Pre-prandial Insulin Administration Clinical Project Final Report

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Abstract

Diabetes mellitus (DM) is a detrimental disease that afflicts approximately 23.6 million Americans and costs $176 billion dollars annually in direct medical expenses (American Diabetes Association [ADA], 2015). Approximately 208,000 children and adolescents with diabetes are under the age of 20 years (ADA, 105; CDC, 2014). Currently, the standard of medical practice in school-aged children and adolescents with type 1 diabetes is to administer insulin after the child or teen has eaten. The most current evidence has demonstrated a decrease hemoglobin A1C (HbA1c) and preference for pre-prandial insulin administration (Cobry et al., 2010; Danne et al., 2003; DePalma et al., 2011; Enander et al., 2012; Luijf et al., 2010; Scaramuzza et al., 2010). This Doctor of Nursing Practice (DNP) project delivered an educational program for parents of school age children and adolescents with type 1 diabetes and instituted pre-prandial insulin administration as the standard of care in an outpatient pediatric endocrine clinic. Education was delivered in both verbal and written formats. Data collection included weekly blood glucose reports and HbA1c at initial and follow-up sessions. Descriptive statistics were utilized to analyze the data. No post intervention data was able to be collected due to participant drop out. Future directions to promote this practice change are discussed.

Background and Significance

According to the United States (U.S.) Department of Health and Human Services (2014), diabetes mellitus (DM) affects approximately 23.6 million people and is the seventh leading cause of death in the U.S. The total cost for direct medical expenses due to DM in 2012 was 176 billion dollars (ADA, 2015). Data from the Center of Disease Control and Prevention (CDC) and the American Diabetes Association (ADA) in 2008-2009, estimated 208,000 individuals with diabetes are under the age of 20 years, and roughly 18,436 children are diagnosed with type 1 DM (ADA, 2015; CDC, 2014). The prevalence of diabetes is higher in Hispanic, African American, Asian, Pacific Islander, and American Indians ethnicities (CDC, 2015).

Type 1 DM is a condition resulting from a defective or failure of pancreatic beta cells to secrete insulin (ADA, 2016). Without insulin, glucose cannot enter the cells to be turned into energy and this impairs the body's ability to metabolize carbohydrate, protein, and fat correctly which results in hyperglycemia or high blood glucose (Burns et al., 2013). Prolonged uncontrolled blood glucose can have detrimental health sequelae in adulthood such as hypertension, amputations, blindness, stroke, and renal disease (ADA, 2014; NDEP, 20014). Currently, the standard of care for insulin administration is to dose insulin pre-prandial. However, this type of administration can be difficult in young children due to their unpredictable appetite and oral intake. This creates a barrier in preventing adequate control of blood glucose (BG) and subsequently hemoglobin A1c (HbA1c) levels.

Purpose and Rationale

The goal of diabetes management is to decrease health sequelae and improve quality of life. One way to achieve these goals is through improved management of BG and HbA1c. Therefore, the purpose of this Doctor of Nursing Practice (DNP) project is to implement an

insulin administration practice change which is demonstrating efficacy in the most recent scientific literature. According to the most current evidence, school-aged children and adolescents with Type 1 DM will benefit from changing insulin administration from a post-prandial insulin administration to a pre-prandial insulin administration. The evidence suggests that this timing of insulin administration contributes to better current and future health.

Internal Evidence

Horizon View Medical Center (HVMC) is an outpatient pediatric endocrine clinic in Las Vegas, Nevada. At this clinic, it has been noted that approximately 50% of the daily pediatric patient visits are related to DM. Currently, all of the children who are insulin dependent are administering insulin at the post-prandial time point which is the opposite practice from what this author observed when working as a Registered Nurse on an adult medical-surgical floor. When the healthcare providers at the clinic were questioned about this practice, the reply was simply because some children do not know how much carbohydrate they will consume at each meal in order to correctly compensate pre-prandial insulin administration.

Problem Statement

It is imperative to monitor BG and HbA1c to better manage DM (Chase, 2011; Valent et al., 2010; World Health Organization, 2011). In a cohort study by Samahy, Elbarbary, and Elmorsi (2015), poor glycemic control was detrimental and caused acute complications such as diabetic ketoacidosis (DKA) or severe hypoglycemia. In addition, the following chronic conditions in pediatric patients were the result of uncontrolled BG: neuropathy 6.3%, retinopathy 1.8%, and microalbuminuria 6.8% (Samahy et al., 2015).

Timely insulin administration is both necessary and imperative to adequately control post-prandial BG, episodes of nocturnal hypoglycemia, and HbA1c (Cobry et al., 2010; Danne et

al., 2003; Scaramuzza et al., 2010). According to Scaramuzza et al. (2010), pre-prandial insulin administration, either 15 minutes or immediately prior to a meal, was more effective than post-prandial administration in keeping BG stable and closer to therapeutic levels. A randomized control study by, Enander, Gundevall, Stromgren, Chaplin, and Hanas (2012), showed a significant reduction by 0.5% in HbA1c in participants who administered pre-prandial insulin based on counting their carbohydrate consumption. Another randomized study on pre- versus post insulin administration by Ratner, Wynne, Nakhle, Brusco, Vlajnic, and Rendel (2011) did not find a significant difference in HbA1c level. However, they did find fewer symptoms and episodes of nocturnal hypoglycemia. It appears that there is a growing body of evidence supporting pre-prandial insulin administration to better control BG and HbA1c.

The emerging evidence of the effectiveness of pre-prandial insulin administration has led to the clinically relevant PICOT question: In diabetic school-aged children (P), how does pre-prandial insulin administration (I), versus standard of care (C), affect HbA1c (O) over three months (T).

Search Strategy

In order to answer the aforementioned PICOT question, a comprehensive literature search was conducted via the following databases: Cochrane Library, PubMed, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). A combination of the following keywords were used within each database: school-aged children(s), pediatric(s), adolescent(s), children(s), youth(s), diabetes, diabetic(s), pre-prandial, before meal(s), post-prandial, after meal(s), blood sugar, blood glucose, HbA1c, HgA1c, A1c, insulin administration, insulin injection, meal dosing, meal time injection, and timing of meal injection/administration.

Boolean connectors AND, OR, IN, and FOR were used in various places within the search as well. In addition, an ancestry and cross reference search was identified through relevant articles.

PubMed

Initially, the search in PubMed yielded 148 articles. When searched using "timing of insulin administration AND children AND blood sugar", the search yielded 30 articles. In limiting publication dates to the last five years and the human species, nine articles were found but only two were applicable and retained for further review.

CINAHL

The search in CINAHL resulted in 28 articles with the following terms: timing of insulin administration AND children AND blood sugar. The search was refined to include the English language, within the last five years, all child, and publications for pediatric diabetes which resulted in 10 studies. Boolean phrases used were: Blood glucose/AND OR Diabetes Mellitus. The search was further broken down into major headings using BG yielding a final result of three articles. Two studies were retained for further evaluation.

Cochrane Library

The search for pre-prandial insulin administration in the Cochrane Library yielded 10 studies. Using the MeSH term hemoglobin A, and Glycosylated (HbA1), the search yielded 20 Cochrane reviews. Other MeSH terms used included: Diabetes Mellitus and BG self-monitoring. The search phrase “pre-prandial insulin injection” and limiting the search to articles from 2010 to 2015 yielded 12 articles. Of the 12 articles, four were included for further review.

After this exhaustive literature search, eleven studies were chosen for further review and critically appraised in order to place the salient points in an evaluation table. The studies consisted of five randomized cross over studies, one non-randomized cross over study, one

randomized controlled trial, one non-randomized controlled trial, two pilot studies, and one systematic literature review. Articles pertaining to the adult population and older than five years were included due to limited number of studies performed on the subject and conducted with the pediatric population. However, these studies had significant findings supporting pre-prandial insulin administration. Some studies were excluded because it did not pertain to insulin timing comparison.

Critical Appraisal and Synthesis of Evidence

Overall, the studies chosen for further review were strong, good quality studies consisting of one level I, seven level II, and three level III studies using Fineout-Overholt & Melnyk (2006), rapid appraisal for RCT's. Seven studies were performed within the last five years and four were more dated due to limited studies on the subject matter in the pediatric population. The majority of the studies were randomized crossover studies. The remainder were non-randomized cross over, crossover, or pilot studies.

The eleven studies exhibited a moderate to strong degree of homogeneity in diagnosis, insulin dependence, and major variables as shown in the synthesis Table 2 (Appendix F). However, heterogeneity was observed in the demographics because studies on adults were included (Appendix E). The population age ranges from two to 82 years of age. Although the population age ranged widely across the lifespan, nine of the studies included participants within the targeted age group (Corby et al., 2010; Danne et al., 2003; Danne et al., 2007; DePalma et al., 2011; Enander et al., 2012; Fullerton et al., 2014; Luijf et al., 2010; Scaramuzza et al., 2010; Schernthaner et al., 2004). Four studies were conducted in a hospital setting and six were in an outpatient setting. Although eight studies were conducted outside the U.S., the findings can likely be generalized as they focused on the same diagnosis and utilized similar inclusion and

exclusion criteria. There was strong homogeneity in the variables of interest amongst the eleven studies. Nine of eleven studies had post-prandial BG as the independent variable and timing of insulin administration as the dependent variable. Seven out of eleven studies measured post-prandial BG differences between the timing of insulin administration.

The majority of the studies utilized the following statistical analysis: level of significance (p), ANOVA, and t-test. Other statistical analyses that were used in less than three studies include: 95% confidence interval (CI), trapezoidal method for area under the curve (AUC), standard deviations (SD), Pearson's correlation coefficient, degree of power, Fisher's exact test, 7-point blood glucose profile, and Wilcoxon's test. The statistical analysis aids the reader to extrapolate significant results in order to take action (Kellar and Kelvin, 2013). The brand of glucose monitor used were not consistent in all eleven studies, however, quality controls were performed in most studies to ensure accuracy of the monitors utilized. The measurement tools used to measure BG was not consistent throughout the eleven studies. Six out of eleven studies received funding from various drug and medical equipment companies raising the suspicion for bias, however all authors denied any potential bias.

Conclusion of Evidence

Overall, the eleven studies had a similar conclusion: pre-prandial insulin administration is the preferred practice over post-prandial insulin administration. Improved post-prandial BG, less glucose excursions, greater patient satisfaction, and decreasing BMI also were found as a result of pre-prandial insulin administration. Therefore, this proposed Doctor of Nursing Practice (DNP) project plans to develop and deliver an educational program for parents of type 1 school-aged and adolescents with diabetes and institute pre-prandial insulin administration as the standard of care in an outpatient pediatric endocrine clinic.

Chapter 2

The purpose of this DNP project is to critically analyze the literature for supporting evidence to guide nursing practice in order to promote health. However, translating evidence into practice is an arduous task. The use of theory and models were utilized to assist and guide this DNP project.

John Hopkins Evidence-Based Model

The John Hopkins Evidence Based Practice (JHNEBP) model was chosen to guide this DNP practice change project. The model involves three major process: practice question, evidence, and translation (Newhouse et al., 2007). The practice question is the evidence-based practice (EBP) question and assigning roles. The second process involves identifying internal and external evidence, appraising the evidence, and developing recommendations based on strength of evidence (Newhouse et al., 2007). The final process is translation, which involves determining feasibility, creating an action plan, implementing change, evaluating outcomes, identifying next steps, and communicating findings (Newhouse et al., 2007). The JHNEBP model is fitting to guide the proposed DNP project which will lead to a practice change because it recommends in-depth investigation of evidence, risks, harms, applicability, and outcomes.

In following each step of the process, the model clearly gives guidance to find solutions to clinical problems in need of a practice change. Step 1 of the model was depicted through the identification of the PICOT question. Step 2 involves gathering evidence both in practice and from the literature to support or dismiss the practice change (i.e., pre-prandial insulin administration). In appraising the evidence, strength and applicability of a study can be identified and used to determine the reliability and validity of the results. Lastly, the model suggest that a plan of action be implemented in practice that is based on the evidence which

supports pre-prandial insulin administration in pediatric patients. The goal is to educate parents and children and eventually mainstream pre-prandial insulin administration in school-aged children in an outpatient pediatric endocrine clinic.

Imogene King's theory of goal attainment also was used to guide this project. This mid-range theory incorporates the following concepts: stress, personal space, self, perception, time, growth and development, communication, interaction, transaction, and role (Parker and Smith, 2010). The transaction process model is a universal model that can be applied to just about any scenario involving at least two persons (Parker and Smith, 2010). It is through this interaction that goals are set and obtained. Using the transaction process model, a goal was set with patient and parent. The dyad received education regarding pre-prandial insulin administration and agreed to change their practice of administering insulin after eating. The goal is to improve BG and HbA1c in children with type 1 diabetics through pre-prandial insulin administration. Closer blood glucose control may prevent detrimental future sequelae such as neuropathy, blindness, and amputations.

Methods

Ethical Approval

Online training Collaborative Institutional Training Initiative (CITI) was completed prior to beginning the DNP project. Modules were completed for informed consent, the Health Insurance Portability and Accountability Act (HIPAA), basic IRB regulation and review process, vulnerable subjects, conflict of interest in research involving human subjects, assessing risks, privacy and confidentiality, and data management. A certificate of completion was obtained after completing the modules and exam. In addition, approval from Arizona State University's IRB was granted on January 3, 2016 (Appendix G).

Participants and Setting

Horizon View Medical Center's (HVMC) outpatient pediatric endocrinology office was chosen for the location for this DNP project due to access of the targeted population. A letter of support can be viewed in Appendix H. Recruitment and data collection were performed during routine office visits. All parents with children who have type 1 diabetes were given an explanatory introduction letter from the medical assistant at check-in (Appendix J). The inclusion criteria to participate in the project included: children ages six to 18 years, diagnosed with type 1 diabetes, English speaking, diagnosed for three or more years, have a hemoglobin A1c (HbA1c) of at least eight percent since last visit, and who are medically stable on their current insulin regimen.

Procedure

If parents were interested in participating and met the inclusion criteria, Ngoc Quyen Bui, Doctor of Nursing Practice (DNP) student answered questions or concerns that the parent and child may have. Informed consent, assent, and pre-survey questionnaires were completed during the initial visit by parents and children. The parent created a four digit identification (ID) number with the last four digits of their phone number to ensure confidentiality (Appendix K). Information regarding weekly blood glucose reports and blood results for blood glucose and HbA1c were obtained via electronic medical records. In addition, teaching was done in both verbal and a written format during the initial visit (Appendix L). Verbal teaching regarding insulin injection sites, rotation of sites, rotation techniques, when to change the insulin cartridge, and sick days were reinforced with parent and child during the initial visit. Common injection sites were: abdominal region, lower back side, thigh, and back of arms. The W, M, or circle method can be used for site rotation to prevent scar tissue buildup. Sites should be rotated every

3 days along with the insulin cartridge change. Parents were reinforced to substitute carbohydrates with sugary drinks or soft foods when the child cannot tolerate solids during a gastrointestinal or other minor acute illness. The parents also were taught to check blood glucose more frequently (every 2-3 hours) and urine for ketones when the child was ill. The teaching handout contained information on the sliding scale with different BG levels and time for administration. Parents were instructed to always carry glucose tablets and intramuscular glucagon for hypoglycemic episodes. For medical emergency, parents were advised to call 9-1-1 then notify the endocrinology's office per office routine. The pre-questionnaires contained questions regarding family and child demographics, general diabetes care, and current practice (Appendix M). The follow-up survey was administered at the routine three month visit (Appendix N).

Outcome measures

Content validity of pre and post surveys and educational handout was determined by Dr. Saad and Trisha Briones, CPNP at HVMC. The pre and post surveys utilized a Likert type scale, fill in the blank, multiple choice, and open ended questions. Data was analyzed using the Wilcoxson paired t-test and descriptive statistics.

Data collection

The data was be stored on a password protected computer to ensure that only the authorized users can access the information. Authorized users were Ms. Bui and Dr. Jacobson. Hard copies of the completed surveys were identified only with an identification (ID) number that the parent created with the last four digit of their phone number during the initial visit. The de-identified data is to be stored for 6 months. Hard copies of the surveys were shredded immediately upon completion of data analysis. Ngoc Quyen Bui RN, DNP student and Diana

Jacobson PhD, RN, PPCNP-BC, PMHS, FAANP had full access to the data. Ms. Bui obtained the weekly blood glucose readings from the child's medical record after receiving consent from the parents. Ms. Bui had full access to the medical records to obtain blood glucose, hemoglobin A1c, and weekly blood glucose report from January to May 2016. After this period, no future data was collected. De-identified data is planned to be presented to Horizon View Medical Center medical and nursing health care providers at the completion of the project.

Budget

It was projected that the project would cost less than $30 to complete and the cost met this expectation. The only foreseeable cost incurred was to print the pre- and post- survey questionnaires, consents, educational handouts, introduction letter, instructions, time, and cost for gasoline to travel to the endocrine clinic (Appendix I). However, the providers at HVMC agreed to have the questionnaires printed in the office to help offset the cost. There were no compensation offered for the participants. In addition, the project took place during routine office visits with blood tests ordered and obtained at the clinic with the patient's insurance covering this cost. Therefore, there were no extra costs incurred by the participants to participate in this DNP project. Writing implements were available in every exam room for the participants to complete the questionnaires. Estimated total time and cost for travel to the clinic was six hours and $30 for gasoline. Actual cost of the project was roughly $35 dollars for printing services and gasoline.

Results

Although 20 participants were anticipated to be recruited, this was not achieved due to the following circumstances: child's HbA1c was less than 8%, the parent did not speak English, or the child was not ready to commit to a change in insulin administration. A higher number of

participants could have been recruited if the criteria allowed for Spanish speaking dyads and a longer time frame was allowed for recruitment. A total of seven participating dyads that met all the inclusion criteria were included in the project.

Demographics

The participant age ranged from eight to 17 years. There were four females and, 3 males. The race/ethnicity of the participants included three African Americans, three Hispanics, and one Hispanic/Caucasian.

Means

The participant's average age was 13.9 years and average age at diagnosis was 10 years. The mean HbA1c recorded from the initial session was 10.33%. Three month follow-up appointments were scheduled for late March 2016 or early April 2016. A Wilcoxson paired t-test and descriptive statistics were used to analyze the data.

First Visit Child Survey

Five participants reported their current practice as only administering insulin after meals; one reported administering insulin after meals at school and before meals at home; and one participant administered insulin before meals only. All participants were comfortable with insulin administration but only five knew their insulin to carbohydrate ratio. All seven participants were aware of at least one of four options for treating hypoglycemia and could name at least two out of three potential sites for insulin administration.

Pre-assessment Parental Survey

Three parents thought that pre-prandial insulin administration would help lower their child's blood glucose; three did not know; and one reported only sometimes they think it does. Not every parent was comfortable with insulin administration. In fact, only two reported being

comfortable all the time; three were comfortable most of the time; and two were somewhat comfortable. However, all seven parents had knowledge of their child's current insulin to carbohydrate ratio, site of insulin administration, insulin practice, and what to do on sick days.

Post-data

No post-data information was available. Three patients did not keep follow-up appointments. Spoke with two parents via telephone and sent post-survey via email. Parents were also reminded to send blood glucose reports from the past 3 months. Unfortunately, no data was received. Therefore, post intervention data analysis was unable to be completed.

Limitations and Implications

Although results from data analysis is not yet available, it is expected that the results would mirror that of evidence synthesis from the literature. This DNP project has the potential to lower BG and HbA1c for patients and help providers at HVMC to better manage type 1 DM. Anticipating a positive outcome, it is vital to sustain the pre-prandial insulin administration practice. The biggest limitation of this project was the sample size and waiting three months for post data to be available.

Discussion

Most of the parents I have interacted with were excited and willing to participate in a DNP project that could potentially help their children. The medical assistants, healthcare providers, and dietician helped to identify potential participants for the project. Without the support and aid of the staff, it would not have been possible to complete the project. Ultimately, the goal of this DNP project was to help patients with type 1 DM gain better control of their condition by lowering their blood glucose and HbA1c changing their insulin administration time

from post-prandial to pre-prandial. In turn, this practice change also assisted providers to provide evidence-based care to better manage their patients' condition.

Chapter 3

Although the project got a late start and did not achieve the planned 20 participants as anticipated, the recruiting process went smoothly. The project is low cost and can be easily replicated. Parents were willing to participate because the project had the potential to lower blood glucose and HbA1c. Current policies such as the Affordable Care Act and Children's Health Insurance Program (CHIP) in Nevada helped ensure all children have access to medical care and financial support for medical services. These policies were important especially for children with chronic diseases, such as type 1 diabetes, that require closer monitoring.

Impact of Health Policies

Children of lower-income households are at a disadvantage when it comes to receiving the proper health care. However, with health care initiatives like the Affordable Care Act (ACA) which was enacted in 2010, it is possible. The goal of the ACA was to expand health coverage to all Americans, lower costs, and enhance quality of care (Medicaid, 2016). Under the ACA, revisions to improve the CHIP in Nevada was established. Some of the revisions include: year-round open enrollment and provision for minimum mandatory benefits to prevent and treat health conditions (Medicaid, 2016). This is especially important for low-income children with chronic conditions such as type 1 DM. These children are insulin dependent, require frequent follow-ups, and laboratory blood tests. Without coverage, these children will not have appropriate access to medical care and treatment.

Leadership Role and Sustainability

Prior to this DNP project, I had limited exposure to conducting a translational practice change project. As a first time project director, I had a lot of fear and doubt in completing this project. The topic of the project was changed several times mostly due to feasibility and site permission. Once the topic and site permission was approved, the next problem to tackle was getting Institutional Review Board (IRB). It was a long process but with the help of my mentor Dr. Diana Jacobson, IRB approval was obtained. Sustaining participants in the project proven more difficult than anticipated since the protocol required the collection of post intervention data to be at 3 months. Three months for post intervention follow up was chosen in order to be able to recognize changes in HbA1C. However, as a leader, I have learned how to overcome the challenges of designing and delivering a practice change intervention due to my ability to persevere and continue. Lessons from this project will help with future practice change endeavors.

This is a cost-effective project that will not require any additional training, guidelines, and no additional human labor costs. The providers, in the future, will discuss pre-prandial insulin administration during scheduled visits. Weekly blood glucose reports will continue to be sent via email by the parents for necessary treatment adjustments and ensure the child's safety per office protocol.

Conclusion

Both providers and parents were supportive of this DNP project. Limited resources both human and fiscal are needed to sustain this practice change. During scheduled visits, providers can reinforce the importance of pre-prandial insulin administration. When providers indicate that this practice change is evidence-based, it can help increase parental confidence and compliance. In addition, there are no additional costs to incur since there are no additional extra

staff or materials required. Again, the only change is the timing that insulin is instructed to be given.

The eleven studies selected for critical appraisal showed improved post-prandial BG, less glucose excursions, greater satisfaction, and decreasing BMI as a result of pre-prandial insulin administration. Although larger scale research is needed, specifically in the pediatric population, the evidence suggests pre-prandial insulin administration should be adopted for better glycemic control and management of type 1 diabetes in children. It was expected that the results of this DNP project would show a decrease in children's BG and HbA1c as suggested by the literature.

This DNP project has taught me the value of evidence-based practice (EBP). Learning about EBP in the classroom and actually seeing its potential impact in real life offers a new perspective in my future practice as an advanced practice nurse in pediatrics. Personally, this project has motivated me not to become complacent when practicing but always question and search for a better solution based on evidence!

I hope there will be more data collected within this endocrine practice site with a greater number of participants but the inclusion of other outpatient endocrinology offices in Las Vegas or even statewide may demonstrate even future benefit. In addition, the creation of a national guideline for pediatric insulin administration with specific time frames in which the pre-prandial insulin should be administered should be developed.

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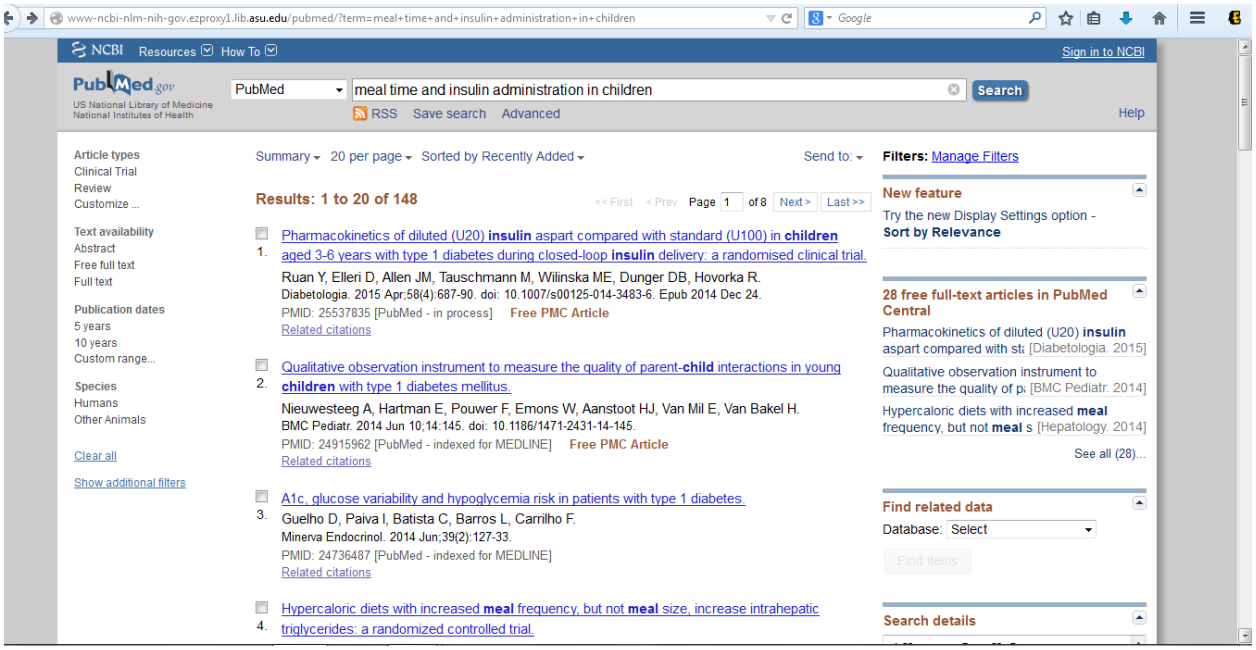
Appendix A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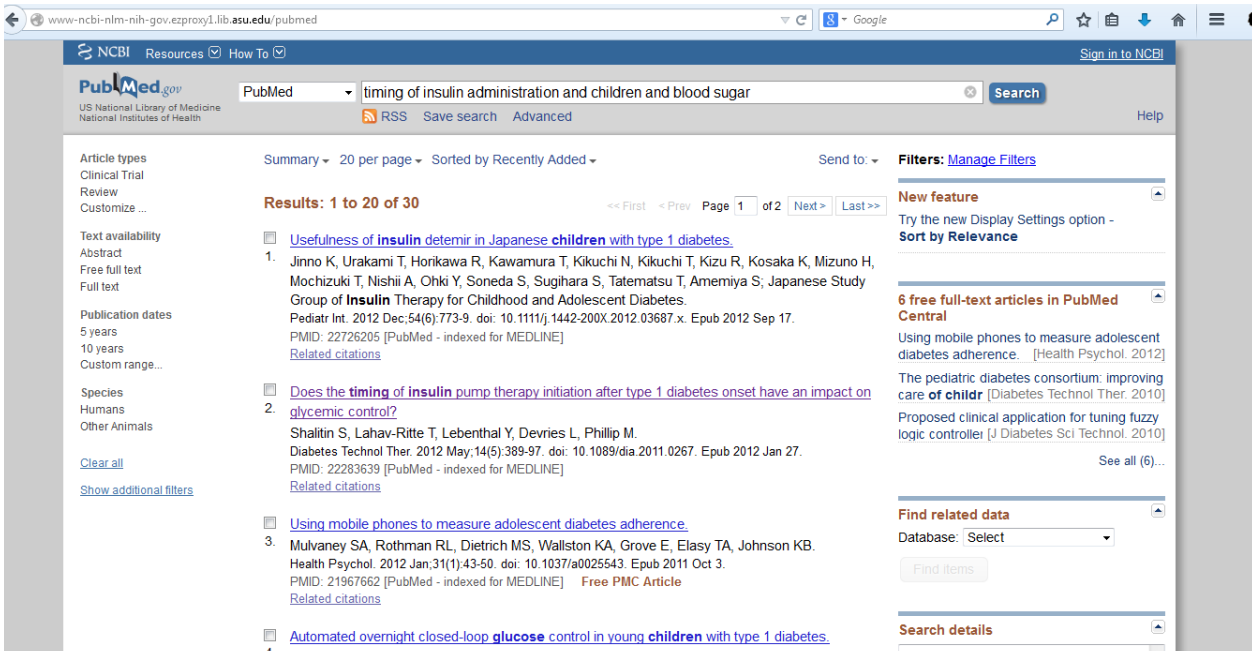
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1. Usefulness of insulin detemir in Japanese children with type 1 diabetes.
Jinno K, Urakami T, Horikawa R, Kawamura T, Kikuchi N, Kikuchi T, Kizu R, Kosaka K, Mizuno H, Mochizuki T, Nishii A, Ohki Y, Soneda S, Sugihara S, Tatematsu T, Amemiya S; Japanese Study Group of Insulin Therapy for Childhood and Adolescent Diabetes.
Pediatr Int. 2012 Dec;54(6):773-9. doi: 10.1111/j.1442-200X.2012.03687.x. Epub 2012 Sep 17.
PMID: 22726205 [PubMed - indexed for MEDLINE]
Related citations
2. Does the timing of insulin pump therapy initiation after type 1 diabetes onset have an impact on glycemic control?
Shalitin S, Lahav-Ritte T, Lebenthal Y, Devries L, Phillip M.
Diabetes Technol Ther. 2012 May;14(5):389-97. doi: 10.1089/dia.2011.0267. Epub 2012 Jan 27.
PMID: 22283639 [PubMed - indexed for MEDLINE]
Related citations
3. Using mobile phones to measure adolescent diabetes adherence.
Mulvaney SA, Rothman RL, Dietrich MS, Wallston KA, Grove E, Elasy TA, Johnson KB.
Health Psychol. 2012 Jan;31(1):43-50. doi: 10.1037/a0025543. Epub 2011 Oct 3.
PMID: 21967662 [PubMed - indexed for MEDLINE] Free PMC Article
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4. Automated overnight closed-loop glucose control in young children with type 1 diabetes.
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Using mobile phones to measure adolescent diabetes adherence. [Health Psychol. 2012]
The pediatric diabetes consortium: improving care of childr [Diabetes Technol Ther. 2010]
Proposed clinical application for tuning fuzzy logic controller [J Diabetes Sci Technol. 2010]
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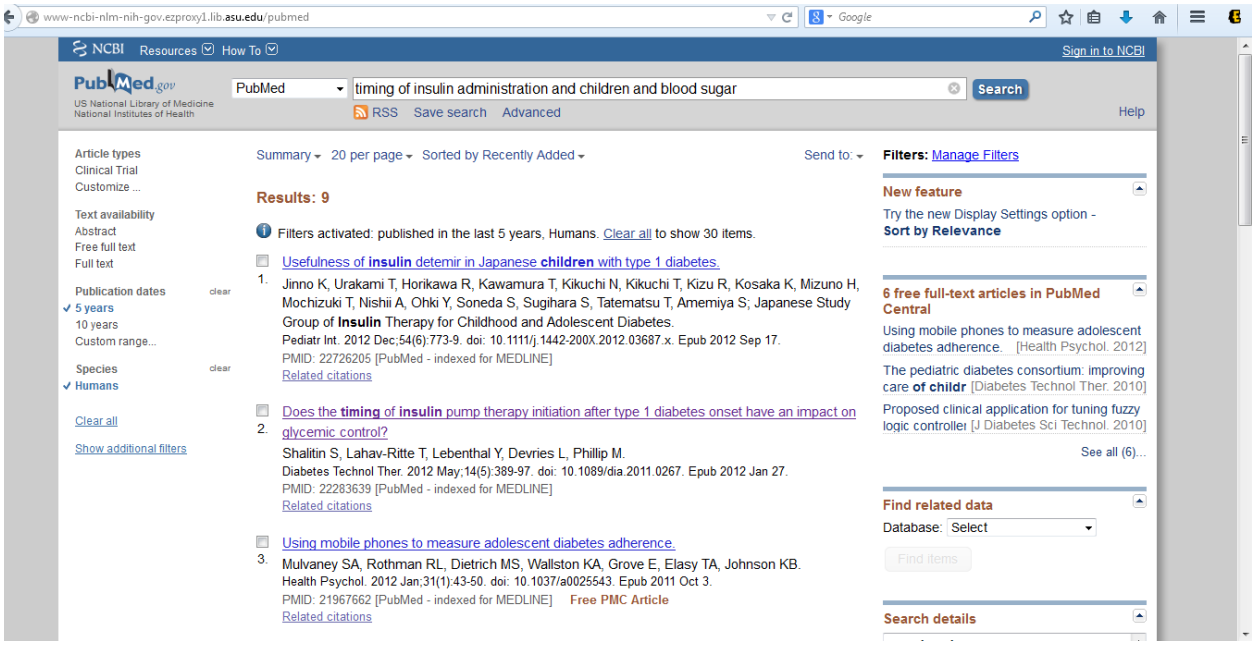
Appendix B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1. Usefulness of insulin detemir in Japanese children with type 1 diabetes.
Jinno K, Urakami T, Horikawa R, Kawamura T, Kikuchi N, Kikuchi T, Kizu R, Kosaka K, Mizuno H, Mochizuki T, Nishii A, Ohki Y, Soneda S, Sugihara S, Tatematsu T, Amemiya S; Japanese Study Group of Insulin Therapy for Childhood and Adolescent Diabetes.
Pediatr Int. 2012 Dec;54(6):773-9. doi: 10.1111/j.1442-200X.2012.03687.x. Epub 2012 Sep 17.
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Related citations
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Shalitin S, Lahav-Ritte T, Lebenthal Y, Devries L, Phillip M.
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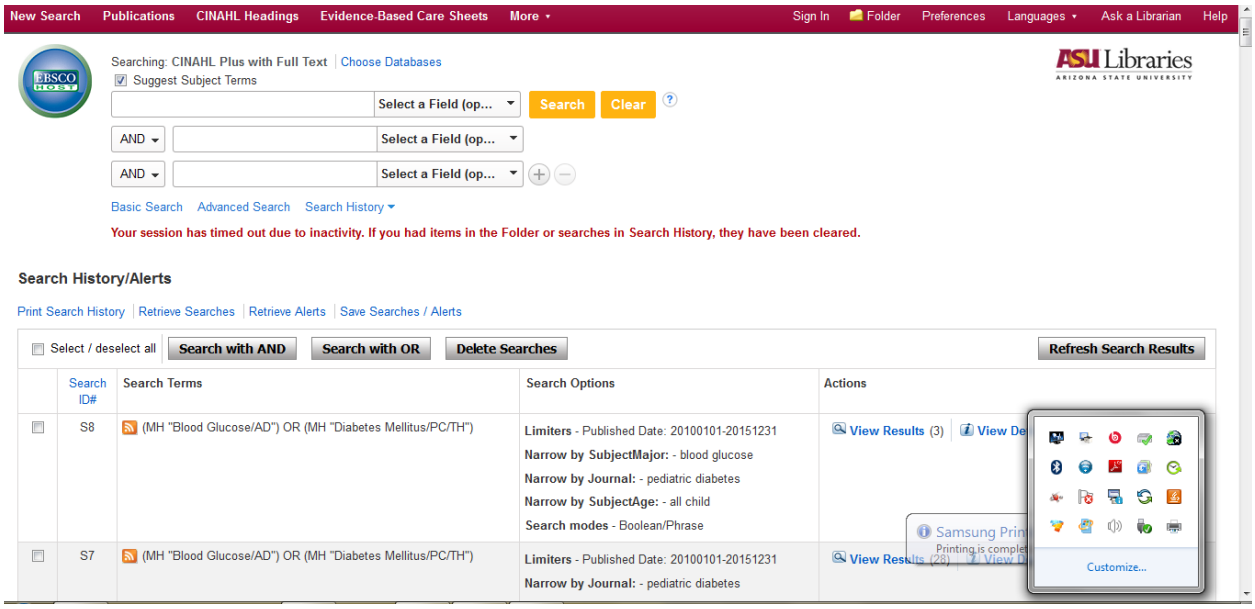
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Select / deselect all
Search with AND
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Search Terms
Search Options
Actions
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(MH "Blood Glucose/AD") OR (MH "Diabetes Mellitus/PC/TH")
Limiters - Published Date: 20100101-20151231
Narrow by SubjectMajor: - blood glucose
Narrow by Journal: - pediatric diabetes
Narrow by SubjectAge: - all child
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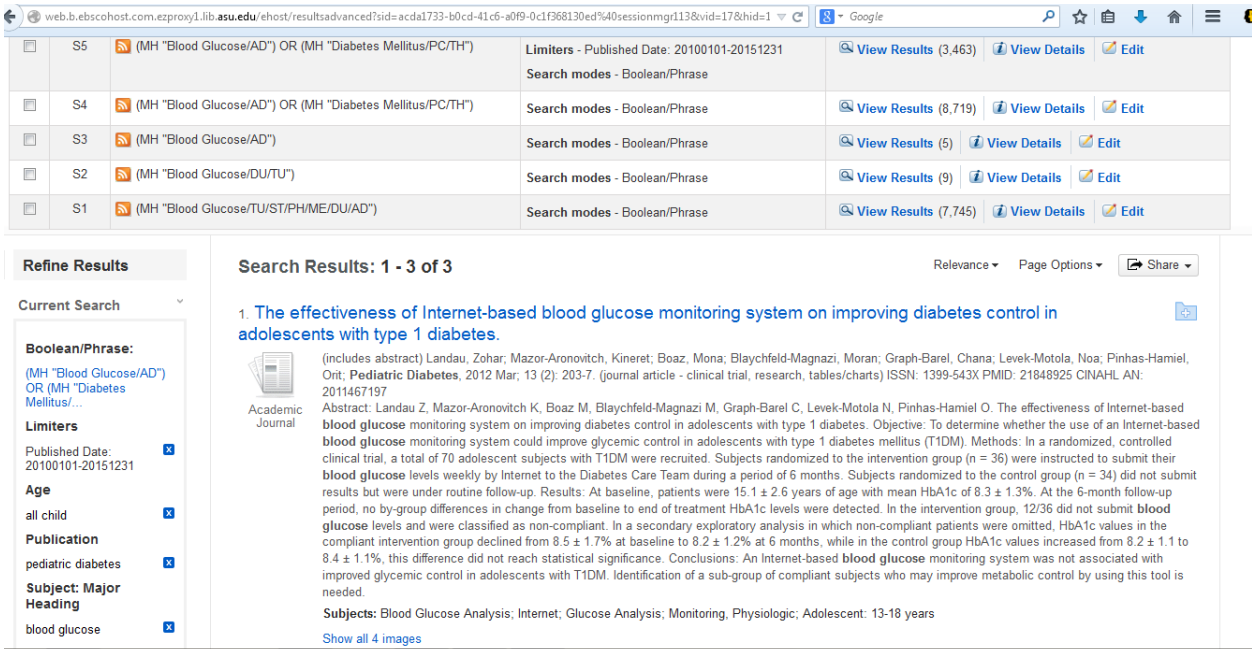
Appendix C



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S5	(MH "Blood Glucose/AD") OR (MH "Diabetes Mellitus/PC/TH")	Limiters - Published Date: 20100101-20151231 Search modes - Boolean/Phrase	View Results (3,463)	View Details	Edit
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S1	(MH "Blood Glucose/TU/ST/PH/ME/DU/AD")	Search modes - Boolean/Phrase	View Results (7,745)	View Details	Edit

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Limiters
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Age
all child

Publication
pediatric diabetes

Subject: Major Heading
blood glucose

Search Results: 1 - 3 of 3

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1. The effectiveness of Internet-based blood glucose monitoring system on improving diabetes control in adolescents with type 1 diabetes.

Academic Journal

(includes abstract) Landau, Zohar; Mazor-Aronovitch, Kineret; Boaz, Mona; Blaychfeld-Magnazi, Moran; Graph-Barel, Chana; Levek-Motola, Noa; Pinhas-Hamiel, Orit; **Pediatric Diabetes**, 2012 Mar; 13 (2): 203-7. (journal article - clinical trial, research, tables/charts) ISSN: 1399-543X PMID: 21848925 CINAHL AN: 2011467197

Abstract: Landau Z, Mazor-Aronovitch K, Boaz M, Blaychfeld-Magnazi M, Graph-Barel C, Levek-Motola N, Pinhas-Hamiel O. The effectiveness of Internet-based **blood glucose** monitoring system on improving diabetes control in adolescents with type 1 diabetes. Objective: To determine whether the use of an Internet-based **blood glucose** monitoring system could improve glycemic control in adolescents with type 1 diabetes mellitus (T1DM). Methods: In a randomized, controlled clinical trial, a total of 70 adolescent subjects with T1DM were recruited. Subjects randomized to the intervention group (n = 36) were instructed to submit their **blood glucose** levels weekly by Internet to the Diabetes Care Team during a period of 6 months. Subjects randomized to the control group (n = 34) did not submit results but were under routine follow-up. Results: At baseline, patients were 15.1 ± 2.6 years of age with mean HbA1c of 8.3 ± 1.3%. At the 6-month follow-up period, no by-group differences in change from baseline to end of treatment HbA1c levels were detected. In the intervention group, 12/36 did not submit **blood glucose** levels and were classified as non-compliant. In a secondary exploratory analysis in which non-compliant patients were omitted, HbA1c values in the compliant intervention group declined from 8.5 ± 1.7% at baseline to 8.2 ± 1.2% at 6 months, while in the control group HbA1c values increased from 8.2 ± 1.1 to 8.4 ± 1.1%, this difference did not reach statistical significance. Conclusions: An Internet-based **blood glucose** monitoring system was not associated with improved glycemic control in adolescents with T1DM. Identification of a sub-group of compliant subjects who may improve metabolic control by using this tool is needed.

Subjects: Blood Glucose Analysis; Internet; Glucose Analysis; Monitoring, Physiologic; Adolescent: 13-18 years

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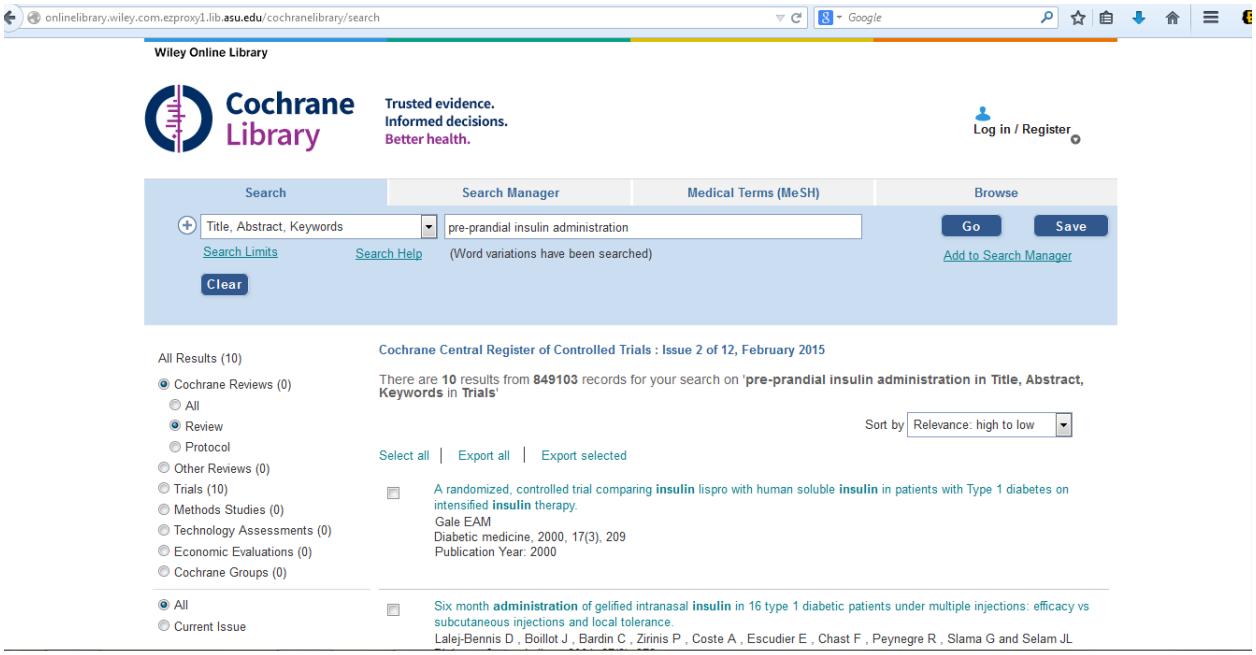

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Title, Abstract, Keywords | pre-prandial insulin administration | Go | Save

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- Other Reviews (0)
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Cochrane Central Register of Controlled Trials : Issue 2 of 12, February 2015

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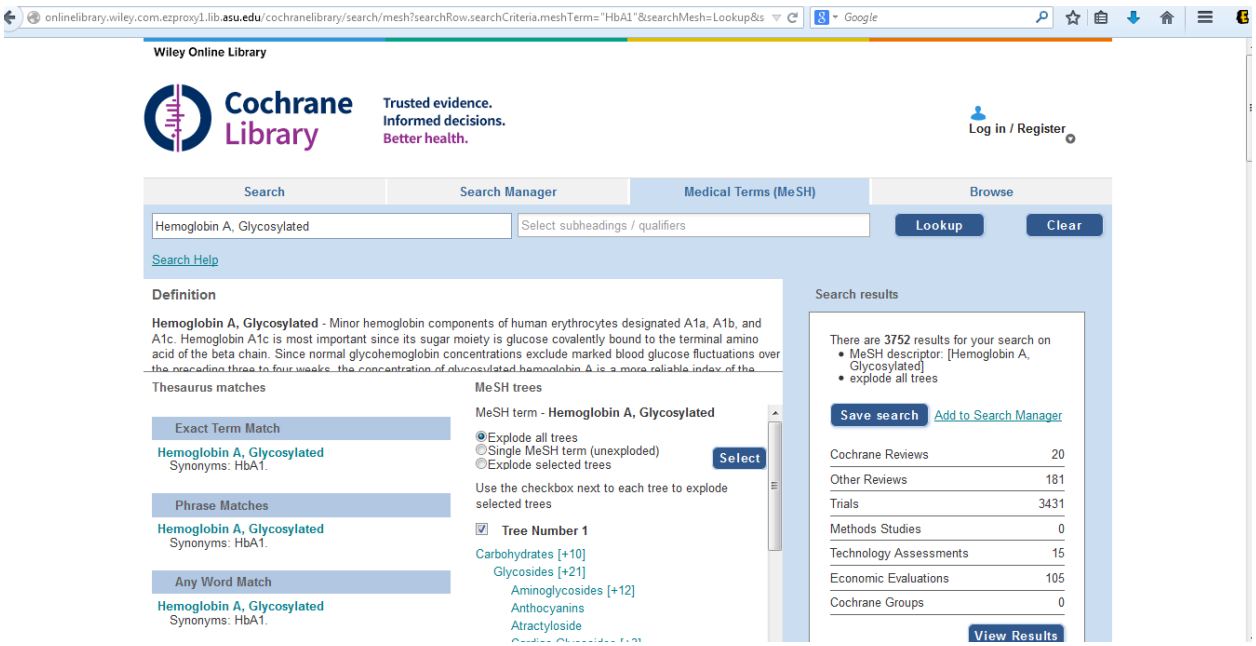
A randomized, controlled trial comparing **insulin** lispro with human soluble **insulin** in patients with Type 1 diabetes on intensified **insulin** therapy.
Gale EAM
Diabetic medicine, 2000, 17(3), 209
Publication Year: 2000

Six month **administration** of gelified intranasal **insulin** in 16 type 1 diabetic patients under multiple injections: efficacy vs subcutaneous injections and local tolerance.
Lalej-Bennis D , Boillot J , Bardin C , Zirinis P , Coste A , Escudier E , Chast F , Peynegre R , Slama G and Selam JL

Appendix D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Definition
Hemoglobin A, Glycosylated - Minor hemoglobin components of human erythrocytes designated A1a, A1b, and A1c. Hemoglobin A1c is most important since its sugar moiety is glucose covalently bound to the terminal amino acid of the beta chain. Since normal glycohemoglobin concentrations exclude marked blood glucose fluctuations over
Thesaurus matches
Exact Term Match
Hemoglobin A, Glycosylated
Synonyms: HbA1.
Phrase Matches
Hemoglobin A, Glycosylated
Synonyms: HbA1.
Any Word Match
Hemoglobin A, Glycosylated
Synonyms: HbA1.
MeSH trees
MeSH term - Hemoglobin A, Glycosylated
Explode all trees
Single MeSH term (unexploded)
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Use the checkbox next to each tree to explode selected trees
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Carbohydrates [+10]
Glycosides [+21]
Aminoglycosides [+12]
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Cochrane Groups 0
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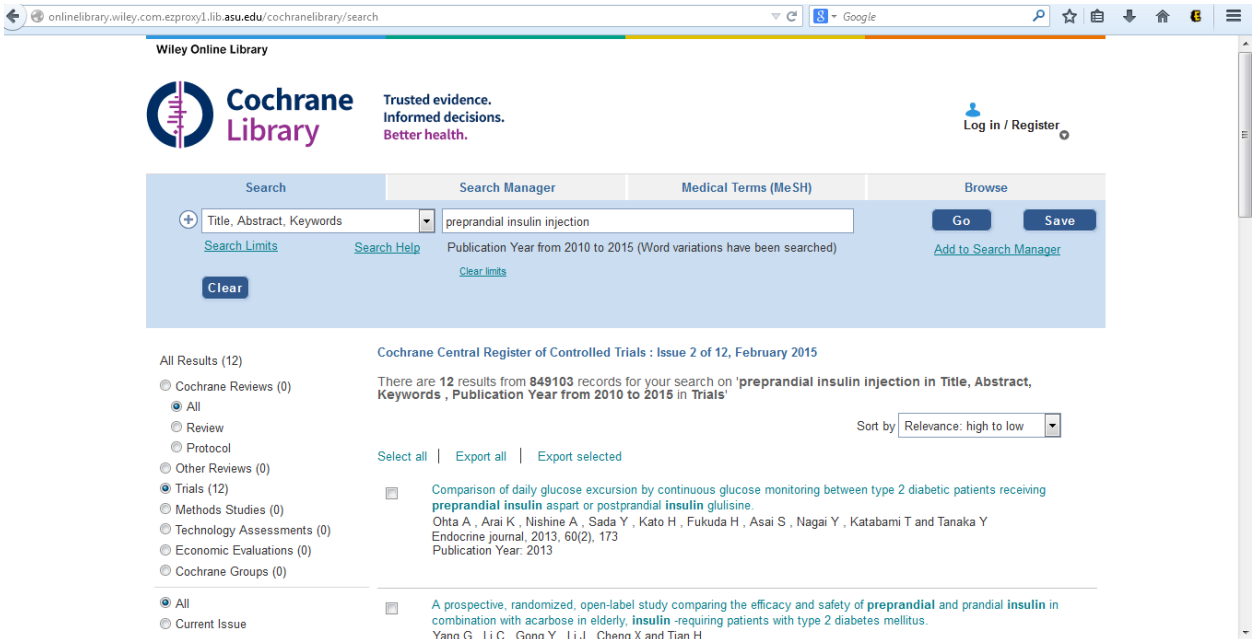
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Publication Year from 2010 to 2015 (Word variations have been searched)
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Add to Search Manager
Clear
All Results (12)
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Review
Protocol
Other Reviews (0)
Trials (12)
Methods Studies (0)
Technology Assessments (0)
Economic Evaluations (0)
Cochrane Groups (0)
All
Current Issue
Cochrane Central Register of Controlled Trials : Issue 2 of 12, February 2015
There are 12 results from 849103 records for your search on 'preprandial insulin injection in Title, Abstract, Keywords , Publication Year from 2010 to 2015 in Trials'
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Comparison of daily glucose excursion by continuous glucose monitoring between type 2 diabetic patients receiving preprandial insulin aspart or postprandial insulin glulisine.
Ohta A , Arai K , Nishine A , Sada Y , Kato H , Fukuda H , Asai S , Nagai Y , Katabami T and Tanaka Y
Endocrine journal, 2013, 60(2), 173
Publication Year: 2013
A prospective, randomized, open-label study comparing the efficacy and safety of preprandial and prandial insulin in combination with acarbose in elderly, insulin -requiring patients with type 2 diabetes mellitus.

Appendix E

Table 1

Evaluation Table

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
Cobry (2010) Timing of meal insulin boluses to achieve optimal postprandial glycemic control in patients with type 1 diabetes L: Colorado, USA F: Sanofi-Aventis C/B: NR	PT	**Design:** CO study **Purpose:** To determine optimal timing of insulin in relation to meal time to minimize post-prandial blood glucose in T1D.	n = 23 **Demographics:** Mean age (18.3) 11 females 12 males 11 < 18 y/o 12 (18-29 y/o) **Setting:** OP **ATR:** 0% **IC:** Diagnosed with T1D for average of 11 years, weighs ~52.3kg, and A1c ~ 7.5% **EC:** Digestive conditions, gastroparesis, and celiac disease	**LOS:** 3 days **DV: PP BG** **IV: TIA -** **IV1: PRE**- 20 mins PRP **IV2: START**- immediately PRP **IV3: POST**- 20 mins PP	M- Freestyle Flash AUC GE BG max	Fisher's exact test S- $p < 0.05$	GE @ 60 mins PP: PRE < START and POST - $p = 0.001$ BG @ 120 mins PP: PRE < START & POST - $p = 0.0408$ PRE AUC < START ($p = 0.0297$) & POST ($p = 0.0463$) PRE BG max < START ($p = 0.0039$) & POST ($p = 0.0027$) PRE had less BG > 180 mg/dL vs. START (	**LOE: III** **Strengths:** Low risk Standardized frozen pre-packaged meals w/ <20g of fat and known carb. content 0% ATR **Limitations:** Small sample **Confidence to Act:** Yes, the study was well designed, low risk, pediatric population, low attrition rate, and easy to replicate.

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
							p < 0.0001) & POST (p < 0.0001)	
Danne (2003) A comparison of postprandial and preprandial administration of insulin Aspart in children and adolescents with type 1 diabetes L: Germany F: NR C/B: NR	PT	**Design:** ROLT & CO **Purpose:** To compare glycemic control of PRP vs PP in children and adolescents with T1D.	n = 76 **Demographics:** Age range (6-17 y/o) 49%-males 55%-<=13 y/o **Setting:** Hospital **ATR:** 7% **IC:** Diagnosed with T1D for average 4.4 y (range 1-9.4y) **EC:** TDID >= 1.8 IU/kg, taking oral antidiabetic agents, unaware/recurrent hypoglycemia,	**LOS:** 5 days **DV: PP BG** **IV: TIA-IV1: PRE:** Immediately before meal **IV2: POST:** Immediately after; 30 mins max after	A1c Serum fructosamine Satisfaction with DV1 vs. DV2	OSNIT for serum fructosamine 7-PBGP for A1c CI 95% SAS 6.12 on UNIX platform	PP BG @ 120 mins. DV1 < DV2 - p = 0.016 Satisfaction with DV1 - p < 0.01	**LOE:II** **Strengths:** Safety was discussed Exclusions discussed Low ATR **Limitations:** Small sample No blinding No discussion of exclusion criteria Standardized meals- not discussed Statistical analysis and numerical data not discussed **Confidence to Act:** Yes, it is applicable to target population and testing methods are easy to replicate.

A-average, **AA**-average age, **A1c**-HbA1c, **AE**- adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			significant concomitant illness pregnant, may become pregnant, allergy to product, and noncompliance with trial procedures					
Danne et al. (2007) Parental preference of prandial insulin aspart compared with preprandial human insulin a basal-bolus scheme with NPH insulin in a 12-wk crossover study of preschool children with type 1 diabetes.	PT	**Design:** RCO **Purpose:** To compare S&E + parental satisfaction of (IAsp + NPH insulin) v. (HI + NPH)	n = 26 nIAsp + NPH = 12 n HI + NPH = 14 **Demographics:** AA = 2.4-6.9 y/o Males: 17 Females: 9 MA: 5 +/- 1.3 y/o DD: 1.8 +/- 1 y A1c: 7.8 +/- 1.1% **Setting:** OP	**LOS:** 12 weeks **DV1: avg PP BG** **DV2: HbA1c** **DV3: fructosamine,** **DV4: satisfaction** **IV: TIA & combo of insulin-IV1: PRE**	Avg PP BG, A1c, fructosamine, and satisfaction	WHO DTSQ-M- to assess treatment satisfaction Seven-point BG profiles	NS: avg PP BG, A1c, or fructosamine of PRE vs. POST	**LOE: II** **Strengths:** Randomized Discussion of search criteria **Limitations:** No blinding No homogeneity of meals and compliance Small sample sized No statistical method described Funding by Eli Lilly & Co **Confidence to Act:** Yes, the study was well designed and easy to replicate with minimal risks.

A-average, **AA-**average age, **A1c**-HbA1c, **AE-** adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
L: Germany F: Novo Nordisk A/S, Denmark C/B: Yes			**ATR:** 15% **IC:** Treatment with insulin or insulin analog >= 6M A1c <= 12% Currently treated with short, intermediate, or long acting HI or insulin analogs or self-mixed >= 1M **EC:** Investigational drug within last month Hypoglycemic unawareness Allergy	(IAsp + NPH) **IV2: POST** (HI + NPH)				
De Palma (2011) Lowering postprandial glycemia in children with	PT	**Design:** PS **Purpose:** To determine most effective	nScreened = 56 n = 38 **Demographics:** AA: 6-19 y/o n-boys = 23	**LOS:** 4 days **DV: PP BG** **IV- TIA & method-**	BG AUC	Stat-graphics Plus 5.1 Trapezoidal method for AUC	AUC 6h BG PP DV3 < DV2 - p = 0.01	**LOE: III** **Strengths:** IC & EC discussed Feasible to replicate No ATR

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type 1 diabetes after Italian pizza "Marghertia" L: Italy F: None indicated C/B: No		type and timing of bolus using insulin pump in children with T1D.	n-girls = 15 DD 8.0 +/- 4.3 Mean BMI 21.9 +/- 4.3 m/kg2 ID: 0.83 +/- 0.30 U/k/day A1c 7.66 +/- 0.81% **Setting:** Hospital **ATR:** 0% **Inclusion Criteria:** DD >= 1 y, IPT > 6 months, knowledge of bolus calculator > 3 months, and invitational only. **Exclusion Criteria:** Eating disorders, diabetes-related complications,	**IV1- 15 mins PRP; DWB (30% PRE & 70% over 6h)** **IV2: START ; DWB (30% PRE & 70% over 6h)** **IV3: 15 mins PRP** **IV4: START- immediately PRP**		t-test S = $p < 0.05$		**Limitations:** Small Sample **Confidence to Act:** Yes, the supporting evidence is strong and is applicable to pediatric population.

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			CD, and FA.					
Enander (2012) Carbohydrate counting with a bolus calculator improves postprandial blood glucose levels in children and adolescents with type 1 diabetes using insulin pumps. L: Sweden F: Fyrbodal Research Foundation, Skaraborg Research Foundation, Halland research Foundation, and Smith's Medical	PT	**Design:** RCT **Purpose:** To compare glycemic control of PRP vs PP in children and adolescents with T1D using carb counting bolus calculator.	n=45 age 13.8+/-3.4y (range 5-19.5) **ATR:** 11% **Inclusion Criteria:** T1D No previous CC experience **EC:** NR	**LOS:** 12 months **DV: PPBG & HbA1c** **IV1: G A -** CG **IV2: G B -** manual CC **IV3: G C-** CC on Cozmo pump	A1c BG BMI	ANOVA t-test Pearson's correlation coefficient S = $p < 0.05$ with 80% power	@ 12 months - DV1 increased basal insulin dosage/kg/24h - p = 0.015 DV3 < BMI - p = 0.029 BG: DV3 < DV1 - p = 0.014	**LOE: II** **Strengths:** Exclusions discussed Randomized Standardized tools with same calibrations **Limitations:** Small sample No blinding No discussion of exclusion criteria Funding **Confidence to Act:** Yes, the study has a low ATR and 80% power. The study is also easy to replicate and applicable to target population.

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Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
C/B: Yes, from Medtronic, Roche, and Infucare								
Fullerton (2014) Intensive glucose control versus conventional glucose control for type 1 diabetes mellitus (Review) L: F: Federal Ministry of Education and Research, Germany C/B: No	PT	**Design:** Literature review of RCT's **Purpose:** To assess effects of intensive vs conventional glycemic targets in T1D in terms of long-term complications.	N Eligible = 154 N Qualitative Studies = 12 = 2230 participants N Quantitative = 11 **Demographics:** MA for 12 studies = 12 years AR = 0-22 y/o MA for 11 studies = 29 y/o AR = 26-43 y/o M A1c = 9.5% and 9.3% **Setting:**	**LOS:** >= 1 year with 1 year follow up **DV:** PO, SO, and A1c **IV- IGC:** * Testing BG >= 4 times a day * Injecting insulin >= 3 times a day * Adjusting insulin doses according to food intake and exercise plan * Making monthly visits to health care	**PO:** * MC- MI, stroke * MIC- manifestation and progression of retinopathy, nephropathy, and ESRD * Severe HE **SO:** * HRQOL * AE- HE, KA, and weight gain * All-cause mortality * Costs	Odds ratios/Risks ratios CI 95% Data analysis- Review Manager 5.2 DerSimonian and Laird's random effects model Sensitivity- odds ratios and fixed-effect models For rare events- fixed-effect method of Peto	* Supports IGC in young people and at early stages of disease. * S ↓ risk for developing MIC in IGC group.	**LOE: I** **Strengths:** R and high level of evidence **Limitations:** **Confidence to Act:** Yes, this review is highly reliable with 95% CI.

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Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			Literature review **ATR:** N/A **IC:** T1D Same treatment regimens in both groups If not same treatment, difference in glycemic target must be clearly identified **EC:** Unspecified treatment targets Non-RCT Study <1 year No relevant outcomes No separate analysis of patients with T1D Duplicate	team **IV2: CGC**				

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			publication					
Jovanovic (2004) Efficacy comparison between preprandial and postprandial insulin aspart administration with dose adjustment for unpredictable meal size. L: California, USA F: Novo Nordisk Pharmaceuticals Inc and Sansum Diabetes Research Institute internship fund	PT	**Design:** RCO **Purpose:** To compare metabolic effects of preprandial vs postprandial injection of bolus insulin lispro.	n = 26 **Demographics:** AR: 22-82 y/o Mean BMI: 26.2 kg/m2 **Setting:** OP **ATR: 27%** **IC:** >= 18 y/o with T1D Treated with multiple daily insulin injections Able to calculate insulin-to-carb ratios, dose adjustments **EC:** Abnormal thyroid, renal	**LOS:** 2 days **DV: PP BG** **IV: TIA** **IV1: PRE** 0-5 mins before start of meal **IV2: POST** Immediately after meal	AUC Max mean (SD) BGC	ANOVA S = $p < 0.05$	AUC 22% less in DV1 - $p < 0.001$ Max means (SD): DV2 149.0 (9.9) mg/dL vs. DV1 102.0 (9.2) mg/dL- $p < 0.001$ both DV1 & DV2 had PP BG < 180 mg/dL - $p < 0.001$	**LOE: II** **Strengths:** R, SV, and LR Discussion of search criteria **Limitations:** No homogeneity of meals and compliance Small sample sized High ATR Funding by Novo Nordisk **Confidence to Act:** Yes, the study was well designed, low risk, and well measured.

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C/B: Yes			disease, cardiac ischemia, pregnant, and breastfeeding.					
Liberty (2012) Timing of insulin bolus in patients with type 1 diabetes: effect on glucose control and variability using CGMS. L: Israel F: Not mentioned C/B: No	PT	**Design:** BNRPS, OWB to BG **Purpose:** Effect of insulin bolus timing on overall daily BG control and variability.	N = 16 nPRE = 12 nPOST = 12 **Demographics:** >= 18 y/o AR: 23-71 y/o MA: 49.3 +/- 14 M BMI: 27 +/- 3.7 kg/m2 M A1c: 6.8 +/- 0.6% DD: 22.1 +/- 11.6 y **Setting:** OP **ATR:** 25% **IC:** T1D Multiple daily injections A1c <= 7.8%	**LOS:** 3 days **DV: BG 1 & 2 hours PP** **IV- TIA-IV1: PRP** **IV2: PP**	CGM-MiniMed Medtronic A BG over 72 hours- LBGI, HBGI, BGRI	SAS 9 software for M Wilcoxon test for CG Sign test- MO MLM for MVA	HGBI- DV2 > DV1- p = 0.003 BGRI- DV2 > DV1 - p = 0.003	**LOE: II** **Strengths:** R, SV, and LR Discussion of search criteria OWB No C/B indicated by authors **Limitations:** No homogeneity of meals Short High ATR **Confidence to Act:** Yes, the study is reliable and can be easily replicated.

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Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			CCID **EC:**					
Luijf (2010) Premeal injection of rapid-acting insulin reduces postprandial glycemic excursions in type 1 diabetes. L: Netherlands F: Medtronic Netherlands provided M's only C/B: No	PT	**Design:** 3-way RCO **Purpose:** Effect of rapid acting insulin when given PRP on PP BG in T1D.	n = 10 **Demographics:** MA: 45.5 +/- 12.1 y/o A1c 8.55 +/- 1.50% DD: 23.8 +/- 7.8 y Insulin therapy: 8.5 +/- 6.1 y **Setting:** Hospital **ATR: 0%** **IC:** Treatment with CSII >= 6M DD: 2 y BMI <= 35 kg/m2 BG 3.5-7.8 mmol/l on day of study	**LOS:** 3 **days** **DV: PP BG** **IV: TIA-IV1: PRE:** 30 minutes prior to meal **IV2: PRE:** 15 minutes prior to meal **IV3: "0"** Immediately before meal	CGM- Sof-Sensor Medtronic BS: q15 mins @ 1h PRP, q 10 mins @ 2h PP, and q20 mins @ 3 & 4 hour PP AUC	Trapezoid method SPSS 17 for S = $p < 0.005$ ANOVA Paired sample t-test Fisher exact	DV1 had S lower AUC vs. DV2 & DV3 - p <0.029 DV1 had S lower GE vs. DV2 & DV3 - p < 0.009	**LOE: II** **Strengths:** Homogeneity of meals and compliance 0% ATR **Limitations:** Small sample sized Funding by Novo Nordisk **Confidence to Act:** Yes, strong evidence, easily replicated, and can be generalized to population.

A-average, **AA**-average age, **A1c**-HbA1c, **AE**- adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			EC: BG < or > 3.5-7.8 mmol/l on day of study					
Scaramuzza (2010) Timing of bolus in children with type 1 diabetes using continuous subcutaneous insulin infusion L: Italy F: NR C/B: No	HBM	**Design:** NRCT **Purpose:** To determine optimal timing of bolus injection in children with T1D.	n = 30 **Demographics:** Age range (6-20 y/o) Mean age = 15.2 13 females 17 males **Setting:** Hospital **ATR:** 0% **IC:** Diagnosed with T1D for average of 8 years, BMI 22.4, insulin requirement 0.77 +/- 0.21	**LOS:** 3 days **DV: PP BG** **IV: TIA** **IV1: PRE:** 15 mins PRP **IV2: START:** immediately PRP **IV3: POST:** immediately PP	**M**- FreeStyle Lite **IP**- Paradigm 522/722 **I**- Novorapid AUC	ANOVA S = $p < 0.05$	BG 60 mins PP: DV1 vs. DV3 - p = 0.044 DV2 vs. DV3- p = 0.024	**LOE: III** **Strengths:** Low risk Used same short-acting analog and same meter; glucose meter calibrated daily Standardized meals Same range of preprandial BG (80-140) NCI 0% ATR **Limitations:** Small sample No blinding and no randomization No discussion of exclusion criteria **Confidence to Act:** Yes, the study has no ATR, easy to replicate, and low risk.

A-average, **AA**-average age, **A1c**-HbA1c, **AE**- adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			U/kg/d, and using insulin pump >= 6M **EC:** NR					
Schernthaner (2004) Preprandial vs. postprandial insulin lispro-a comparative crossover trial in patients with type 1 diabetes L: Austria F: Eli Lilly & Co C/B: Yes	PT	**Design:** RCO **Purpose:** To compare metabolic effects of preprandial vs postprandial injection of bolus insulin lispro.	n = 31 nPRE = 16 nPOST = 15 **Demographics:** Mean age = 31 Mean BMI = 24.3 +/- 2.3kg/m2 **Setting:** OP **ATR**: NR **IC:** ID, diagnosed before 40 y/ with T1D, II 3+ times/day, HbA1c <= 8%, BMI <35kg/m2, no advanced/rapidly progressing	**LOS:** 6 months **DV: HbA1c & Fructosamine** **IV: TIA - IV1: PRE-** immediately PRP **IV2: POST-** immediately to 30 minutes PP	High performance liquid chromatography for A1c Colorimetric test by reaction with nitroblue tetrazolium for fructosamine with coefficient of variation of 2%	Model appropriate for crossover design to test for carryover effects if any Analysis of variance 8-point BG measurements	Mean A1c in from baseline to final - DV1 < DV2 - p = 0.008 Mean PP BG DV2 > DV1 - p = 0.031	**LOE: II** **Strengths:** Randomized Discussion of search criteria **Limitations:** No homegeneity of meals and compliance Small sample sized Funding by Eli Lilly & Co **Confidence to Act:** Yes, the study was well designed with reliable results.

A-average, **AA-**average age, **A1c**-HbA1c, **AE-** adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Author	Conceptual Framework	Design/Purpose	Sample/Setting	Major Variables	Measurement	Data Analysis/Stats Used	Study Findings	Evidence/Strengths/Limitations /Confidence to Act
			complications. **EC:** History of severe hypoglycemia, proliferative retinopathy, nephropathy, liver disease, or insulin allergy/resistance					

A-average, **AA-**average age, **A1c**-HbA1c, **AE-** adverse events, **AR**-age range, **ATR-**attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC-**carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**- microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Appendix F

Table 2

Synthesis Table

	Cobry	Danne	Danne	De Palma	Enander	Fullerton	Jovanovic	Liberty	Luijf	Scaramuzza	Schernthaner
Year	2010	2003	2007	2011	2012	2014	2004	2012	2010	2010	2004
LOE	III	II	II	III	II	I	II	II	II	III	II
Design	CO	RCO	RCO	PS	RCT	Literature review	RCO	NRPB	RCO	NRCT	RCO
Demographics											
N	23	76	26	38	45	23 studies	26	16	10	30	31
Age range	12-30	6-17	2.4-6.9	6-18	5-19.5	0-43	22-82	23-71	45.5 +/_ 12.1	6-20	23.3-53
Setting	OP	Hospital	OP	Hospital	OP	Literature review	OP	OP	Hospital	Hospital	OP

A-average, **AA**-average age, **A1c**-HbA1c, **AE**- adverse events, **AR**-age range, **ATR**-attrition rate, **AUC**-area under the curve, **BG**-blood glucose, **BGC**-blood glucose concentration, **BGRI**-blood glucose risk index, **BNRPS**-blinded non-randomized pilot study, **BS**- blood sample, **C/B**-conflict/bias, **CC**-carb counting, **CCID**-carbohydrate counting for insulin dose, **CD**-celiac disease, **CFB**-change from baseline, **CG**-comparison group, **CGC**- conventional glucose control, **CGM**-continuous glucose monitoring, **CO**-crossover, **CSII**-continuous subcutaneous insulin infusion, **DD**-diabetes duration, **DV**-dependent variable, **DWB**-dual wave bolus, **E**-efficacy, **EC**-exclusion criteria, **F**-funding agency, **FA**-food allergy, **G**-group, **G A**-group A, **G B**-group B, **GE**-glucose excursion, **HBGI**-high BG indices, **HBM**-health belief model, **HE**- hypoglycemic episodes, **HRQOL**- health related quality of life, **I**-insulin, **IC**-inclusion criteria, **ID**-insulin dependent, **IGC**- intensive glucose control, **II**-insulin injection, **IPT**-insulin pump therapy, **IV**-independent variable, **KA**- ketoacidosis, **L**-location, **LBGI**-low BG indices, **LOE**-level of evidence, **LOS**-length of study, **LR**-low risk, **M**-meter, **MA**-mean age, **MC**- macrovascular complications, **MI**- myocardial infarction, **MIC**-microvascular complications, **MLM**-mixed linear model, **MO**-matched observations, **MVA**-multivariable analysis, **NRCT**-non-randomized control trials, **NS**-non-significant, **NR**-not reported, **OSNIT**-one sided non-inferiority test, **OP**-outpatient, **OWB**-one way blinding, **P**-potential, **PBGP**-point BG profile, **PG**-parallel group, **PM**-post meal, **PO**- primary outcome, **PP**-postprandrial, **PRP**-preprandial, **PRP II**- preprandial insulin satisfaction, **PS**-pilot study, **PT**-physiologic theory, **R**-randomized, **RCO**-randomized cross over, **RCT**-randomized controlled trials, **ROLT**-randomized open-label trials, **S**-significant, **SO**- secondary outcome, **SV**-supervised, **TIA**-insulin administration, **T1D**-type 1 diabetes, **T2D**-type 2 diabetes, **TDID**-total daily insulin dose, **STSQM**-Diabetes treatment satisfaction questionnaire, **Y/O**-years old

Location	USA	Germany	Germany	Italy	Sweden	N/A	USA	Israel	Netherlands	Italy	Austria
ATR %	0	7	15	0	11	N/A	27	25	0	0	NR
Diagnosis	T1D	T1D	T1D	T1D	T1D	T1D	T1D	T1D	T1D	T1D	T1D
DV	PP BG	PP BG	Avg.PP BG, A1, Fructosamine, & satisfaction	PP BG	PP BG & A1c		PP BG	PP BG	PP BG	PP BG	A1c & Fructosamine
IV	TIA	TIA	TIA and combo of I	TIA	CC mechanism	IGC or CGC	TIA	TIA	TIA	TIA	TIA and PRE
S Findings											
A1C					Adjusted pre-meal insulin dosages based on carb content had 0.5% lower	↓ with IGC					↓ mean from baseline in PRP II v. POST

BG	↓PRP II v. START & POST	↓PRP II v. POST			↓ CC with pump v. CG		PRP & PP II had PP BG < 180 mg/dL	↑ when II PP v. PRP		↓ PRP II v. POST ↓ START v. POST	↑ in mean BG in POST v. PRP II
BG max	↓ PRP II v. START & POST										
BMI					↓in CC with pump						
GE	↓ PRP II v. START			↓when II 15-30 mins PRP					↓ 30 mins PRP v. 15 mins PRP & immediately PRP		
AUC	↓ PRP II v. START & POST			↓when II 15-30 mins PRP			↓ 22% in PRP II		↓ 30 mins PRP v. 15 mins PRP & immediately PRP		
Fructosamine											
Satisfaction		↑ PRP II									
Basal Insulin					↑ in CG						

MIC						↓ in IGC					
Recommendations	II 20 mins PRP	PRP II	PP II is preferred for parents of pre-school aged children	II 15 mins PRP	CC with bolus calculator can help ↓ PP BG	PRP	PRP II	PRP II	II 15 mins PRP	II 15 mins PRP	PRP II preferred but PP II is acceptable

Appendix G

ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Diana Jacobson
CONHI - Research Faculty and Staff
602/496-0863
DIANA.JACOBSON@asu.edu

Dear Diana Jacobson:

On 1/3/2016 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Pre-Prandial Insulin Administration for Children with Type 1 Diabetes
Investigator:	Diana Jacobson
IRB ID:	STUDY00003484
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Bui Pre-session survey for child final dec 22 version 3.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Bui Parent Post-session survey final nov 12 version 1.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Bui Post-session survey for child Final dec 22 version 3.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • IRB modification letter, Category: Other (to reflect anything not captured above); • Child Assent Form Final Nov 20 Version 1.pdf, Category: Consent Form; • HIPPAA, Category: Other (to reflect anything not captured above); • References of Literature used for pre-prandial insulin adminsitration project.pdf, Category: Resource list; • Parent Consent Form Final Jan 6 Version 4.pdf, Category: Consent Form; • Teaching handout Final Nov 20 Version 1.pdf, Category: Recruitment materials/advertisements /verbal scripts/phone scripts; • Bui Pre-session survey for Parents Final Nov 12 version 1.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • ID creation instructions.pdf, Category: Participant materials (specific directions for them); • Introductory Letter Final Dec 11 Version 2.pdf, Category: Recruitment Materials; • Bui IRB Proposal final dec 22 version 3.docx, Category: IRB Protocol; • Letter of Support Final Jan 12.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc);

The IRB approved the protocol from 1/3/2016 to 1/2/2017 inclusive. Three weeks before 1/2/2017 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 1/2/2017 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

Appendix H

6850 North Durango Drive, Suite #301, Las Vegas, Nevada 89149
Phone: 702-641-8500 • Fax: 702-641-8502 • pedsendo@horizonviewmc.com

January 12, 2016

To Whom It May Concern,

On behalf of Horizon View Medical Center, it is my pleasure to write a letter of support on the proposed evidence-based project on Pre-prandial Insulin Administration in School-aged Children and Teens, presented by faculty mentor Diana Jacobson and Ngoc Quyen Bui, RN, BSN, ASU-DNP student at Arizona State University.

I understand the proposed project aims to educate type 1 diabetics, ages 6-18 to prepare them pre-prandial insulin administration. Education will be provided to both the parents and the patients during scheduled office visits. As the goal of the project benefits our patient's health and well-being, I am granting permission for the project to be done at Horizon View Medical Center and Ms. Bui to have access to our electronic medical records.

Sincerely,

Rola Saad, MD

Briones, CPNP

Trisha Briones, CPNP

Appendix I

Demographic Table

Gender	**Male**	**Female**	
	3	4	
Ethnicity	**African American**	**Hispanic**	**Hispanic & Caucasian**
	3	3	1
Age	**8-12**	**13-17**	
	2	5	
Age of Diagnosis	**7-10**	**11-14**	**15-18**
	5	2	

Cost Analysis

Materials	**Cost**
Printing costs	5-10
Pens (available in each exam room)	0
Travel time & cost (gasoline)	6 hours ; $30
Total	35

Appendix J

6850 North Durango Drive, Suite #301, Las Vegas, Nevada 89149
Phone: 702-641-8500 • Fax: 702-641-8502 • pedsendo@horizonviewmc.com

Dear Parents of Horizon View Medical Center,

My name is Ngoc Quyen Bui RN, and I am a Doctor of Nursing Practice at Arizona State University. I have been granted permission from Dr. Rola Saad and Nurse Practitioner Trisha Briones APRN, CPNP to complete a practice change project for Horizon View Medical Center. I am working under the direction of Diana Jacobson PhD, RN, PPCNP-BC, FAANP at Arizona State University College of Nursing and Health Innovation.

The purpose of this Doctor of Nursing Practice (DNP) project is to educate you and your child about giving your child's insulin prior to the planned meal instead of giving the insulin after your child completes his or her meal. As a part of this DNP project, we would like to have you and your child fill out two short surveys, once at the beginning of the project and once again three months later, that ask questions about you, your child's health, your child's diabetes management and your knowledge about diabetes. Your child's blood glucose, hemoglobin A1c, and weekly blood glucose reports will be obtained from the electronic medical records at Horizon View Medical Center as part of this project. Your part in the DNP project will take the length of a routine office clinic visit (15-30 minutes) on two different days and this includes the time for diabetes management education and the completion of the surveys.

The inclusion criteria for parents and children in this project include a diagnosis of type 1 diabetes for at least 3 years for the child, stability of your child's health on his or her current health plan, the child's age between 6-18 years old, English speaking for both the child and parent, and the child with a HbA1c greater than 8% since last office visit.

A four digit identification (ID) number using the last four digits of your telephone number will be created at the initial visit. The purpose of this ID number is to protect you and your child's privacy.

Please let the front office staff or one of the providers know if you are interested in participating and Ms. Bui will give you more information.

Sincerely,

Ngoc Quyen Bui RN

Appendix K

How to create an identification (ID) number

- Choose a home, work, or cell phone that you and your child can easily remember.
- Use the last 4 digits of this phone number to create your personal ID for this research study.

Appendix L

Teaching Handout

Glycemic goals:

	HgA1c	Before Meals BG	Bedtime/Overnight BG
6-12 years	≤ 7.5%	90-180 mg/dL	100-180 mg/dL
13-19 years	≤ 7%	90-130 mg/dL	90-150 mg/dL

Recommended carbohydrates per meal:

	5-12 years	13-19 years
Male	45-60g	60-75g
Female	45-60g	45-75g

For hypoglycemic episodes, fast acting snacks need to provide 15-30g of carbohydrate

- 3-5 pieces of hard candy
- 4-6 ounces of regular soda or orange juice
- 2 tablespoons of raisins
- 8 ounces of nonfat or low fat milk

Schedule for Insulin Administration:

If blood glucose level is:	Give the insulin at this time before eating:
< 200 mg/dL	10 minutes prior to meal
200-300 mg/dL	20 minutes prior to meal
> 300 mg/dL	30 minutes prior to meal
If unable to predict carb intake	Correct the blood sugar prior to eating using the chart above

Contact information:

- In case of emergency: call 9-1-1
- For questions or concerns: call 702-641-8500 or email diabetes@horizonviewmc.com

References:

1. Centers for Disease Control and Prevention http://www.cdc.gov/features/diabetesinschool/
2. International Diabetes Federation https://www.idf.org/sites/default/files/attachments/HI62553-Carbohydrate-Counting-for-Children.pdf
3. American Diabetes Association http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/understanding-carbohydrates/carbohydrate-counting.html

Appendix M

First visit Child Survey

ID number **Date:**
Age: What was your last **HbA1c: _____**
Gender: Boy or Girl
Ethnicity:
Hispanic/Latino Asian Caucasian Black Pacific Islander Native American Other

1. **When do you give yourself insulin shots?**

   Before meals During meals After meals

2. **Are you comfortable giving yourself insulin shots?**

0	1	2
No	Maybe	Yes

3. **Do you know your current insulin to carbohydrate ratio (I:C)? If yes, what is it?**
   Yes No I don't know

4. **Put a check next to all the snacks that give you at least 15g of carbohydrates in case your blood sugar is less than 70 mg/dL?**

◯ 3-5 pieces of hard candy
◯ 4-6 ounces of regular soda or orange juice
◯ 2 tablespoons of raisins
◯ 8 ounces of nonfat or low fat milk

5. **Where on your body can you give insulin? Put a check mark next to all that are true.**

◯ Stomach
◯ Back of your arms
◯ Thighs

6. **How many days go by before you change where you give insulin?**

◯ I never change where I inject insulin.
◯ 1 day
◯ 2 days
◯ 3 days
◯ 4 days
◯ 5 days

Pre-assessment survey for Parents

ID number **Date:**
Child's current age: **Current HbA1c:**
Child's Age at diagnosis:
Please circle Parent Ethnicity:
Hispanic/Latino Asian Caucasian Black Pacific Islander Native American Other

1. **When do you or your child currently administer short-acting insulin?**

Before meals During meals After meals

2. **Do you think administering insulin before meals would improve your child's blood glucose control?**

Yes No I don't know

3. **How comfortable are you with insulin administration?**

1	2	3	4	5
Uncomfortable at all times	A little uncomfortable most of the time	Somewhat comfortable	Most of the time I am comfortable	Very comfortable all the time

4. **What is your child's current Insulin to carbohydrate ratio (I:C)?**

5. **Fill in the blank:**

If your child's blood glucose level is:	**Give the insulin at this time before eating:**
< 200 mg/dL	____ minutes prior to meal
200-300 mg/dL	____ minutes prior to meal
> 300 mg/dL	____ minutes prior to meal
If unable to predict carbohydrate intake	Correct the blood sugar prior / after (circle one) to eating using the chart above

6. **What area does your child use for insulin administration?**

7. **How often does your child rotate injection sites?**
8.

9. **What do you do if your child is sick and does not want to eat?**

Appendix N

Second Visit Child Survey

ID number **Date:**
Age: What was your last **HbA1c:** _____
Gender: Boy or Girl

1. **When do you give yourself insulin shots?**

Before meals During meals After meals

2. **Are you comfortable giving yourself insulin shots?**

0	1	2
No	Maybe	Yes

3. **Do you know your current insulin to carbohydrate ratio (I:C)? If yes, what is it?**

Yes No I don't know

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4. **Put a check mark next to all the snacks that give you at least 15g of carbohydrates in case your blood sugar is less than70 mg/dL?**

◯ 3-5 pieces of hard candy
◯ 4-6 ounces of regular soda or orange juice
◯ 2 tablespoons of raisins
◯ 8 ounces of nonfat or low fat milk

5. **Where on your body can you give insulin? Put a check mark next to all answers that are true.**

◯ Stomach
◯ Back of your arms
◯ Thighs

5. How many days go by before you change where you give insulin?

◯ I never change where I inject insulin.
◯ 1 day
◯ 2 days
◯ 3 days
◯ 4 days
◯ 5 day

Post-assessment survey for Parent

ID number: **Date:**

1. **Did you notice a change in blood glucose control with pre-meal administration? If yes or sometimes, what did changes did you notice?**

Yes No Sometimes

_____

2. **In the last week, how many times did your child have symptoms of hypoglycemia (IE. dizziness, clamminess, confusion, seizures)?**

0 days per week 1-3 days per week 4-5 days per week 6-7 days per week

3. **How comfortable are you with administering insulin for your child?**

1	2	3	4	5
Uncomfortable at all times	A little uncomfortable most of the time	Somewhat comfortable	Most of the time I am comfortable	Very comfortable all the time

4. **Are you satisfied with pre-meal administration of insulin for your child?**

1	2	3	4	5
Extremely dissatisfied	Somewhat dissatisfied	Neither satisfied or dissatisfied	Satisfied	Extremely Satisfied

5. **Was your child hospitalized, injured, or ill in the last 3 months? Describe the changes, if any, that occurred with your child's blood sugar control during these times. Please explain below.**

6. **What do you do if your child is sick and does not want to eat?**

7. **What area does your child use for insulin administration?**

8. **How often does your child rotate injection sites?**

9. **Fill in the blank:**

If your child's blood glucose level is:	**Give the insulin at this time before eating:**
< 200 mg/dL	____ minutes prior to meal
200-300 mg/dL	____ minutes prior to meal
> 300 mg/dL	____ minutes prior to meal
If unable to predict carb intake	Correct the blood sugar prior / after (circle one) to eating using the chart above

10. **Please write any other comments or concerns about pre-meal insulin administration here:**