Effectiveness of using Educational modules via bedside tablet in Newly Diagnosed Type 1 Diabetes

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Background:

Type I diabetes is one of the most common diseases of childhood and its incidence has been increasing worldwide. By age 18, 1 in 300 children will be affected by Type 1 Diabetes[1]. Not only are children diagnosed with diabetes met with significant morbidity due to their disease, but they are also expected to be active participants in daily often complicated treatment regimens. As children with Type 1 diabetes grow older and eventually spend time away from their parents or caregivers, they are forced to manage their own care. Over the last several years, health systems in the United States have become more patient-centered and have focused on autonomy and patient preference. With the advent of technology that makes self-directed education possible, this patient-centered approach needs to be applied to children diagnosed with Type I diabetes.

When clinicians are at the center of educating patients with diabetes, they often communicate more directly with parents, who then use the information they receive to manage their child's care. This model, however, does not account for the fact that children with diabetes will one day need to manage their own care and that patients who are active participants and who understand their disease process will be more likely to cooperate with treatment regimens and lifestyle interventions. It is often difficult for any patient, child or adult, to process educational information provided verbally in a physician's office, especially immediately after they have been diagnosed with a life-long disease. Educational tools therefore need to focus on incorporating methods that best serve the patients being educated.

Recent studies have shown that planned education through the use of technology leads to better outcomes in medication compliance, self-care, self-efficacy and psychosocial well-being[2]. Since individuals learn in different ways and at different paces, interactive educational tools can help patients and their families learn in a way that can be individualized and private and can also be fun and creative. As our patients are growing up surrounded by technology, the use of this technology for education might provide a sense of normalcy to children and teenagers already overwhelmed by processes that are often difficult for them to identify with or understand. We hope that patients and families who are given the opportunity to learn independently will become better equipped to manage self-care and will develop a sense of involvement in their treatment. Interactive tools will also help patients and families become more actively engaged in understanding their disease process and can help them to become more active participants in their care.

Study Design:

This is a prospective, randomized trial to evaluate the effectiveness of using educational modules accessed through a bedside tablet in patients newly diagnosed with Type 1 Diabetes as an adjunct to *standard HUMC diabetes education in comparison to only receiving *standard HUMC diabetes education. (standard HUMC diabetes education consists of paper based reading material and nursing education). *(See Data Dictionary Page 4 for definitions of education)*

Objectives of the Study:

Primary Objectives:

1. Study the effectiveness of using education modules accessed through a bedside tablet in patients newly diagnosed with Type 1 Diabetes with standard HUMC diabetic education in comparison to only receiving standard HUMC education as measured by pre-discharge diabetic knowledge questionnaires.

Secondary Objectives:

1. Study the use of education modules accessed through a bedside tablet in patients newly diagnosed with Type 1 Diabetes for improved subject compliance with glucose monitoring as measured by:
   a. Lower Hemoglobin A1C at initial follow up visit
   b. Lower number of hypoglycemic episodes during before initial follow up visit
   c. Increased compliance with daily blood glucose monitoring before initial follow up visit

Inclusion Criteria:

A subject may be considered for inclusion in the study if:

1. New diagnosed Type 1 Diabetes admitted to HUMC Pediatric Unit
2. Patient/Caretaker/Family willing to complete questionnaires

Exclusion Criteria:

A subject should be excluded if any of the following occur:

1. Patients with previous history of Diabetes
2. Patients with no plans to follow up at Hackensack UMC Pediatric Endocrinology – Molly's Center for Children with Diabetes and Endocrine disease
3. Non English speaking patients/family/caretaker

Methodology:

Subjects who meet all the inclusion criteria and none of the exclusion criteria will be eligible to participate in the study. Each subject who agrees to participate in the study will be required to sign consent (or Assent as necessary) and HIPAA prior to any study procedures.

Subjects will be considered enrolled in the study once consent is obtained.

Subjects will then be randomized to one of 2 arms:

Group 1 - HUMC standard Diabetic education
Group 2 - HUMC standard Diabetic education plus Bedside tablet with Diabetic modules
(See Data Dictionary Page 4 for definitions of education)

Subjects/family/caretakers from both randomized groups will then receive a diabetic knowledge pre-test questionnaire to be completed once consent is signed. *(See appendix #1)*

Subjects randomized to Group 1 will only receive standard diabetic education with HUMC nurses and handouts. Subjects who are randomized to Group 2 will receive standard diabetic education with HUMC nurses, handouts and access to a bedside tablet with diabetic modules. The Subjects/family/caretakers will be able to utilize the bedside tablet with educational modules at any time during their hospitalization.

Subjects/family/caretakers from both randomized groups will be required to complete a diabetic knowledge post-test questionnaire on the day of discharge from hospital *(See appendix #2).*

Labs such as Hemoglobin A1C *(See page 4)* and Blood Glucose monitoring values, which are standard of care, will be collected from subject's hospitalization and at subject's initial visit to the Molly's Diabetes Center. *(See schedule of events)*

Randomization:

Randomization to the study assignment will be generated via sealed envelope group assignment. Before randomization occurs, it is the responsibility of the study site staff to ensure eligibility has been met and that the ICF has been signed. Once subject has signed consent and eligibility has been confirmed, the subject will be randomized by pulling the next envelope in sequential order.

Discomforts and Risks:

No discomfort or risks are more than that which would be experienced with procedures associated with standard of care.

Duration of Study Participation:
Subjects will be followed until their initial appointment at Hackensack UMC Pediatric Endocrinology – Molly's Center for Children with Diabetes and Endocrine disease. Subject's initial appointment will be considered end of participation.

Subject Withdrawal:
Subjects may withdraw from the study at any time without penalty. Subjects or Study staff should notify the Principal Investigator of his/her desire to withdraw. The investigator may decide to withdraw subjects at any time during participation. All data that are collected up until the subject withdraws including an exit form should be submitted for review including the reason for subject's withdrawal.

End of participation:
A subject's participation would be considered completed after any of the following:

1. All Study visits complete
2. Subject/Principal Investigator withdrawal
3. Subject Lost to follow-up

Benefits:
There can be multiple benefits from this study. Many studies have shown that the intervention of technology in the chronically ill patients have great benefit. It will also reinforce the education they are receiving from HUMC staff, which could decrease length of stay of patient and also alleviate patients and families' anxieties regarding diabetes care.

Criteria for Evaluation Response:
Responses will be evaluated by questionnaires collected upon discharge and lab values at initial appointment at Hackensack UMC Pediatric Endocrinology – Molly's Center for Children with Diabetes and Endocrine disease.

Recruitment Procedures:
Subjects who meet all the inclusion criteria and none of the exclusion criteria will be eligible to participate in the study. Subjects will then be recruited at the hospital, which the Principal Investigator is associated with.

Data Analysis
The study will provide data that will be used to assess the effectiveness of using educational modules through a bedside tablet for newly diagnosed Diabetics. The analysis will be completed by the investigator and will be used to improve the education for newly diagnosed Diabetics at Hackensack UMC.

Confidentiality:

Study participants will be assigned a unique number at enrollment- All data will be coded. Identified patient data will not be released outside of HUMC. Only study personnel will have access to the list of participants and their codes.

Participants will use the number assigned at study enrollment for access to tablet.

Schedule of Events

	Enrollment	Discharge from Hospital	Follow Up
Inclusion/Exclusion	**X**		
ICF	**X**		
Labs (**)	**X**		**X**
Randomization	**X**		
Bedside Tablet (##)	**X**		
HUMC Standard Education	**X**		
Questionnaire	**X**	**X**	

****- Labs (Hemoglobin A1C) and Blood Glucose Monitoring are standard of Care**

- Group 2 randomized subjects only

Credentials, Training

No additional training is needed for the study.

References

1. Maahs DM, West NA, Lawrence JM , Mayer-Davis EJ. Chapter 1: Epidemiology of Type 1 Diabetes. Endocrinology and metabolism clinics of North America 2010;39:481-97.
2. Tait AR, Voepel-Lewis T , Levine R. Using Digital Multimedia to Improve Parents' and Children's Understanding of Clinical Trials. Archives of disease in childhood 2015;100:589-93.

Data Dictionary:

HUMC standard Diabetic education: Standard education consists of "one on one" education with a HUMC Registered Nurse as well as patients/family/caregivers receive HUMC approved diabetic educational handouts. *(See appendix # 3)*

Bedside Tablet Modules: The Diabetic education modules on the bedside tablet for this study consist of the approved HUMC diabetic handouts created into an online applications. *(See appendix# 4-8)*

Hemoglobin A1C – Lab test used to screen for and diagnose Diabetes. It tells the average blood sugar over 2 – 3 months.

Appendix #1 (Pre-Test)

1) What is Type 1 DM?
   a) Autoimmune disorder
   b) Caused by insensitivity to insulin
   c) Thyroid problem
2) How is Type 1 DM treated?
   a) Pills
   b) Diet and exercise alone
   c) Insulin therapy
3) Diabetes is treated by how many types of insulin:
   a) Humalog-Short acting along
   b) Lantus-Long acting alone
   c) Both insulins together in basal/bolus strategy
4) Hypoglycemia is treated by:
   a) Giving protein
   b) Giving 15 grams of fast acting carbohydrates (4oz of juice)
   c) Eating chocolate
5) Ketones are treated by:
   a) Increased insulin amounts
   b) Fasting acting carbohydrates
   c) Increased insulin and hydration
6) After exercise your blood sugar can be:
   a) Lower
   b) Higher
   c) Both
7) In diabetes management:
   a) Increased carbohydrates are good
   b) Healthy diet with less carbohydrates and more protein
   c) It does not matter what you eat
8) New ways of managing diabetes include:
   a) Insulin pump and Continuous Glucose Monitoring Sensor (CGMS)
   b) Mechanical pancreas
   c) My doctor will control
9) If you cannot take any fluids or foods by mouth, what are your options:
   a) Come to ER
   b) Just wait and see what happens
   c) Come to Doctor the next day
10) When should I take my insulin for my meals:
   a) Before my meal
   b) Within 15 min of starting to eat
   c) After I eat
   d) Both a and b could be correct depending on age

Appendix #2 (Post-Test)

1) What is Type 1 DM?
   a) Autoimmune disorder
   b) Caused by insensitivity to insulin
   c) Thyroid problem

2) How is Type 1 DM treated?
   a)Pills
   b) Diet and exercise alone
   c) Insulin therapy
3) Diabetes is treated by how many types of insulin:
   a) Humalog-Short acting along
   b) Lantus-Long acting alone
   c) Both insulins together in basal/bolus strategy

4) Hypoglycemia is treated by:
   a) Giving protein
   b) Giving 15 grams of fast acting carbohydrates (4oz of juice)
   c) Eating chocolate

5) Ketones are treated by:
   a) Increased insulin amounts
   b) Fasting acting carbohydrates
   c) Increased insulin and hydration
6) After exercise your blood sugar can be:
   a) Lower
   b) Higher
   c) Both
7) In diabetes management:
   a) Increased carbohydrates are good
   b) Healthy diet with less carbohydrates and more protein
   c) It does not matter what you eat
8) New ways of managing diabetes include:
   a) Insulin pump and CGMS(Continuous Glucose Monitoring Sensor)
   b) Mechanical pancreas
   c) My doctor will control

9) If you cannot take any fluids or foods by mouth, what are your options:
   a) Come to ER
   b) Just wait and see what happens
   c) Come to Doctor the next day

10) When should I take my insulin for my meals:
   a) Before my meal
   b) Within 15 min of starting to eat
   c) After I eat
   d) Both a and b could be correct depending on age

Appendix #3 – Hackensack Diabetes Care Guide

Appendix# 4 – 7 Modules

a. Diabetes and Technology
b. Exercise and Diabetes
c. Hypoglycemia
d. Nutrition and Type 1 Diabetes
e. Post test
f. Pre test
g. Sick Day Management