process can sometimes make you more likely to have a low sugar. An aging nervous system does not have the same ability to alert you with symptoms of low sugars like it did when you were younger. Aging also affects your muscle mass and the way

insulin and food are absorbed in the body. The goal is to keep you healthy so you continue to age, but aging can increase the risk of having a low sugar.

Other Medications or Supplements

The risk of having a low sugar is higher when you take other diabetes medications in combination with insulin. Additionally, some complementary or alternative therapies including over the counter medications can make you more prone to low sugars. These include: Cinnamon, Fenugreek, Bitter melon, Ginseng, Nopal, Aloe Vera, Banaba, Caiapo, Bilberry, or Milk Thistle. You also need to be aware that use of any prescription or over the counter products that can cause sedation or slow your heart rate may have the ability to mask symptoms of low sugars.

> By failing to prepare, you are preparing to fail-
> Benjamin Franklin

Be Prepared!

Having a quick fix treatment available to treat a low sugar is extremely important. Make up small packets or treatment bags with non-perishable items containing carbohydrates and strategically place them in an area that you can access them at all times but do not use them or allow anyone else to use them unless you are having a low sugar. Some examples include: in your car, on different floors in your home, in your desk or locker at work, or on a keychain that you carry.

Use a medic alert bracelet or necklace, shoelace tag, wallet identification card, or medical tattoo. Consider putting very pertinent data on your emergency screen of your cell phone if this is possible or consider an app for a smartphone that stores pertinent emergency data.

Ask your provider to give you a prescription for a glucagon emergency kit and makes sure that you and your loved ones know how to use it.

Alert people in close proximity to you if it is appropriate in the event of an emergency. Keep your loved ones informed of where you are traveling.

Driving, operating machinery, or completing tasks that require strict attention should not be attempted if you believe you could be experiencing a low sugar. You should immediately stop what you are doing, alert someone if possible, and eat or drink a form of sugar to correct the problem. If you are prone to unpredictable low sugars, you should

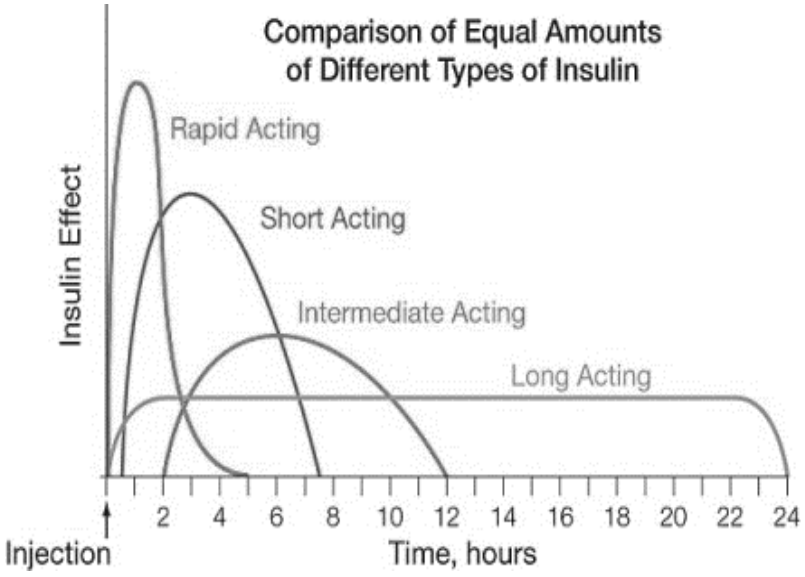
test your sugar before driving and for every 30 minutes of continuous driving to ensure your safety and the safety of the public. Severe hypoglycemia can cause you to lose your driving privileges or cause serious injury if you are attempting to operate machinery.

The Action of Insulin

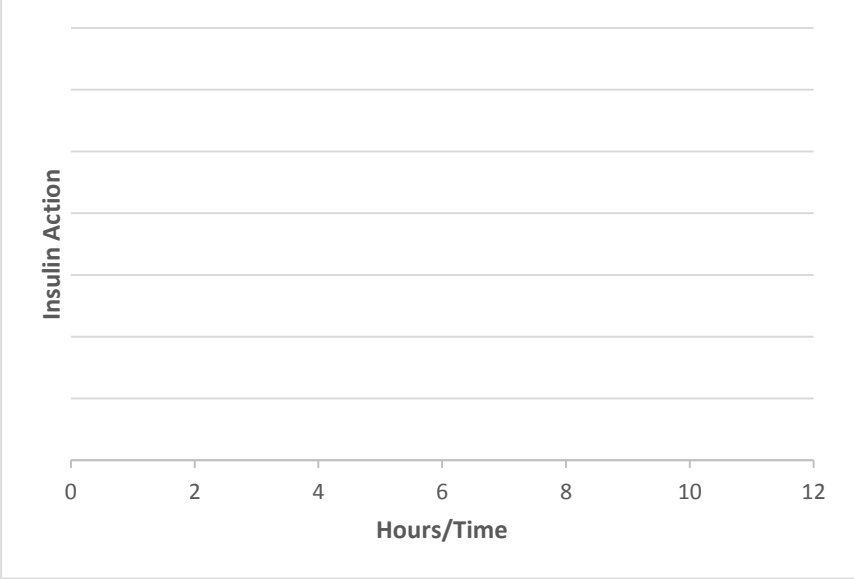
Insulin is a medication that lowers your blood sugar and substitutes for the inability of your pancreas to make enough insulin. There are many types of insulin and each act differently in the body. It is important for you to know how your insulin works. The onset of the insulin's action refers to when the insulin starts to work. The peak of the insulin's action refers to when the insulin is at its greatest potential for lowering your sugar. You are most likely to have a low sugar when your insulin is at its peak action, especially when physical activity or reduction in food intake occurs at the same time. The duration of insulin's action refers to how long the insulin works in your body.

The following chart with help you to understand how your insulin works.

Type of Action	Name	When to Take	Onset	Peak	Duration
Rapid Acting (also referred to as *bolus* or *mealtime* insulin	Humalog Novolog Apidra Afrezza	0-15 minutes before the meal	10-30 minutes	30 minutes to 3 hours	3-5 hours
Short Acting (may also be referred to as *bolus* or *mealtime* insulin)	Regular (R)	15-30 minutes before the meal	30-60 minutes	2-5 hours	Up to 12 hours
Intermediate Acting	NPH (N)	Does not need to be given with a meal	90 minutes to 4 hours	4-12 hours	Up to 12 to 24 hours
Long Acting (also referred to as *basal* or *background* insulin	Lantus Levemir Toujeo	Does not need to be given with a meal	45 minutes to 4 hours	Very little peak	Up to 24 hours



Practice plotting the time you take your insulin and calculating when your insulin will peak to help you anticipate where you may be at most risk to have a low sugar.



Users of Humalog, Novolog, Apidra, Afrezza or Regular ®

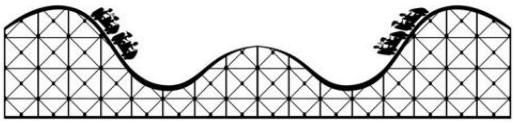
You may have been advised to take these insulins when you eat (mealtime insulin dose) or to add additional insulin units (correction insulin dose) to your usual doses if your sugar before a meal is elevated.

Mealtime insulin doses should be held if your sugar is too low until it has been corrected and retested. It should also be held in the event you are not eating a meal.

If you take doses of insulin too close together, the ending action of the previous insulin injection can overlap with the beginning action of the next insulin injection and can "stack" the effects of the insulin action on top of one another. This is known to predispose you to a low sugar when the two different insulin doses are working at the same time and is known as "stacking insulin". You may need to consider a reduction in any short acting insulin doses that follow a previous short acting insulin injection within 1-3 hours.

Users of Lantus, Levemir, Tujeo or NPH

You may have been advised to take these insulins one or two times daily, but they are not required to be administered with food. You should avoid prolonged meal skipping. If your sugar is too low at the time you are due to take the dose, correct the sugar to an acceptable range before administering the dose. This insulin should be kept on a routine schedule.



Treatment of hypoglycemia

Treating low sugars can sometimes feel like you are on a rollercoaster ride. There are a few simple tips that you need to adhere to when treating low sugars so your body can adapt.

If it is not possible to verify your sugar by testing, for safety sake, you should treat immediately anyway. However, it is better to be prepared and carry your meter so you can verify the symptoms you feel are actually a low sugar.

Remember the Rule of 15

Treat a low sugar with 15 grams of carbohydrate; wait 15 minutes; retest sugar and repeat if still low; once corrected, repeat glucose one hour after to confirm not recurrent.

Example items to treat a low sugar can include: 3-4 glucose tablets, ½ can of regular soda, 4 ounces of fruit juice, 2 tablespoons of raisins, 1 tablespoon of sugar, or 8 ounces of non-fat milk

Glucagon should be given if you are unresponsive.

Keep in mind that once you eat or drink something it will take a minimum of 10-15 minutes for your symptoms to stop and another 15 minutes before you feel better. If you continuously keep eating until your symptoms are gone, this will result in overtreatment, a high blood sugar, and can lead to weight gain.

If you are going to eat a meal within 2-3 hours of having a low sugar, immediate treatment and continued surveillance is enough, but if you are not planning on eating a meal within the next 2-3 hours after having the low sugar, you should follow up the initial treatment with a protein food source.

Try not to treat your sugar with an item that you love to eat as this sometimes leads to over-treating.

It is VERY hard use your logic rather than letting your fear of low sugar and the desire for the symptoms of a low sugar to go away as quickly as possible drive your choices; but you need to try to not to panic and follow a step by step approach to treating the low sugar. Do not over-react and do stick to one method to treat the low sugar.

Once you have treated your low sugar, try to see if you can identify the trigger that could have caused the low sugar so you may react to the situation differently in the future.

If you are taking Acarbose (Precose) or Glyset (Miglitol) in addition to insulin and you experience a low sugar, you must treat with dextrose only as the these medications may slow the rate of absorption of other types of carbohydrates.

General Rules of Thumb

Always bring a written list of ALL of your current prescribed and over the counter medications to EVERY visit with your health care provider. This may seem very annoying, especially when things do not change much, but this is a very critical part of communication that is needed as health care providers often rely on your reports of what medication you are or are not taking.

Check expiration dates of insulin, test strips, glucagon, or other supplies.

Let your provider know if you need new equipment.

Know your glucose targets.

Bring a glucose log with at least 3-5 days of recorded glucoses to your healthcare visits.

Involve your friends and family in education and treatment. They want to help and need to know how.

Protect yourself and others around you by using your common sense and testing your sugars.

Knowledge + Action = Power

Appendix B

FH-15 Scale

1. How often do you fear not recognizing the symptoms of hypoglycemia?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

2. How often are you afraid of not knowing what to do in the event of hypoglycemia?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

3. How often are you afraid of having hypoglycemia at work?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

4. How often are you afraid of having hypoglycemia outside of a hospital or health care setting?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

5. How often are you afraid of hypoglycemia while alone?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

6. How often do you avoid social situations (meetings, outings, etc.) due to fear of having a hypoglycemic episode?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

7. How often do you stop doing things you used to for fear of having a hypoglycemic episode?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

8. How often do you have hypoglycemia that makes you unable to drive or use machinery?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

9. How often do you have hypoglycemia that makes you unable to work?

   □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

10. How often do you have hypoglycemia that interferes with your leisure activities?

    □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

11. How often do you have hypoglycemia that interferes with your family life? □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

12. How often do you have hypoglycemia that interferes with your social life?

    □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

13. How often do you worry about losing consciousness due to hypoglycemia?

    □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

14. How often are you afraid of falling asleep for fear of having hypoglycemia at night?

    □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

15. How often are you afraid of taking a trip/holiday for fear of experiencing hypoglycemia?

    □ Never □ Almost Never □ Sometimes □ Almost Always □ Every Day

Appendix C

Measurement of Self-Reported Incidence of Hypoglycemia

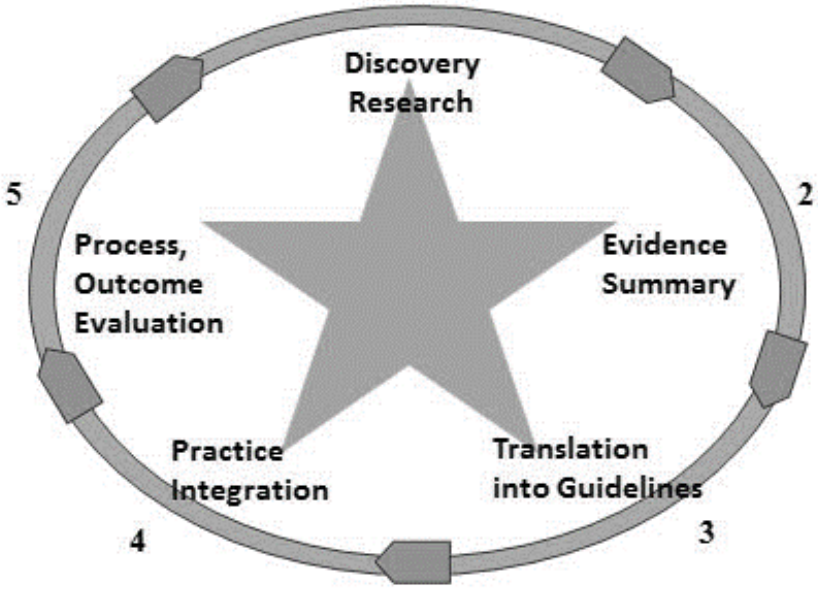
1. Estimate the number of times you have experienced hypoglycemia in the past four weeks. _____ (Pre-intervention)
2. Estimate the number of times you have experienced hypoglycemia in the past four weeks. _____ (Post-intervention)

Appendix D

Assumptions of the ACE Star Model of Knowledge Transformation for EBP
1. Knowledge transformation is necessary before it can be used in clinical decision making. 2. Knowledge is obtained from multiple sources. 3. Generalizable knowledge is discovered through the research process. 4. Evidence is hierarchically categorized according to the strength of the evidence as determined by rigor. 5. Knowledge is found in different forms. 6. Knowledge is relative to its contextual use. 7. The form of the knowledge determines its utility. 8. Knowledge is transformed by the steps of summarization, translation, integration, and evaluation (Stevens, 2004).

Appendix E

The ACE Star Model



Appendix F

Informed Consent

Informed Consent

The Retrospective Evaluation of the Effectiveness of Implementing Standard of Care Best Practices on the Improvement of Fear of Hypoglycemia (FOH) in insulin requiring diabetics

You are being asked to take part in this quality improvement project to help us evaluate the effectiveness of the care of patients with insulin requiring diabetes. Please read this form carefully and ask any questions that you have may have before agreeing to take part in this project.

What is the project about: The purpose of this project is to evaluate the effectiveness of implementing standard of care best practices in patients who need insulin therapy.

What will you be asked to do: There are no special activities you will be asked to do beyond usual care. If you agree to participate in this project, at the end of your 12 week treatment period, a retrospective chart review of your medical record will be conducted. **All information will be reported anonymously using de-identified information. No information which can be used to identify you will be used.**

Risks and benefits: Risks for participation in this project are no more than the normal risks of any standard treatment for diabetes. Benefits may include that we will be able to learn more about how to best assist diabetic patients who require insulin.

Compensation: There is no compensation for participating in this quality improvement project.

Your information will be confidential: Privacy and confidentiality of your medical information will be maintained. No identifying information will be used when reporting the outcomes of the quality improvement project.

Taking part is voluntary: Taking part in this quality improvement project is voluntary. If you decide not to take part in this study, it will not affect your current or future relationship in our practice. If you decide to take part, you are free to withdraw at any time.

IF you have questions: the investigator conducting this quality improvement project is Melissa La Porte, MSN, CRNP, DNP student. Please feel free to ask any questions you have now. If you have and questions later, you may contact Melissa La Porte at 570-270-4699 or Dr. Brenda Hage, Director of DNP Programs at Misericordia University, Dallas, PA at 570-674-6760 or at bhage@misericordia.edu If you have any questions or concerns about you rights as a participant in this project, you may contact the Misericordia Institutional Review Board Chairperson at 570-674-8108. You will be given a copy of this form for your records.

APPROVED UNTIL

AUG 15 2015

MISERICORDIA IRB

The Retrospective Evaluation of the Effectiveness of Implementing Standard of Care Best Practices on the Improvement of Fear of Hypoglycemia (FOH) in insulin requiring diabetics

Statement of Consent: I have read the above information, and have received answers to any questions I have asked. I consent to take part in this quality improvement project.

Your signature_____ Date_____

Your name (printed)_____ Date_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____ Date_____

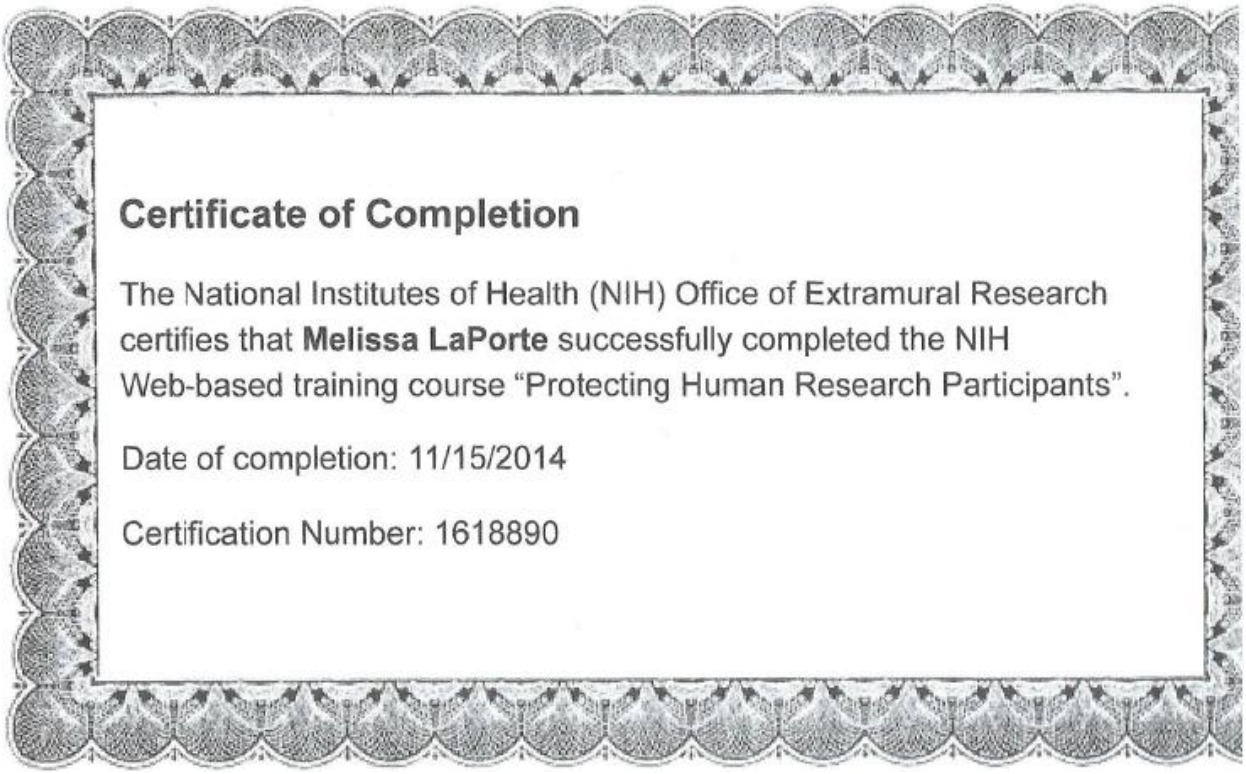
This consent form will be maintained by the researcher for at least three years beyond the end of this project.

Investigator Name (printed)_____ Date_____

Investigator's signature_____ Date_____

Appendix G

Certification of Completion of Protection of Human Subjects



Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Melissa LaPorte** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 11/15/2014

Certification Number: 1618890

Appendix H

Letter of IRB Approval

Institutional Review Board

MISERICORDIA
UNIVERSITY

May 13, 2015

Melissa LaPorte, MSN
Brenda Hage, Ph.D.
Nursing Department
Misericordia University
Dallas, PA 18612

Dear Ms. LaPorte and Dr. Hage:

Thank you for submitting the modifications to your IRB application, *The Retrospective Evaluation of the Effectiveness of Implementing Standard of Care Best Practices on the Improvement of Fear of Hypoglycemia (FOH) in Insulin Requiring Diabetics,* number 10-15-T1. Your study is now approved by the IRB.

As part of the approval, the IRB has received and accepted the consent form as submitted. The attached consent form with a valid period of eligibility is the only consent form to be used. Any modifications must be approved by the IRB. The date stamp indicates the eligible period.

You will be reminded one month prior from the expiration date of your research protocol to complete an End-of-Project Report. You also have the responsibility to notify the IRB of any changes in the conduct of this study or injury to study subjects and to retain all approved application documents and signed consent forms for a minimum of three years following completion of the study (this includes student research). Please refer to the IRB Policies and Procedures document for specific details on what is expected.

If you have any questions, please feel free to contact me.

Sincerely,

M. Manasco

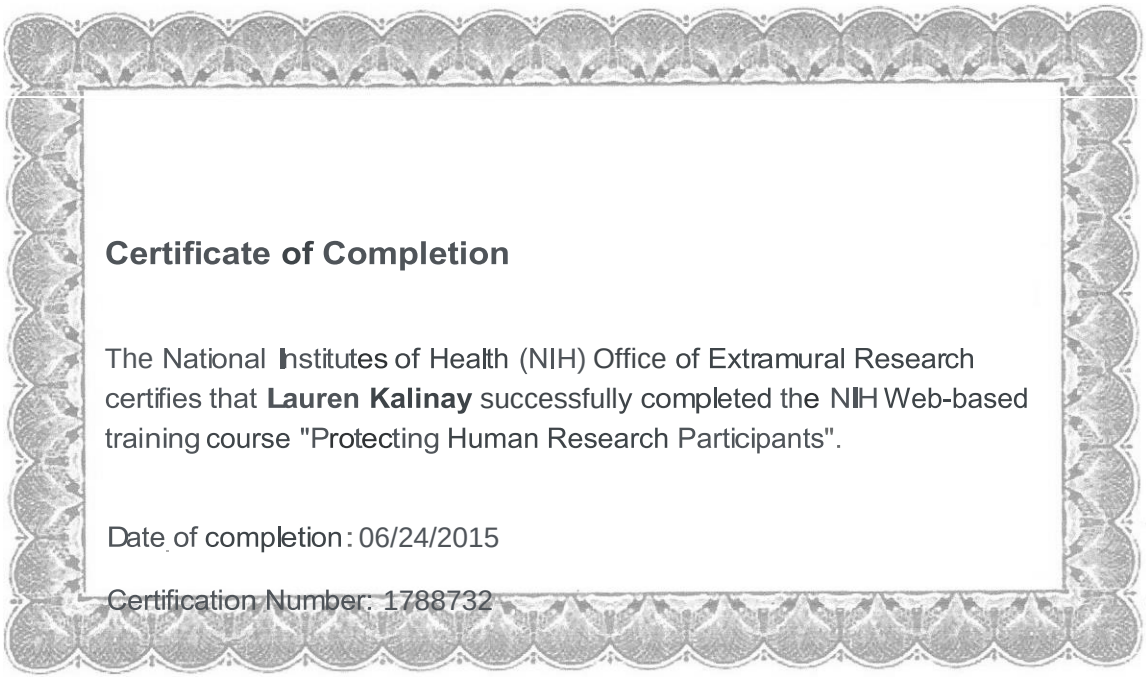
McKinley H. Manasco, Ph.D.
Chairperson, IRB

Misericordia University Dallas, PA 18612-1090 *Founded by the Sisters of Mercy*
Tel: 570-674-1483 Toll free: 866-262-6363 Fax: 570-674-3364 Web: www.misericordia.edu

Appendix I

LPN Assistant to Project Investigator Certification of Completion

Protecting Human Subject Research Participants



Certificate of Completion

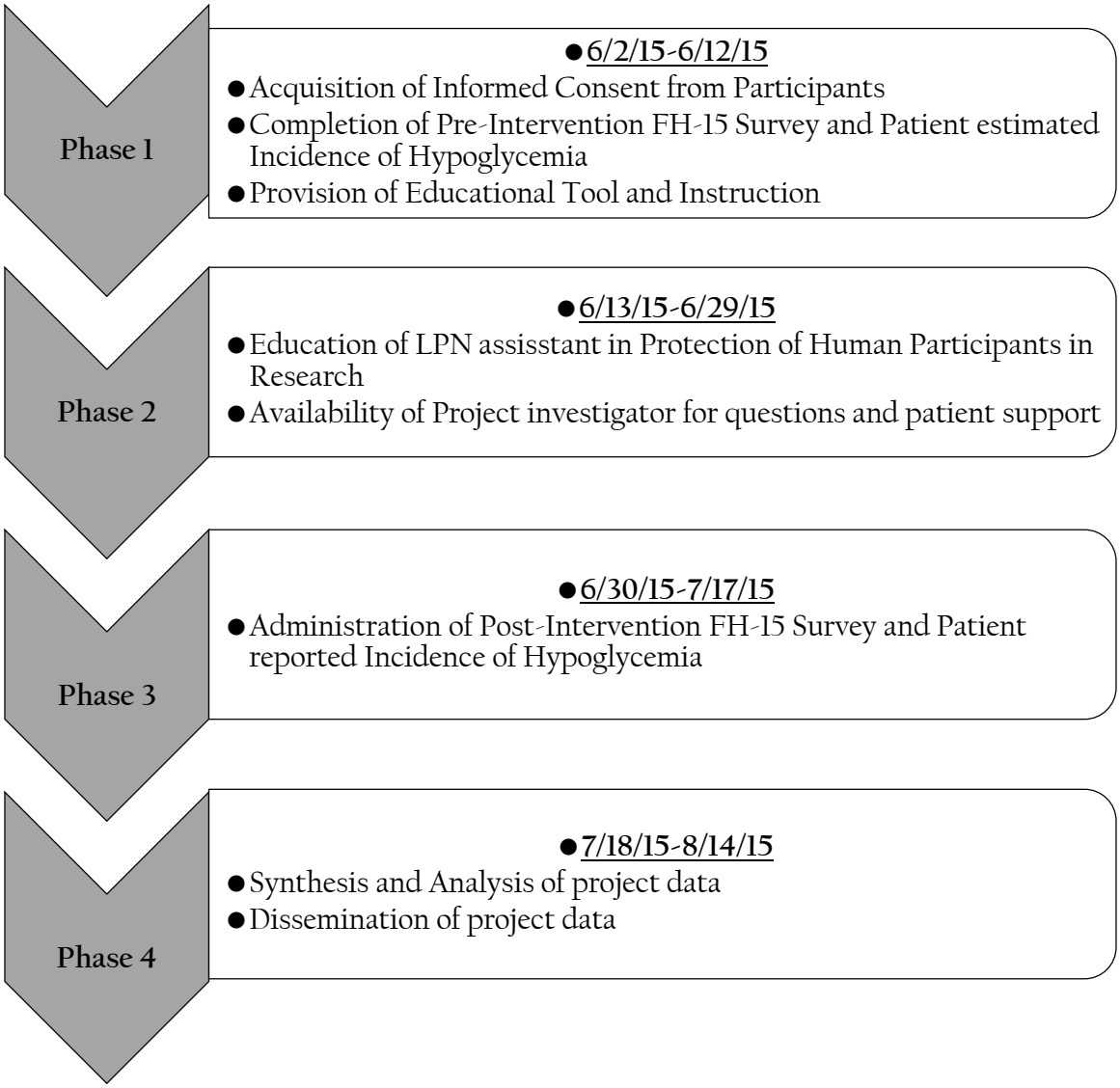
The National Institutes of Health (NIH) Office of Extramural Research certifies that **Lauren Kalinay** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 06/24/2015

Certification Number: 1788732

Appendix J

Project Implementation Timeline



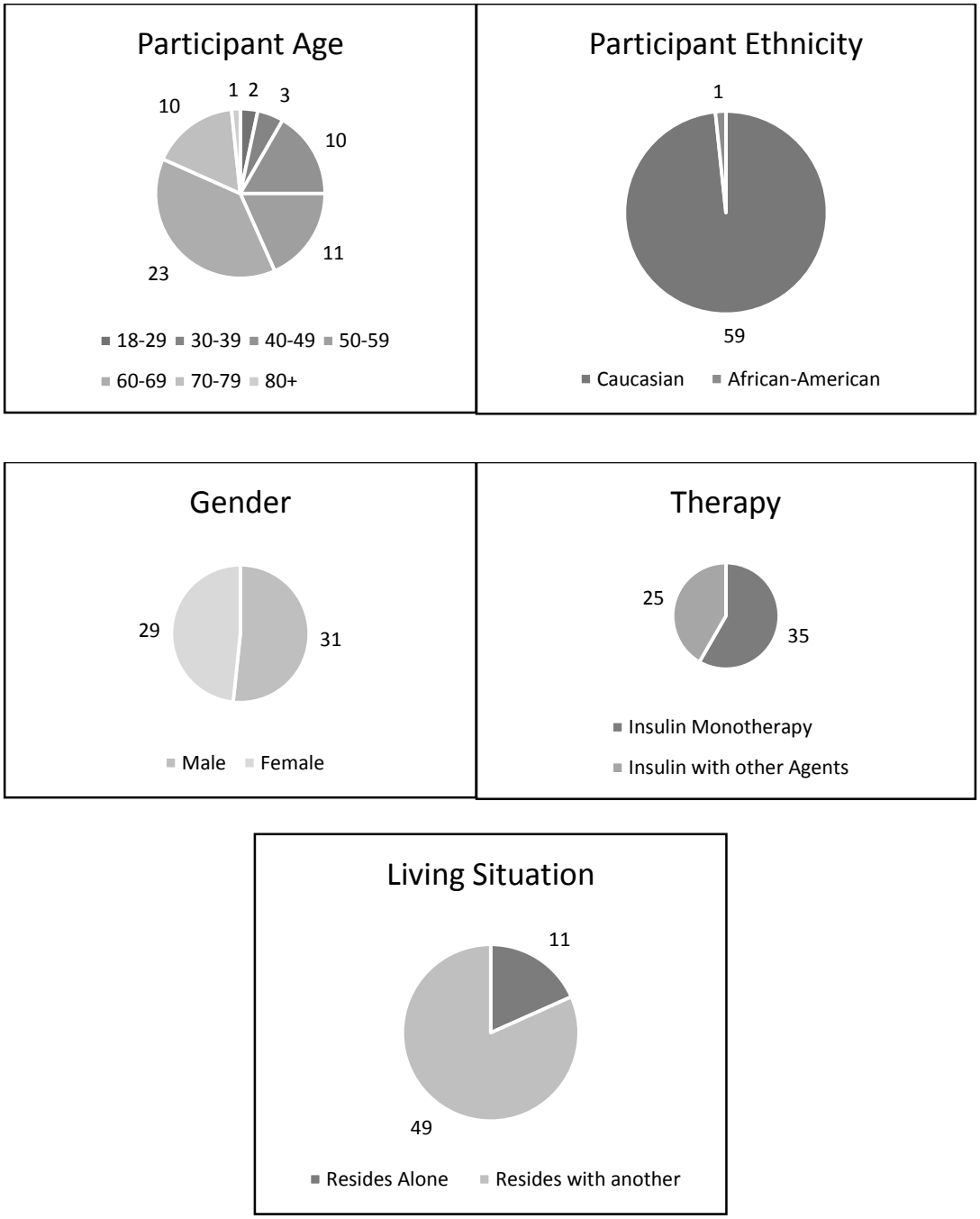
Appendix K

Data Table

Absence of FoH												Thematic Comments
Presence of FoH Pre-Intervention												0= No Comments
Development of FoH Post-Intervention												1= Assisted in Self-Management
												2= Increased Self-Management Behaviors
Participant #	Age	Ethnicity	Gender	Therapy	Living Situation	Pre-Intervention FH-15 Score	Post-Intervention FH-15 Score	paired diff FH 15 score	Pre-Intervention IoH	Post-Intervention IoH	paired diff IOH Score	Thematic Comments
1	60-69	C	M	I	vr/other	37	17	20	3	0	1.5	1 & 2
2	60-69	C	F	I	vr/other	43	43	0	4	4	4	0
3	70-79	C	F	I+	vr/other	15	15	0	3	1	2	0
4	70-79	C	M	I	vr/other	18	15	3	0	1	0.5	0
5	60-69	C	M	I+	vr/other	49	38	11	6	4	5	0
6	50-59	C	F	I	alone	33	31	2	15	20	17.5	1
7	50-59	C	F	I	vr/other	20	15	5	1	30	15.5	1 & 2
8	30-39	C	F	I	vr/other	59	54	5	20	6	13	1 & 2
9	60-69	C	M	I+	vr/other	20	21	-1	0	0	0	0
11	60-69	C	M	I	vr/other	20	20	0	9	0	4.5	1
12	60-69	C	F	I	vr/other	36	48	-12	5	12	8.5	1 & 2
13	60-69	C	M	I	vr/other	15	15	0	0	0	0	0
14	40-49	C	F	I	vr/other	39	27	12	20	8	14	1
16	50-59	C	M	I+	vr/other	27	23	4	2	1	1.5	0
17	50-59	C	M	I	alone	31	18	13	16	9	12.5	1 & 2
18	60-69	C	F	I+	vr/other	26	21	5	1	0	0.5	1
19	80+	C	M	I	alone	29	15	14	2	2	2	1
22	60-69	C	F	I+	vr/other	35	30	5	0	0	0	1
24	40-49	C	F	I	vr/other	20	21	-1	3	3	3	0
25	30-39	C	M	I	vr/other	33	28	5	10	9	9.5	1
28	50-59	C	M	I+	vr/other	20	22	-2	0	0	0	1
29	40-49	C	F	I	vr/other	29	30	-1	4	6	5	1
30	60-69	C	M	I+	vr/other	18	19	-1	0	0	0	1
32	60-69	C	F	I	alone	37	33	4	3	2	2.5	1
33	40-49	C	F	I+	vr/other	17	21	-4	0	2	1	0
34	60-69	C	M	I	vr/other	34	27	7	1	2	1.5	1
35	70-79	C	M	I	vr/other	27	32	-5	1	2	1.5	1
36	40-49	C	F	I	vr/other	43	37	6	7	3	5	0
37	60-69	C	F	I+	vr/other	21	19	2	1	0	0.5	1
38	60-69	C	M	I+	alone	17	20	-3	2	1	1.5	1
39	40-49	C	F	I	vr/other	50	36	14	8	5	6.5	1
40	50-59	C	F	I	vr/other	28	20	8	0	2	1	1
42	60-69	C	M	I+	vr/other	39	31	8	0	0	0	1
43	18-29	C	F	I	alone	20	17	3	3	2	2.5	1
44	60-69	C	M	I+	vr/other	16	18	-2	0	0	0	0
46	50-59	C	M	I+	vr/other	28	15	13	0	0	0	1
47	50-59	C	M	I	vr/other	26	25	1	2	2	2	1
49	60-69	C	M	I+	vr/other	31	31	0	6	3	4.5	1
50	60-69	C	M	I+	vr/other	17	24	-7	1	1	1	1
52	70-79	C	F	I	vr/other	34	29	5	2	5	3.5	0
53	70-79	C	M	I+	alone	28	19	9	3	4	3.5	0
55	40-49	C	F	I	vr/other	30	36	-6	8	1	4.5	0
56	70-79	C	M	I+	vr/other	17	20	-3	1	0	0.5	0
57	60-69	C	F	I	vr/other	17	19	-2	1	4	2.5	0
58	40-49	C	F	I	vr/other	30	19	11	2	5	3.5	1
59	18-29	C	M	I+	vr/other	16	15	1	0	0	0	1
60	70-79	C	F	I	vr/other	32	21	11	1	2	1.5	1
61	70-79	C	F	I	vr/other	22	35	-13	1	2	1.5	1 & 2
62	60-69	C	F	I+	alone	16	15	1	0	0	0	1
64	60-69	C	F	I	vr/other	31	24	7	2	2	2	1
65	50-59	C	M	I+	vr/other	22	19	3	1	0	0.5	1
66	30-39	C	F	I	vr/other	33	21	12	1	0	0.5	1
67	70-79	C	M	I+	alone	16	16	0	0	0	0	0
68	50-59	C	F	I+	vr/other	20	21	-1	4	2	3	0
69	40-49	C	M	I	vr/other	25	21	4	6	2	4	0
70	40-49	C	M	I	alone	68	65	3	35	30	32.5	1
71	60-69	C	M	I+	alone	30	24	6	1	0	0.5	1
72	60-69	C	M	I+	vr/other	20	15	5	0	0	0	1
73	70-79	C	F	I	vr/other	16	15	1	0	0	0	1
75	50-59	Af. Am.	M	I	vr/other	31	41	-10	0	0	0	1

Appendix L

Population Demographics



Appendix M

Population Descriptive Statistics