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Improving Hypoglycemia Protocol Compliance through Nursing Education

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Dedication

This project is dedicated to the memory of my father, Francis Onyatta. I hope I was able to make you proud even if you never had an opportunity to witness my success. Rest in peace.

Acknowledgment

I want to acknowledge the faculty at Jacksonville State University that has supported me through this process. I want to thank Dr. Gulledge for her expertise in reviewing and guiding me with my project. I would not have made it this far without her pushing me to grow and expand myself as a doctoral-prepared nurse. I want to thank Dr. Keith for her compassionate and caring mentorship throughout the program. I want to thank my family for this journey. I thank my husband James, who has provided me unconditional support through my struggles and especially during the Doctor of Nursing Practice program. I thank my wonderful Doctor of nursing classmates; they have been my greatest cheerleaders!

Without the support of the faculty at Jacksonville State University, my family, and DCH regional medical center administration and staff, this project would not have been possible.

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Abstract

Nurses hold a vital role in glucose management in order to ensure safety and quality outcome for hospitalized patients. Background: Assessing serum and point of care glucose results and bringing abnormal results to the attention of the healthcare team can help maintain optimal management. Despite challenges to hypoglycemic protocol compliance, informed nurses can advocate effectively for their patients. Understanding insulin action and the effective use of evidence-based guidelines/protocols can help nurses promote optimal patient outcomes. Common barriers to glucose control and education of current best practices in the acute care setting were reviewed. Purpose**:** To improve hypoglycemic protocol compliance through education in the acute care setting. To achieve Healthy People 2020 goals of reducing the disease and economic burden of diabetes and improving the quality of life for all persons with diabetes. Design methods: A retrospective chart review of hypoglycemic episodes analyzing the nursing behavior in rechecking blood sugars per hospital protocol and education implementation to improve hypoglycemic management protocol compliance. Conclusion: N=13. Thirteen registered nurses participated in the hypoglycemia protocol compliance training and pre-survey. A two-sample t-test was used at the end of the implementation to determine statistical significance between pre-survey and post-survey mean scores. Compliance with Hypoglycemia Protocol is a quality measure at this healthcare system. Improving the nursing staff's compliance with hypoglycemia protocol is likely to decrease cost, length of stay, improve patient quality of care and prevent avoidable deaths.

Keywords: Hypoglycemic protocol, quality improvement, compliance, education, glucose management.

Improving Hypoglycemia Protocol Compliance through Nursing Education

Introduction

According to the American Diabetes Association (ADA) (2016), early recognition and treatment of mild to moderate hypoglycemia (40–69 mg/dL) can prevent deterioration to a more severe episode with potential adverse sequelae. The protocol requires treatment either with dextrose or glucagon depending on the patient's level of consciousness and rechecking the blood sugar until at 80 mg/dL. However, rechecking blood glucose 15 minutes after treatment for hypoglycemia, as outlined in the protocol, has been challenging for nursing staff. The majority of the adult diabetic patients are on glucagon and dextrose to treat hypoglycemic episodes. With the nursing staff not following the protocol, data reveals consistent low blood sugars in the morning, requiring more interventions, extra cost, and increased length of stay. Education was provided through the online learning system, and hypoglycemia badge reference cards issued to reinforce the protocol compliance, which has remained low. The nursing staff were educated that hypoglycemia treatment takes several minutes, therefore recheck should occur at 15–30 minutes from the time hypoglycemia identification is noted. The use of timers to remind nursing staff to perform the recheck were incorporated in education (Destree, Vercellino, & Armstrong, 2017).

Background

The Centers for Disease Control and Prevention (CDC) report that the rate of new diabetes diagnoses remains steady. However, the disease continues to represent a growing health problem as the seventh leading cause of death in the United States (U.S.) based on 79, 535 death certificates in 2015 (CDC,2018). Diabetes is a chronic disease that can often be managed through physical activity, diet, and the appropriate use of insulin and other medications to control blood

sugar levels. People with uncontrolled blood sugar are at increased risk of extreme health complications, including premature death, vision loss, heart disease, stroke, kidney failure, and amputation (CDC, 2018). In 2014, a total of 14.2 million emergency department visits were reported with diabetes among adults aged 18 years or older, 245,000 for hypoglycemia and 207,000 for hyperglycemic crisis (CDC, 2017). Over the last 17 years, the number of people diagnosed with diabetes in the United States has more than doubled, reaching 23.7 million in 2017. Due to complications associated with diabetes such as heart disease, kidney failure, and blindness, diabetes costs the United States healthcare system and employer 237 billion dollars every year (American Diabetic Association, 2017).

The clinical goal in the treatment of diabetes is to achieve reasonable glycemic control (Ornstein, 2018). Tight glycemic control achieved with intensive glucose lowering therapy reduces the risk of long-term micro- and macro-vascular complications of diabetes, resulting in an improvement in quality-of-life for the patient and decreased healthcare costs. The positive impact of reasonable glycemic control is, however, counterbalanced by the negative effect of an increased incidence of hypoglycemia (Freeland, 2016). In people with type 1 or type 2 diabetes, hypoglycemia is associated with a reduction in quality-of-life, increased fear and anxiety, reduced productivity and increased healthcare costs. Fear of hypoglycemia may promote compensatory behaviors to avoid hypoglycemia, such as decreased insulin doses, resulting in poor glycemic control and an increased risk of severe health consequences (Adolfsson, Rentoul, Klinkenbijl, & Parkin, 2018).

Problem Statement

Hypoglycemia is detrimental to patient safety, posing both short- and long-term dangers. There is increasing evidence that episodes of hypoglycemia also can cause long-term

effects. Several studies have demonstrated a relationship between inpatient hypoglycemic episodes and patients' length of stay, 1-year post-discharge mortality, and dementia rates (Akirov, Grossman, Shochat, & Shimon, 2016). The total cost of treating diabetes and its complications is costly, of which $174 billion is as a result of direct and indirect medical care, approximately over $ 200 billion (ADA, 2016). The evidence-based hypoglycemia protocol and treatment were developed to provide safe and effective management of hypoglycemia throughout the hospital and to support organizational goals to achieve blood glucose control (Destree, Vercellino, & Armstrong, 2017). Lack of compliance with the hypoglycemic protocol presents a question, In nursing staff, how does education improve hypoglycemia protocol compliance on an acute care unit compared to no education in a 90-day time period? Lack of structured disease management protocol compliance, lack of education, competency, and leadership support in accountability will result in poor patient outcomes. The study shows that regular education, supervision, team meetings, and shared vision are crucial factors to increase adherence to treatment protocols (Bruijniks, Franx, & Huibers, 2018). The aim for this quality improvement project was to improve compliance with hypoglycemic protocol through education.

Organizational Description of Project Site

The setting of the project was held in a rural hospital located in Tuscaloosa, Alabama. The project focused on one acute care unit, which comprised of thirteen registered nurses and fifteen patient care assistants. This unit admits mostly patients with chronic conditions such as diabetes and renal failure. Through chart review and staffing rotation, challenges to following diabetic management protocols were noted. Most of the nurses' complaints were related to lack of knowledge on types of insulins and the impact of hypoglycemia on patient outcome. The unit has been without a manager for over six months, therefore, lacking leadership support and

accountability. Due to high staff turnover, half of the nursing staff have less than one year experience in on the unit. The transition to quality and safety in the new graduate registered nurses' practice remains problematic, directly impacting patient outcomes. Effective mentoring during the transition from new nurses to experts empowers these nurses on the "knowing how," allowing the development and establishment of safe, quality nursing practice (Murray, Sundin, & Cope, 2019). The plan for this setting was education on general information specific to diabetes, types of insulin, the importance of clinical protocols, and their impact on patient safety and quality outcomes.

Review of the Literature

According to Destree, Vercellino, & Armstrong (2017), evidence-based hypoglycemia protocol and a treatment algorithm was developed to provide safe and effective management of hypoglycemia throughout the hospital and to support organizational goals to achieve blood glucose control. Destree et al. 2017 emphasizes the critical element of all hypoglycemia management protocols is to treat the patient with 15–20 g of glucose and to follow with a recheck of the blood glucose level 15 minutes later, sometimes called the "15-15 rule" or the "Rule of 15". If the patient is still hypoglycemic after 15 minutes, the process is repeated. The recheck is a crucial step to treating the unresolved hypoglycemia to ensure patient safety and prevent recurrent episodes. Protocols are essential to driving the highest quality care and best outcomes in practice. Ornstein 2018 noted the same vital functions of protocols: Protocols are imperative to drive better quality care and outcomes in clinical practice.

The literature indicates that adherence to existing guidelines and protocols to treat hypoglycemia is poor (Akirov, Grossman, Shochat, & Shimon, 2016). Evidence review by Adolfsson, Rentoul, Klinkenbijl, & Parkin, 2018 reveals that hypoglycemia remains a significant

health concern and a primary obstacle to optimal adherence to prescribed diabetes treatment. In addition to its adverse clinical consequences, hypoglycemia negatively impacts the quality of life and places additional financial burden on patients, patient families, employers, and healthcare payers. Bruijniks, Franx, & Huibers, 2018 conclude that education, regular supervision, team meetings, and a shared vision were identified as crucial factors to increase adherence to treatment protocols. Additional organizational factors to protocol adherence, among which includes a change of mindset, may facilitate adequate protocol implementation. Murray, Sundin, & Cope, 2019 shows the transition to quality and safety in the new graduate registered nurses' practice remains problematic, directly impacting patient outcomes. Effective mentoring during transition serves to enhance experiential learning, allowing the development and establishment of safe and quality care**.** According to Durks, Fernandez-Llimos, Hossain, Franco-Trigo, Benrimoj, & Sabater-Hernández, 2017 change in healthcare professional practice requires exhaustive planning for it to be successful and sustainable. Icek Ajzen in 1985 states that human behavior is guided by behavioral beliefs, strength and motivation to comply(normative), and control beliefs (strength and perceived power). Agency of Healthcare Research and Quality (AHRQ) 2018 emphasize that engaging primary care practices in quality improvement (QI) activities is essential in improving the health of the population, patient experiences and outcomes, and reducing the per capita cost of care.

Theoretical Framework

Change in healthcare professional practice requires exhaustive planning to increase the probabilities that are successfully and sustainably implemented (Durks, Fernandez-Llimos, Hossain, Franco-Trigo, Benrimoj, & Sabater-Hernández, 2017). The theory of planned behavior (TPB) with permission was incorporated onto providing a framework for this quality

improvement project (see Appendix A & B). The theory which was initiated by Icek Ajzen in 1985 stating that human behavior is guided by behavioral beliefs (beliefs strength and outcome evaluations), normative beliefs (strength and motivation to comply), and control beliefs (strength and perceived power) (Ajzen, 1991). Specifically, the theory is comprised of three components: (1) attitude towards the behavior, (2) subjective norm, and (3) perceived behavioral control. These three components are used to predict an individual's behavioral intention to perform a given behavior. The TPB model appears a particularly suitable foundation for the healthcare interventions as it includes attitudes and environmental variables (Ajzen, 1991).

Intentions are the proximal determinant of behavior and reflect one's motivation to perform a given behavior emphasizing in three factors: attitudes, subjective norms and perceived behavioral control. Attitudes can be defined as the overall positive or negative evaluation of the target behavior and has both an affective (e.g., enjoyable vs. unenjoyable) and instrumental (e.g., beneficial vs. harmful) component. Subjective norms also consist of two related components. A descriptive norm is an individual's perception of how often important others (e.g., coworkers and team leaders) display a given behavior; whereas an injunctive norm represents an individual's perception of how much others want one to perform a given behavior. Finally, perceived behavioral control is one's perception of one's ability to perform a given behavior in line with intentions (Ajzen, 1991). The framework was utilized to examine barriers to following hypoglycemia protocol guidelines and the development of intervention that were to positively influence the compliance and patient outcome.

The TPB model emphasizes the roles played by knowledge regarding necessary skills for performing the behavior, environmental factors, and experience with the behavior. According to the TPB, the nursing staff are likely to follow the hypoglycemia protocol if they believe that the

behavior will lead to positive patient outcomes which they value, if they believe that people whose views they value (leaders and fellow coworkers) think they should carry out the behavior, and if they feel that they have the necessary resources, knowledge and opportunities to perform the behavior (Ajzen, 1991). The implications of the model on nursing education are to consider attitudes and reinforcing the importance of the target behavior and address barriers, developing strategies for improving control over environmental factors such as time constraints and staffing shortage issues and social environment and influences.

Goals, Objectives and Expected Outcomes

According to Agency of Healthcare Research and Quality (AHRQ) 2018, engaging primary care practices in quality improvement (QI) activities is essential to achieving the triple aim of improving the health of the population, enhancing patient experiences and outcomes, and reducing the per capita cost of care, and enhancing provider experience. The objective of this quality improvement project assessed for barriers between hypoglycemia management guidelines and nursing staff practices, provided education intervention to address these barriers, with a goal of improving compliance and patient outcomes. The main goal of the project was to empower the nursing staff with a three month education on diabetes disease process, promote hypoglycemic protocol compliance, and to address the impact of not adhering to the guidelines on patient quality and safety. The primary aim of the project was to improve hypoglycemia protocol compliance in nursing staff receiving education interventions. The outcome was that the nursing staff will have an increase in hypoglycemic protocol adherence after a 90 days education intervention.

Project Design

The objective of this quality improvement project was to identify the gaps between evidence-based hypoglycemic protocol and nursing practices, provide education to address the gaps and impact patient outcome. The improvement project utilized the Theory of Planned Behavior (TPB) model in assessing behavior compliance to hypoglycemia protocol in an acute care unit.

Project Site and Population

The city of Tuscaloosa, Alabama is located along the banks of the Black Warrior River in west-central Alabama. According to the United States Bureau, Tuscaloosa's population has grown 12% from 90,550 in 2010 to 101,113 in 2018. In 2017, Tuscaloosa had a population of 97, 400 with a median age of 28.6 and a median household income of $42,428. The population of Tuscaloosa is 49.5% Caucasian, 44.1% Black or African American, and 2.6% Hispanic or Latino. Seven percent of the people in Tuscaloosa speak a non-English language, and 96.5% are U.S. citizens (U.S. Census Bureau Report, 2018).

The local hospital system consists of six acute care units. Direct patient care nursing staff at the local hospital consist of registered nurses both baccalaureate and associate degree prepared and patient care technicians. The hospital utilizes very few travelling staff in acute care unit, float pool staffing and no licensed practical nurses. The nursing staff works either an eight-hour shift or a twelve-hour shift but with due to nursing staff shortage, some staff may work four hours extra per shift. The population of interest for this project involved voluntary nursing staff in one of the acute care unit that manages chronic conditions. The nursing staff that chose to participate were informed that the project was voluntary and their rights to opt out at any time. In the acute care unit, the facility offers care of patients with diabetes, congestive heart failure, coronary heart disease, kidney failure (dialysis), and chronic obstructive pulmonary diseases.

The quality improvement project was made available to all eligible nursing staff in acute care unit. The project's impact depended upon getting the stakeholder support in identifying the barriers, cultural change and attitude change in following the hypoglycemia protocol. The DNP student met with the director of acute care units, the director of quality, laboratory director, diabetic educators and the director of nursing operations for support in participation, implementation process, dissemination and sustainability of the project. The DNP student attended the acute care staff meeting to introduce the project to the staff prior to implementation. The DNP student made rounds on the unit prior to the beginning of the project to encourage participation.

Setting facilitators and barriers

The DNP student met with the above name leaders in addition to the unit team leaders. The unit initially did not have a manager thus lack of direct leadership support to encourage the nursing staff in project participation and overseeing the project implementation process. This problem was solved by involving the unit team leaders and the acute care director who were managing the unit. The unit was staffed with travelling nurses who float from one campus to the other and works on an eight to thirteen-week contract. The travelling nurses were rounded more frequently and encouraged to participate in the project before the end of their contract.

Implementation Plan/Procedures

Measurement Instruments

In order to measure the outcomes of this DNP project in compliance with hypoglycemia treatment guidelines, the facility's quality director assisted the DNP student in conducting an active surveillance identify gaps between hypoglycemia protocol and practice. The surveillance data were initiated before the DNP student set up the goals and at the end of the implementation

for comparison to the baseline. The student created a modified pre and post survey tool, "Attitudes Regarding Practice Guidelines," adapted from previous work by Elaine Larson, 2004 with permission to examine barriers to adherence to practice guidelines. The survey focused on the current knowledge, attitudes and beliefs related to hypoglycemia protocol and compliance. The information gathered from the pre and post surveys were compared using the Wilcoxon signed rank statistical text. The pre and post knowledge, beliefs and attitudes surveys were made available through Mind lab, the facility's education learning system. The intervention consisted of nursing staff training, dissemination of hypoglycemia protocol handouts, and PowerPoint presentations on diabetes overview delivered by the DNP student.

Data Collection Procedures

Eligibility to participate in the project included employment with the facility, working a minimum of twenty hours per pay period, and providing direct patient care. Pre-intervention of the project were conducted to identity the nursing staff's beliefs through a survey addressing common knowledge, attitudes and beliefs associated to the implementation and compliance of hypoglycemia practice protocol. The participants were asked to grade each question on a Likert scale of 0-5, 0 meaning strongly disagree to 5 meaning strongly agree (see appendix C). The pre-survey which consisted of fifteen questions generated data needed to drive the focus of the training and future recommendations (see appendix D).

Intervention stage of the project began with the administration of the pre survey. The information gathered from the pre-survey were used to set goals and designing the training intervention. The DNP student will deliver multiple in-service training sessions. Post-intervention stage was the administration of the post Knowledge, Beliefs and Attitudes survey

and facility surveillance of hypoglycemia staff compliance guiding in compliance improvement recommendations within the participating unit and for future practice/ process change.

The DNP student applied for project exempt approval or expedited review from both the facility and the school's Institution Review Board since it was not collecting data with any personal identifiers. All information collected as part of evaluating the impact of this project was aggregated data from the project participants and did not include any potential patient identifiers. The data collected was protected in Mind Lab with password access given to the DNP student and the preceptor.

Data Analysis

Data from each nursing staff participant was collected from Mindlab over a one-week period. The data collection period was adjusted accordingly in order to avoid interfering with patient care. Data was reviewed for consistencies and any errors. The data from mindlab was entered into the Microsoft Excel Software and analyzed by using the Statistical Package for Social Sciences (SPSS). The data was saved in two different shared drive for entry accuracy comparison.

All data was saved in the secure share drive with a limited access only to the DNP student and the student preceptor. Any identified extreme outliers were removed to prevent the chance of Type I or Type II error. A two-sample t-test was utilized at the end of the implementation to determine statistical significance between pre-survey and post-survey mean scores.

Cost-Benefit Analysis/Budget: Timeline: Ethical Considerations/ Protection of Human Subjects

There were no funds budgeted for implementation of the hypoglycemia protocol compliance project. The DNP student absorbed the minimal incurred expenses during project

implementation. The expected expenses were minimum cost for statisticians, fliers and handouts. Computer access, internet access, and extra copies were provided at the project site. Participants were provided with online access tools through the project site's education system (Mindlab) at no cost.

Timeline

The project occured over three months and consist of three phases (Appendix E). Phase 1 of the project focused on identifying staff beliefs through the administration of the pre-survey. Phase 2 of the project began by evaluating the pre-survey data as a basis for intervention. The DNP student delivered multiple thirty to forty-five-minute training sessions on the unit. Phase 3 followed with the administration of the post-survey and monitoring nursing staff compliance. Data analysis was conducted for project impact evaluation and future recommendations.

Ethical Considerations/ Protection of Human Subjects

Before initiation of the project, the DNP student applied for project approval from the Institution Review Board at DCH Medical Center (Appendix F). The project was also approved by the Jacksonville State University's Institution Review Board. All information collected as part of evaluating the impact of this project were aggregated data from the project participants and did not include any identifiable patient data. Participants were assigned a unique code for access into the Mindlab learning system. Participants were allowed to ask questions before enrolling in the project and informed that participation was voluntary and could be terminated at any time. Data collected from Mindlab were stored in a secured shared drive with password access only by the DNP student and the student preceptor.

Conclusion &Analysis

The project incurred barriers during the implementation process due to Corona virus pandemic. In order to comply with the infection prevention requirement of six feet apart, any non-essential training was placed on hold. Thirteen registered nurses participated in the hypoglycemia protocol compliance training and pre-survey. A two-sample t-test was used at the end of the implementation to determine statistical significance between pre-survey and post-survey mean scores. Compliance with Hypoglycemia Protocol is a quality measure at this healthcare system. Improving the nursing staff's compliance with hypoglycemia protocol is likely to decrease cost, length of stay, improve patient quality of care and prevent avoidable deaths.

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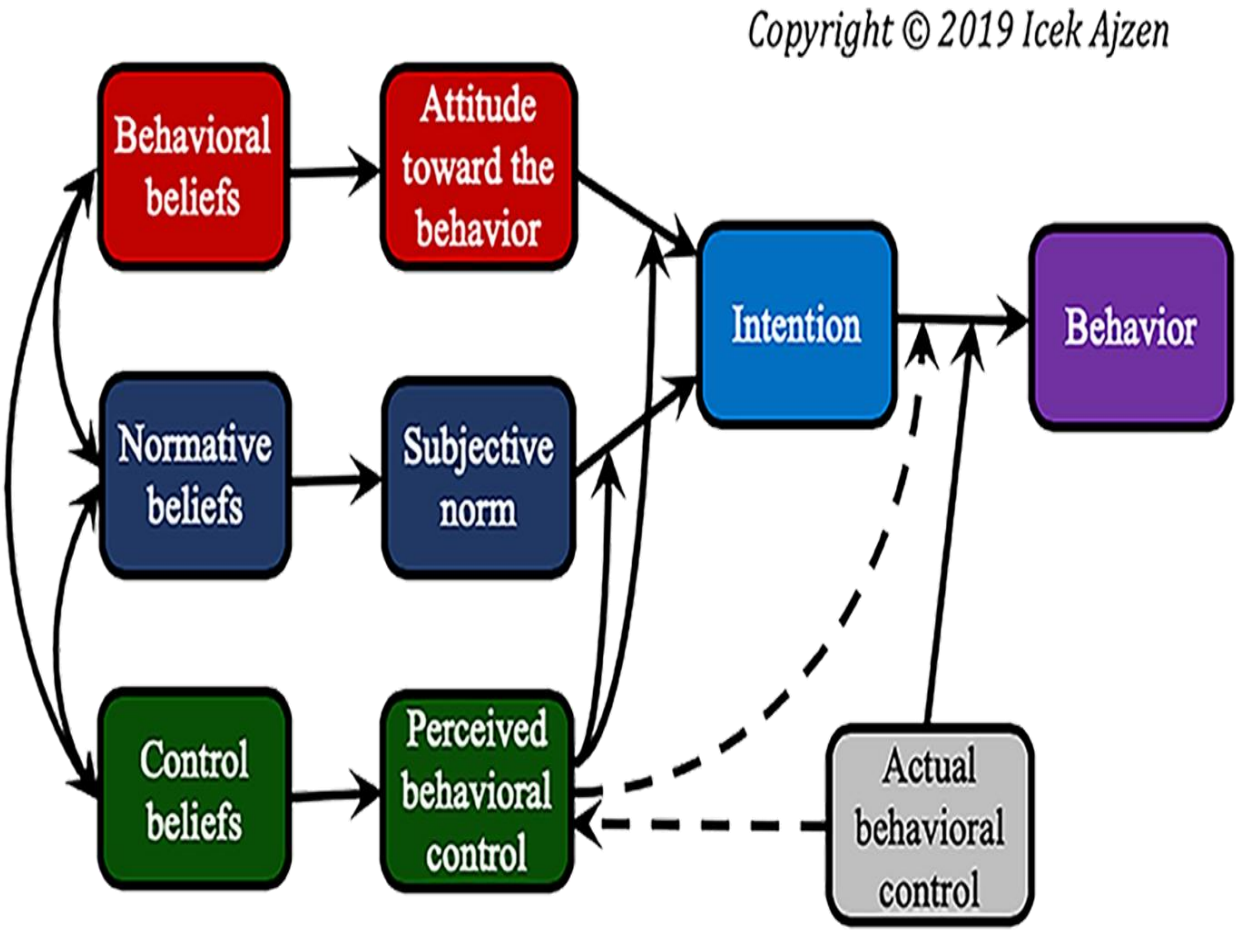
Appendix A

Figure 1. Theory of Planned Behavior model. Reprinted from "Behavioral interventions based on the theory of planned behavior: Brief description of the theory of planned behavior," by I., Ajzen, n.d.



Appendix B

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Appendix C

Figure 3: Grading Pre & Post Knowledge, Beliefs and attitudes Survey

Strongly Disagree	**Disagree**	**Somewhat disagree**	**Somewhat Agree**	**Agree**	**Strongly Agree**
0	1	2	3	4	5

Appendix D

Figure 4: Grading Pre & Post Knowledge, Beliefs and attitudes Survey questionnaire

Knowledge	**Question 1, 2, 4**
I am familiar with the hypoglycemia protocol and its recommendations for diabetic patients?	
My hospital has hypoglycemia policies addressing hypoglycemia management and compliance?	
I am aware and able to locate my hospital's hypoglycemia policy and protocol?	
Belief	**Question 3, 5 11, 12, 13, 14, 15**
My hospital's hypoglycemia policies are based on evidence-based guidelines?	
In this hospital hypoglycemia protocol is important?	
I don't have time to comply with the hypoglycemia protocol?	
In my unit there is enough leadership support and resources to comply with hypoglycemia practice guidelines?	
Hypoglycemia protocol is cumbersome and inconvenient?	
I am not really expected to comply with hypoglycemia protocol	
I have necessary supplies and equipment for following hypoglycemia protocol?	
Attitude	**Question 6, 7, 8, 9,10**

Hypoglycemia protocol are practical to use in this unit?
Following the hypoglycemia protocol will likely decrease the patient length of stay?
Hypoglycemia protocol help standardize patient care?
Hypoglycemia protocol improve patient safety and overall outcome?
Hypoglycemia protocol are relevant to my patient population?

Appendix E: Timeline

Timeline Tasks		**Start**	**Finish**
Project preparation	Obtain the participating unit baseline data, data collection tools and finalize the surveys.	10/2019	10/2019
Phase I	Administer the pre-survey	11/2019	11/2019
Phase II	Staff education session on the unit	12/2019	12/19
Phase III	Administer Post survey, data management and data analysis Project evaluation and	1/2020	1/2020

	results		
Project completion	Project writing, completion, submission, and presentation	4/2020	4/2020

Appendix F

September 27, 2019

Concepta Onyatta, RN, MSN DCH Regional Medical Center 600 Bryant Drive East Tuscaloosa, Alabama 35401

Dear Mrs. Onyatta:

SUBJECT: REGULATORY OPINION: IRB EXEMPTION Investigator: Concepta Onyatta, RN, MSN Protocol Title: Improving Diabetic Management Protocol Compliance through Nursing Education

This letter is in response to your request for an opinion as to whether the above mentioned project would constitute human subject research requiring IRB review. This opinion is based on federal regulation 45 CFR 46 and associated guidance.

Under 45 CFR 46.102(l), the definition of research includes "…a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities."

The Office of Human Research Protection has issued guidance indicating that quality improvement projects do not meet the definition of research. This guidance states:
Question 2: Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes? Answer: No. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore, the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

This project does not involve research. This project seeks to improve diabetes patient care at a single medical facility. Therefore, WIRB has determined this project is not research and does not require IRB review. This determination that this project is not research subject to 45 CFR 46 can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make such determinations. WIRB cannot provide a determination that overrides the jurisdiction of a local IRB or other institutional mechanism for making such determinations. You are responsible for ensuring that each site to which this determination applies can and will accept WIRB's determination.

Please note that any future changes to the project may affect its status as research, and you may want to contact WIRB about the effect these changes may have on the status before implementing them. WIRB does not impose an expiration date on its determinations of research. If you have any questions, or if we can be of further assistance, please contact Kelly FitzGerald, PhD, at 360-252-2578, or e-mail RegulatoryAffairs@wirb.com.

KAF:mr Not Research-Quality Improvement-Exemption-Onyatta (09-27-2019) cc: WIRB Accounting WIRB Work Order #1-1224016-1