Summer 8-9-2019

The Effectiveness of Registered Dietitians in Diabetes Case Management

Meghan C. McLarney
University of Nebraska Medical Center

Follow this and additional works at: https://digitalcommons.unmc.edu/etd

Part of the Dietetics and Clinical Nutrition Commons

Recommended Citation
https://digitalcommons.unmc.edu/etd/386

This Thesis is brought to you for free and open access by the Graduate Studies at DigitalCommons@UNMC. It has been accepted for inclusion in Theses & Dissertations by an authorized administrator of DigitalCommons@UNMC. For more information, please contact digitalcommons@unmc.edu.
The Effectiveness of Registered Dietitians in Diabetes Case Management Compared to Usual Care

by

Meghan McLarney, RD, LMNT, CDE, CNSC

A THESIS

Presented to the Faculty of the University of Nebraska Graduate College in Partial Fulfillment of the Requirements for the Degree of Master of Science

Medical Sciences Interdepartmental Area Graduate Program (Medical Nutrition)

Under the Supervision of Professor Corrine K. Hanson

University of Nebraska Medical Center Omaha, Nebraska

May 2019

Advisory Committee:
Ann Anderson Berry, MD
Elizabeth Lyden, MS
Glenda Woscyna, MS, RD
ACKNOWLEDGEMENTS

This thesis would not have been possible without the genuine encouragement and direction provided by my advisor, Corrine Hanson. Corri, I thank you for your example and guidance which planted seeds of determination to develop my abilities and to pursue an education beyond the classroom. Thank you for supporting me as I sought to developed my integrity, understanding and contribution as a member of the scientific community. I will be forever grateful for your willingness to allow me into the Master of Science program at the University of Nebraska Medical Center and will carry the torch to continue my learning.

My appreciation also extends to my advisory committee, Dr. Anderson Berry, Elizabeth Lyden and Glenda Woscyna. Your patience, time, instruction, and expertise have been invaluable in my learning process and I cannot thank each of you enough. It has been truly meaningful to learn in your company.
Effectiveness of Registered Dietitians in Diabetes Case Management Compared to Usual Care

Meghan McLarney, RD, LMNT, CDE

University of Nebraska, May 2019

ABSTRACT

Advisor: Corrine K Hanson, PhD, RD, LMNT

OBJECTIVE: The objective of this paper is to investigate the effectiveness of diabetes education provided by registered dietitians (RD) in a diabetes case management (DCMs) model, compared to diabetes education provided by RDs in the usual care model (UCM) at an outpatient endocrinology clinic in Omaha, Nebraska. This study hypothesizes that education by RD DCMs will be equal or more efficacious in regards to primary outcomes of A1C and BMI and secondarily, lipid results and adherence (total encounters) when compared to outcomes of UC.

METHODS: This is a cross sectional retrospective review of patients with diabetes (n=946), receiving traditional RD education (n=445) and DCM (n=501). Groups had like distribution of A1C and lipids at baseline. The DCM group had a higher BMI, higher percentage of male subjects and older population compared to the UCM at baseline. BMI, Lipids, A1C and total encounters were compared from initial visit to 12 months. SPSS software provided descriptive statistics of the sample groups and independent samples t-test for differences of means between groups. P-value of < 0.5 was considered statistically significant.

RESULTS: Primary outcomes were endpoint A1C and BMI and mean change in A1C and BMI at 1 year. Endpoint A1C was lower in the DCM (8.0 vs. 8.4, p= 0.02). Mean A1C change was -0.4 in DCM, compared with -0.2 in UCM (p=0.06). Endpoint BMI was higher in the DCM (32.7 vs 31.5, p=0.04), however BMI declined slightly ( -0.04) in DCM and increased slightly ( + 0.2) in the UCM (p=0.07). Secondary findings included greater mean change in LDL in DCM (+1.78 vs - 4.16, p=0.002) and higher number of overall encounters with RD (10.01 vs 7.39) and
Endocrinogist (11.11 vs 8.22) (p=0.001) in DCM group. No significant differences were found in HDL or Triglycerides.

**CONCLUSION:** The DCM group had improvements in endpoint and change in A1C and change in LDL. Of note, the DCM group results for mean change in BMI showed a trend toward significance. DCM subjects attended more visits with the RD and Endocrinologist, suggesting more engagement in the DCM than the UCM. Further research should analyze interventions within the DCM model, compared to the UCM. Additional study is needed regarding cardiovascular risk benefit over time and cost-benefits of the model.
# TABLE OF CONTENTS

**ACKNOWLEDGEMENTS** .................................................................................................................. i

**ABSTRACT** ...................................................................................................................................... ii

**TABLE OF CONTENTS** ................................................................................................................. iii

**LIST OF FIGURES** ......................................................................................................................... v

**LIST OF TABLES** ............................................................................................................................. vi

**LIST OF ABBREVIATIONS** ........................................................................................................... vii

**CHAPTER 1: INTRODUCTION** ...................................................................................................... 9

**CHAPTER 2: BACKGROUND & REVIEW OF LITERATURE** .......................................................... 10

  **OVERVIEW OF DIABETES EDUCATION MODELS** ................................................................. 10
    Usual Care Model and Diabetes Self-Management Education ...................................................... 10
    Diabetes Case Management .......................................................................................................... 12

  **DIETITIANS IN DIABETES CASE MANAGEMENT** ................................................................. 16

  **MEASURES OF DIABETES MANAGEMENT** ............................................................................ 18
    Hemoglobin A1C ............................................................................................................................ 18
    BMI and WEIGHT MANAGEMENT ............................................................................................... 19
    BLOOD LIPIDS ............................................................................................................................. 20

**CHAPTER 3: METHODS** ............................................................................................................... 21

  **STUDY DESIGN AND POPULATION** ......................................................................................... 21

  **DATA COLLECTION** .................................................................................................................. 22

  **STATISTICAL ANALYSIS** ......................................................................................................... 21

**CHAPTER 4: RESULTS** ................................................................................................................. 27

  **SUBJECT CHARACTERISTICS** ................................................................................................... 27

    A1C Results ................................................................................................................................. 28

    BMI Results ............................................................................................................................... 29
Blood Lipid Results ........................................................................................................ 29
Number of Encounters .................................................................................................... 29

CHAPTER 6: DISCUSSION .......................................................................................... 34
CHAPTER 7: CONCLUSION ...................................................................................... 40
CHAPTER 8: BIBLIOGRAPHY .................................................................................. 41
LIST OF FIGURES

Figure 1: Components of Diabetes-self Management Training ................................................. 11
Figure 2. Change in A1C at 12 Months .................................................................................. 29
Figure 3. Change in LDL at 12 Months ................................................................................ 31
Figure 4. Total Endocrine MD Encounters at 12 Months .................................................... 32
Figure 5. Total RD Encounters at 12 Months ...................................................................... 32
## LIST OF TABLES

Table 1: A1C and Estimated Average Glucose Correlates ................................................. 19
Table 2: Recommended A1C Targets for Adults................................................................. 19
Table 3: Baseline Comparison .......................................................................................... 28
Table 4: Results ............................................................................................................... 33
Table 5: Primary Outcomes of the RD DCM Compared with Literature Review of Similar
Studies............................................................................................................................... 34
Table 6: Secondary Outcomes of the RD DCM Compared with Literature Review of Similar
Studies............................................................................................................................... 34
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>Hemoglobin A1C</td>
</tr>
<tr>
<td>AND</td>
<td>Academy of Nutrition and Dietetics</td>
</tr>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CCM</td>
<td>Certified Case Manager</td>
</tr>
<tr>
<td>CDE</td>
<td>Certified Diabetes Educator</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular Disease</td>
</tr>
<tr>
<td>CDM</td>
<td>Chronic Disease Model</td>
</tr>
<tr>
<td>DCM</td>
<td>Diabetes Case Management Model</td>
</tr>
<tr>
<td>DDL</td>
<td>Diabetic Dyslipidemia</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>DSM</td>
<td>Diabetes Self-Management</td>
</tr>
<tr>
<td>DSMT</td>
<td>Diabetes Self-Management Training</td>
</tr>
<tr>
<td>IRB</td>
<td>Internal Review Board</td>
</tr>
<tr>
<td>HDL</td>
<td>High Density Lipoprotein</td>
</tr>
<tr>
<td>LDL</td>
<td>Low Density Lipoprotein</td>
</tr>
<tr>
<td>NM</td>
<td>Nebraska Medicine</td>
</tr>
<tr>
<td>NCM</td>
<td>Nurse Case Manager</td>
</tr>
<tr>
<td>NCP</td>
<td>Nutrition Care Process</td>
</tr>
<tr>
<td>RD</td>
<td>Registered Dietitian</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse</td>
</tr>
<tr>
<td>TG</td>
<td>Triglyceride</td>
</tr>
<tr>
<td>UCM</td>
<td>Usual Care Model</td>
</tr>
</tbody>
</table>
CHAPTER 1: INTRODUCTION

Diabetes is a chronic disease approaching national and international epidemic proportions and is predicted to impact as many as 1 in 3 Americans by 2050.\textsuperscript{1,2} The crux of chronic disease management is patient understanding which facilitates patient adherence to an evolving and dynamic care plan. Thus, patient education is foundational to diabetes clinical care. It is crucial that optimal interventions be identified and developed to improve outcomes for the people affected by diabetes. Standards of care are founded upon diabetes self-management training and medical nutrition therapy from a registered dietitian.\textsuperscript{3,4,5,6,7,8,9,10,11} Emerging evidence shows that diabetes educators are effective as case managers who facilitate improved adherence and glycemic control.\textsuperscript{12,13,14,15}

Registered Dietitian (RD) educators are integral to the traditional, nutrition focused diabetes education model, which this paper refers to as the Usual Care Model (UCM). Although there are a smattering of publications supporting the role of the RD in DCM, there are no studies demonstrating the clinical outcomes of patients educated by an RD Case Manager.\textsuperscript{12,13,14,15,16} Research is needed to determine if RDs can be effective in improving patient outcomes when utilized in the case manager role. Research is needed to define diabetes case management as it applies to the outpatient clinic setting in order to develop recommendations for optimal education and care, thereby maximizing potential positive health outcomes.
CHAPTER 2: BACKGROUND

Population

Diabetes is a chronic disease which is driven by complex genetic and lifestyle factors. The diabetes population is comprised of approximately 90 percent type 2 diabetes, 10 percent type 1 diabetes and a small number of variant types.\(^\text{17}\) In this paper, reference to UCM or DCM will include type 2 and type 1 diabetes only. Type 2 diabetes is classified as “progressive insulin secretory defect on the background of insulin resistance,” whereas type 1 diabetes is classified as an autoimmune condition which damages the pancreas resulting in loss of insulin production.\(^\text{17}\)

The cornerstones of diabetes management are glycemic and weight control as they precede a multitude of comorbid risks.\(^\text{18}\) Uncontrolled diabetes is related to a 10 fold increase in risk of end stage renal failure and a 2 to 3 fold risk of cardiovascular disease.\(^\text{18}\) Related to management and prevention of complications, the cost of diabetes in the United States is staggering, and was estimated at 245 billion dollars per year in 2012. Poorly controlled diabetes is profoundly detrimental to quality of life for PWD as the burden of the disease impacts financial stability, emotional wellbeing and coping abilities.\(^\text{19,20,21,22}\)

Usual Care Model

The ethos of diabetes care is self-management, which specifies that a person with diabetes (PWD) must engage in their disease management in order to prevent complications. To achieve self-management, PWD should receive diabetes self-management training (DSMT) which provides individualized education focused on providing foundational knowledge and strategies to implement beneficial lifestyle modification.\(^\text{3,4,5,8,9,10,23,24}\) DSMT is a collaboration between the educator and the PWD which is recommended at diagnosis, annually, with new complications and at transitions of disease management. Essentially, DSMT is relevant throughout the course of the disease. The seven primary facets of DSMT which are known as the AADE7, are listed in Figure 1.\(^\text{9}\)
Figure 1. Components of Diabetes-self Management Training

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Healthy Eating</td>
</tr>
<tr>
<td>2.</td>
<td>Exercise</td>
</tr>
<tr>
<td>3.</td>
<td>Taking Medications</td>
</tr>
<tr>
<td>4.</td>
<td>Monitoring</td>
</tr>
<tr>
<td>5.</td>
<td>Healthy Coping</td>
</tr>
<tr>
<td>6.</td>
<td>Problem Solving</td>
</tr>
<tr>
<td>7.</td>
<td>Reducing Risks</td>
</tr>
</tbody>
</table>

DSMT is delivered by nurses, registered dietitians, exercise physiologists, pharmacists and other health care professionals, who traditionally hold a specialty credential title such as certified diabetes educator (CDE). Advanced training and certification lend a specialized skill set to the CDE who must facilitate DSMT through the process of assessment, goal setting, counseling, education and evaluation.$^8,9,10$

Referral to an RD for medical nutrition therapy (MNT) is a widely accepted standard of the UCM and is stated as such in consensus statements from The American Diabetes Association, American Association of Clinical Endocrinologists, American Association of Diabetes Educators and Academy of Nutrition and Dietetics. The standards recommend that the RD provide MNT at diagnosis. The American Diabetes Association, American Association of Diabetes Educators and Academy of Nutrition and Dietetics also recommend that in addition to MNT by an RD at diagnosis, an evaluation of needs for MNT should be provided with new complications and transitions of care.$^3,4,8,9,10,39$

Though DSMT and MNT are recommended as the standard in the UCM, the structure of such interventions remains undefined. Recommendations are ambiguous, for example DSMT may be provided in absence of MNT and likewise, MNT may be provided in absence of DSMT. In the UCM, the frequency, order and source of education are not defined; a PWD may see the
RD for MNT and the CDE for DSMT in a series of classes or individually. Such ambiguity may result in lower than desired referral rates; Overall, national referral rates to diabetes education are strikingly low at approximately 5% of those diagnosed.20

One potential benefit of the DCM is ongoing support and education, which may help sustain benefits attained through education. Although DSMT improves diabetes control, effects diminish over time. Improvements in glycemic control, weight loss and behavior change typically regress by approximately 6 months post-intervention.22, 25 This can be explained in part by the challenge of increased risk for hypoglycemia with lifestyle changes such as diet and exercise. Fear of hypoglycemia negatively influences physical activity, eating and adherence to diabetes medications. Additionally, medication induced glycemic control often comes at the cost of weight gain. For example, the addition of hypoglycemic medications such as insulin and oral sulfonylureas are strongly correlated to weight gain. In the large multicenter United Kingdom Prospective Diabetes Study (UKPDS), PWD gained weight over time, and required additional medications after just 3 years. PWD using insulin had the most weight gain and hypoglycemia complications. UKPDS was a pivotal study, and contributed to current standards of practice by demonstrating the need for education and support in managing diabetes. The study found that although diabetes progressed in all groups regardless of medication regimen, subjects who remained diet controlled with good adherence had better glycemic results, or slower regression of control.25

The progressive nature of diabetes and the inherent complexities of self-management require ongoing support. In answering this challenge, chronic care models are shifting toward a component of just-in-time education and ongoing support methods, including the novel approach of case management.

**Diabetes Case Management**

The principles of chronic disease case management are the underpinning of DCMs, which serve as a platform to support and guide patients through chronic disease care. There is no
standard definition of the specific role of the diabetes case manager; some DCMs utilize the case manager as an educator whereas others focus on coordination and referrals to providers of education. One assumption of case management is that coordinated care and education is better for patient outcomes. The comprehensive nature of case management lends itself to the diabetes management role and accommodates coordination of comorbid conditions such as obesity, hypertension, dyslipidemia and renal disease. Currently, the prevailing providers of DCM are RNs and RN CDEs.

The Commission for Case Manager Certification (CCMC) defines case management as “a collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet the client's health and human service needs. It is characterized by advocacy, communication, and resource management and promotes quality and cost-effective interventions and outcomes.” Populations with comorbidities of diabetes are of particular focus in pilot studies of DCM with the aim of improving glycemic control, comorbid complications and cost. The CCMC offers a reason that chronic disease case management is on the rise, asserting that it holds benefits for all health care stakeholders. “The benefits of case management accrue to all participants in the process. Consumers gain an advocate and emotional support. Physicians and hospitals have complex cases facilitated. And payers’ costs are reduced while their customers are retained.”

Outcomes of the DCM

Primary studies showcasing DCMs have targeted improved Hemoglobin A1C, cholesterol, blood pressure, adherence, quality of life and cost reduction as outcomes. Though weight management is a primary target of diabetes management, DCM studies lack data on this outcome. Gilmer, et al measured weight and BMI change but found no significant difference in BMI even with a large sample size of 3,893 and therefore excluded the results from reported outcomes.
DCM’s are a burgeoning practice, therefore publications of protocols and standards are useful and timely. One randomized control trial published by Ishani et al. utilized a medication titration protocol, referred to as a “therapeutic algorithm” as part of the DCM in a veteran population. The protocol describes pharmacological targets and titration schedule for blood pressure, blood lipid and blood glucose regulation, including oral hypoglycemic medications and insulin. Ishani’s DCM emphasizes the role of supportive non-pharmacological dietary interventions and provides instruction to refer to an RD if 1.) Mealtime insulin is started or 2.) If lipids are not in target. In the case of dyslipidemia, an RD referral is made in addition to referral to the MOVE weight loss program.27

Another publication by Watts et al. has outlined the role of the diabetes case manager and clearly documented protocols followed in their DCM.22 Watts provides a detailed look at the DCM, providing examples of the educator’s role in DCM. More publications of this nature are needed, in order to define standards for diabetes case management. Watts defines case management as “the assignment of authority to a professional (the case manager) who is not the provider of direct health care, but who oversees and is responsible for coordinating and implementing care,” and furthermore, published definition of the (nurse) case manager (NCM) role in diabetes management outlined the duties of diabetes case management as:

- Treatment planning, glucose monitoring, medication regulation and titration, and close observation of patients’ progress through telephone and face to face encounters.
- Work on lifestyle and medication management practices that will improve clinical outcomes.
- Work closely with patients to help them accept responsibility for the management of their diabetes and health related problems.
- Possess a high level of skill in diabetes clinical practice, interpersonal relationship, and leadership skills to positively affect diabetes care for adult and aging patients.
• NCMs enable practices to enhance access to care for patients.

• NCMs align with adult learning theory (i.e., adults learn best via problem-based learning and problem-solving that is directly relevant to the individual learner).
  
  • The patient apprenticeship to learn self-management provides unique and ideal pairing of education and medical management to benefit the patient; NCMs engage patients in problem-solving the management of their own daily glucose patterns in real-time at a faster pace than is typical for medical practice relying solely on appointments with experts and PCPs.⁸⁻⁹

**Cost Effectiveness of DCM**

One study by Gilmer et al. estimated lower healthcare costs in a DCM after an average of 5 visits per year with an RN CDE in a DCM. Cost estimates were made using a CDC cost effectiveness calculator called QALY and were compared to the Center for Outcomes Research Model (CORE) which has also been used to assess cost savings of diabetes prevention. Overall estimated cost savings were lowest in the uninsured group (saving $7,933 per year) and highest in the commercially insured group ($57,587 per year). The study found that the first year of case management would result in a reduction of approximately $707 in emergency and hospital costs however would not offset an overall increase of costs by approximately $1,383 dollars with approximately $507 attributed to education fees, $1,582 attributed to pharmacy costs (p=0.06). Approximately 50 percent of the participants in this study also saw an RD or attended a 4 part group class as part of the DCM.₂⁶ Although this complicates study design, it is true to actual diabetes management as mentioned earlier, the use of DSMT, group class and MNT are variable.

**Glycemic Outcomes**

Overall, the DCM made positive improvements on glycemic control and when compared to a UCM, the DCM had a greater impact on lowering A1C and LDL. Shea et al. showed a 5 year treatment effect of 0.29 % lower A1C in the DCM versus the UCM.²⁹
There has long been significant evidence that nutrition education from a registered dietitian (RD) improves dietary intake and glycemic control, among other diabetes management outcomes. Similarly, diabetes nurse educators have improved health outcomes such as A1C and patient adherence through the DCM. There are synergetic concepts shared by the theoretical framework used in nutrition management, which is called the Nutrition Care Process (NCP) and the Case Management Model (CMM), positioning RDs to be effective as case managers. The RD manages patients using the NCP framework, which consists of accordant concepts and applications to the DCM. “The Nutrition Care Process is a systematic approach to providing high quality nutrition care. The NCP consists of four distinct, interrelated steps: nutrition assessment, diagnosis, intervention, monitoring/evaluation. Use of the NCP does not mean that all patients get the same care. Use of a care process provides a framework for the RDN to individualize care, taking into account the patient’s needs and values and using the best evidence available to make decisions.”

There are few studies which indirectly demonstrate the RD as a case manager, however none of these studies provide a true DCM intervention where the RD coordinates and/or provides DSMT. One study by Franz et al. alludes to the RD in a manager role, compared to the UCM. The study defined the UCM as 1 visit with the RD and DCM as 3 visits with the RD and therefore was not designed to provide the basic standard of individualized care or the minimum standard of DSMT, focusing instead on MNT alone. A randomized control trial in Taiwan utilized the RD as the sole provider of education for patients with diabetes. The study did not cite any specific case management protocols and maintained an MNT focus, as it measured dietary adherence to calorie, fat and carbohydrate reduction as primary outcomes.

Gaps
No publications outline the role of the RD case manager, nor protocols demonstrating the scope of work of the RD case manager. This study aims to provide such preliminary documentation. Little is known of the clinical effectiveness of RDs in case manager roles, despite consensus that RDs are essential in the education team, thus showing a need for data demonstrating the effectiveness of the RD in the diabetes case manager role. Though weight management is a primary intervention for those with type 2 diabetes, who comprise 90% of all cases, no DCMs have used weight change as a primary outcome. It is possible that weight management was not considered as an outcome in publications of DCM because the providers are primarily RNs and may be outside of the scope of the educator. Conversely, in the RD DCM, MNT could be integrated with DSMT by the RD who is specially trained in weight management.

One publication printed in 2002, titled “Case Management Positions Offer Rewarding Educational Opportunities for Registered Dietitians” provided interview commentary from RD case managers. The investigators did not cite outcomes of the RD in the DCM or prevalence of the RD in such a role but noted “strong affirmations of why registered dietitians are positioned for taking on the disease and case management role”.

The literature has documented RDs working as diabetes case managers for over 25 years, however there is almost no focused research defining this work or studying outcomes. Although RDs are qualified to work as diabetes case managers, and despite the rise of employment in case manager roles, there are few RD diabetes case managers. The absence of research on the effectiveness of RDs as diabetes case managers has likely contributed to the lag in development of standards and resources needed to develop RDs as diabetes case managers. Currently, the value of the RD in the outpatient diabetes setting has been well documented and nutrition education by an RD is considered a standard of care, however there is a significant gap in research on the effectiveness of RDs working within newer models i.e. disease case management. We need further research showing the effectiveness of RDs in case manager roles.
in order to develop standards for diabetes case management and in turn, drive new opportunities for RDs to improve outcomes for patients with diabetes, as diabetes case managers.

The RD DCM may prove especially relevant in endocrinology populations as they are capable of comprehensively managing the education needs of complex patients who have significant nutrition management needs.

MEASUREMENTS OF DIABETES CONTROL

Standard measurements of diabetes management and control are the A1C test, BMI and blood lipids. These standard measurements provide insight to clinical management of cardiovascular risk and overall glycemic control. Blood pressure and quality of life are also common measurements, though less commonly reported. The ADA recommends a goal glucose range of 70-180 mg/dl on average.

A1C

The A1C is a blood test used to diagnose and monitor diabetes. The A1C test is scored on a scale of 4 to 16 which correlates to an estimated average glucose level. The test takes into account the previous 90 days though it is weighted toward the most recent 30 days. Annual A1C testing is a standard of diabetes care. Biannual and quarterly A1C testing is indicated in patients with uncontrolled disease.
### Table 1. Estimated Average Glucose and A1C Correlates\(^{5,39,42}\)

<table>
<thead>
<tr>
<th>Categorization of Glycemic Control</th>
<th>A1C %</th>
<th>Estimated Average Glucose mg/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good Control</td>
<td>6.0*</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td>7.0</td>
<td>150</td>
</tr>
<tr>
<td>Uncontrolled</td>
<td>8.0 **</td>
<td>180</td>
</tr>
<tr>
<td>Uncontrolled</td>
<td>9.0</td>
<td>215</td>
</tr>
<tr>
<td></td>
<td>10.0</td>
<td>250</td>
</tr>
<tr>
<td></td>
<td>11.0</td>
<td>280</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>315</td>
</tr>
<tr>
<td></td>
<td>13.0</td>
<td>350</td>
</tr>
<tr>
<td></td>
<td>14.0</td>
<td>380</td>
</tr>
<tr>
<td></td>
<td>15.0</td>
<td>410</td>
</tr>
<tr>
<td></td>
<td>16.0</td>
<td>440</td>
</tr>
</tbody>
</table>

*6.5% is diagnostic for diabetes  
**8% A1C is uncontrolled with exception of those at risk for hypoglycemia, intentionally controlled at a higher average glucose level

### Table 2. Recommended A1C Targets for Adults\(^{5,39}\)

| A1C Parameter | Treatment Goal                                                                 |}
|---------------|--------------------------------------------------------------------------------|
| <6.5%         | • Short duration of diabetes  
|               | • Long life expectancy  
|               | • No concurrent illness  
|               | • Goal can be achieved without significant hypoglycemia or other adverse effects of treatment |
| <7.0%         | • Goal for most patients  |
| <8.0%         | • History of severe hypoglycemia  
|               | • Limited life expectancy  
|               | • Advanced microvascular or macrovascular complications  
|               | • Extensive comorbid conditions  
|               | • Long-standing T2D in which A1C goal has been difficult to obtain despite intensive efforts |

**BMI**

Body mass index (BMI) is a measure of body fat which factors both height and weight. A BMI between 18.5 and 24.99 is considered optimal. BMI of 25 to 29.99 is categorized as overweight and a BMI of 30.0 or higher is classified as obesity. Obesity is a driver of insulin resistance and progression of type 2 diabetes and exacerbates comorbidities including hypertension, renal disease and cardiovascular disease. Treatment of obesity is foundational to diabetes management. In the 1999-2004 NHANES study of people with type 2 diabetes, 27% of the participants were overweight (BMI 25–29 kg/m\(^2\)) and 61% were obese (BMI ≥30 kg/m\(^2\)).\(^{30,41}\)

**Blood Lipids**

Blood lipids are monitored at least annually in the UCM and are checked as often as quarterly if aggressive drug or lifestyle treatment is implemented. Dyslipidemia is a common condition in PWD where cholesterol, LDL or TG are too high and/or HDL is too low.\(^6,20\) The National Health and Nutrition Examination Survey (NHANES) cohort found that from 1999-2004 found that 46% of PWD had elevated blood lipids\(^{33}\). Guidelines by the American Association of Clinical Endocrinologists as well as the American Diabetes Association recommend annual screening with a fasting lipid profile.\(^{6,9,22,23,25,30,38}\)
CHAPTER 3: METHODS

STUDY DESIGN AND POPULATION

Study Design

This study was approved by the institutional review board at the University of Nebraska Medical Center. The study design is a retrospective chart review of patients seen at the Nebraska Medicine Endocrinology Clinic Diabetes Education Center. All 945 subjects were reviewed and coded into one of two independent groups: UCM or DCM based upon date of initial RD visit.

Study Population

The study population included adult patients with a diagnosis of diabetes who had a new referral for diabetes education between 2011 and 2014. In this time period, the clinic adopted a change in education models, implementing the DCM which allowed for observation of outcomes in UCM prior to the change as well as DCM after the change occurred. Subjects in this study were treated either with a UCM or treated with a DCM, with no overlap. Subjects seen between 2011 and 2012 received usual care. In the UCM, the primary focus of the patient visit is nutrition education, given by an RD CDE. Subsequent visits could have been assigned to any educator working at the clinic, and may have included a different RD, RN, exercise physiologist or the initial RD educator. In the UCM follow up with the initial educator was not a standard practice. In December of 2012 the endocrinology clinic changed the diabetes education model from a UCM to a DCM. In the DCM, all patients who were referred to an RD CDE were provided MNT and all other DSMT with the same RD in subsequent visits, placing an emphasis on relationship-based care. The DCM group had a protocol which allowed for to adjust of insulin in increments of 5-10% every 3 to 7 days until patients were in a goal glycemic range of 70-120mg/dl fasting or 121 to180 mg/dl post prandial. We assumed that the education model did not change immediately and that a transition phase occurred while education, training, and cultural adaptation of DCM took place; therefore a washout period of three months was used during this time in order and any subjects seen from December 2012 to February 2013 were omitted.
Exclusion Criteria:

Patients who did not have a follow up visit were deleted from the dataset prior to analysis, as those patients were considered to have incomplete education per the UCM and therefore did not qualify as case management DCM. Any values outside of a plausible biological range in an adult population with diabetes were omitted. Baseline BMI values under 18.5 were omitted. Patients with a baseline A1C at or below 7% or those who had no documented current (within 3 months before) A1C test results at the initial visit were also excluded from the comparison analysis.

Data Collection

All data were collected by a trained graduate students who was also a qualified RD CDE via medical record review. After obtaining Institutional Review Board approval, an electronic report was prepared to include patient information from new encounters seen by the RD between 2011 and 2014. Specifically, data were collected for patients seen in the UCM from January 2011 to January 2012 as well as patients seen by the RD case manager after the model change to DCM, from February 2013-February 2014. Only patients with type 1 and type 2 diabetes were included. Subjects with type 1 and type 2 diabetes were identified by having an active diagnosis listed in the electronic medical record with ICD-9 codes (250.0, 250.01, 250.02) indicating diagnosis of type 1 or type 2 diabetes.

Data collected included the number of return visits, A1C levels at initial visit (baseline), 3, 6 and 12 months, LDL, HDL and TG at 3, 6 and 12 months, BMI at initial visit and at 3, 6 and 12 months. Due to variability both in frequency of visits and measurements taken, endpoint values were defined as the last value recorded in the 12 month review period, excluding the baseline value at visit 1.
**A1C**

It was standard practice for PWD to have A1C labs drawn and processed at the Nebraska Medicine Clinical Laboratory quarterly at MD visits. A1C, also referred to as hemoglobin A1C and glycated hemoglobin, was chosen as a primary biomarker of diabetes control. Compared to glucose testing, the A1C has no special preparation (such as fasting) necessary. This test is superior to blood glucose values due to the cumulative nature of the test and linear association with estimated average glucose. The A1C mitigates variability seen in singular glucose values, which have limitations and only reflect a point in time versus overall control.\(^{39,43}\) Per protocol at the Nebraska Medicine Clinical Laboratory, hemoglobin A1C is measured by obtaining a 1 - 2.5 mL of whole blood sample, accepted by finger stick or venous draw. Whole blood chemistry diagnostics are conducted through Trinity Biotech Boronate Affinity Chromatography onsite at the Nebraska Medicine Clinical Laboratory. Quality controls for the Trinity Biotech Boronate Affinity Chromatography require analysis within 6 days of blood draw. A1C results used in this study were completed on the same day as the lab draw Monday through Friday, or on the next business day if drawn after 4pm or a Saturday or Sunday. Therefore, the Nebraska Medicine Clinical Laboratory protocol is written in accordance with Trinity Biotech specifications\(^{34,40,43}\)

**BMI**

It was standard practice for PWD to have BMI measured at least quarterly at MD visits. BMI was calculated as kg/m\(^2\) by an automated algorithm in the EPIC electronic medical record. Weight and height were measured by a trained medical assistant at the beginning of each visit and entered into the electronic medical record to the hundredth decimal value. Weight was taken on a calibrated bariatric-capable scale and height taken from a wall measurement; self-reported values were not included.
Blood Lipids

It was standard practice for PWD to have a blood lipid panel drawn and processed at the Nebraska Medicine Clinical Laboratory annually or more frequently as needed at MD visits. Blood lipids considered for this study included LDL, HDL and TG. Venous blood samples were measured at the Nebraska Medicine Clinical Laboratory via blood lipid panel. With exception of medications and water, subjects were required to fast for minimum of 12 hours prior to blood draw. The lipid panel measures Total Cholesterol, triglycerides, HDL Cholesterol, calculated LDL and VLDL and a calculated Cholesterol/HDL ratio. Triglycerides, HDL and LDL were chosen in this study for relevance and total cholesterol, VLDL and cholesterol/HDL ratio were not included in the dataset. Chemistry was performed on a 0.5 – 1.0 mL whole blood sample with the Beckman Coulter AU5800, a device in which cholesterol esterase, an enzymatic reagent, prepares cholesterol molecules with an oxidation preparation, treatment with red dye and measurement by spectrometry. LDL was calculated with the formula: LDL = Cholesterol - (HDL + VLDL). Specifications of the Beckman Coulter test indicate that optimally, samples should be processed as soon as possible, though they may be stored at 15-30 degrees Celsius for up to 14 hours or 2-8 degrees Celsius for up to a week.\(^{42,4}\) The Nebraska Medicine Clinical Laboratory protocol appears to be in accordance with specifications, as the policy states that blood lipid panel will be completed on the day of the test.

DATA COLLECTION PROCEDURES

Procedures following Institutional Board Approval

a. The list of acceptable ICD9 codes were obtained from medical records.

b. A list of primary and secondary outcome variables and parameters were determined to include: A1C, LDL, HDL, TG, BMI, Number of RD encounters, Number of endocrine MD encounters.

c. Dates of data collection were determined. One year of data were collected from the index date. Baseline values were any values within a month of index date and
secondarily accepted as any recorded values 3 months prior to index if not taken at index date. Endpoint values were the last value recorded within 3 months of last visit date.
d. Charts were accessed and the following data were collected:
e. Data were sorted into two groups: UCM and DCM
f. Descriptive information was collected: Age, Gender
g. Primary outcomes were collected:
i. A1C at initial visit and at 12 months, change in A1C at 12 months
ii. BMI at initial visit and at 12 months, change in BMI at 12 months
h. Secondary outcomes were collected:
i. Number of documented encounters with RD, including phone encounters
ii. Number of encounters with the endocrinologist, including phone encounters with a nurse, which indicated an interaction with the endocrinologist such as medication management questions.
iii. Lipids (LDL, HDL, TG) at baseline within the 3 months before initial visit and change in values at 12 months

All data were stored in a de-identified protected database

STATISTICAL ANALYSIS

Statistical analysis of the study data were computed using IBM SPSS Statistics 26 software. Statistical significance was set at a p-value of 0.05. Descriptive statistics were used for continuous and categorical variables. Statistically significant baseline characteristics were assessed for clinical relevance. Distribution of group characteristics was also assessed by histogram, boxplots and scatter plot and outliers were critically assessed for plausibility and data entry errors. Continuous variables (change in A1C, change in BMI, change in LDL, change in HDL, change in triglyceride) were analyzed using a two tailed t-test to measure difference of
means and were interpreted using Levene’s Test for Homogeneity of Variances to choose the appropriate significance. Alpha was determined at 0.05 and therefore a small p value of 0.05 or lower was considered evidence against our null hypothesis, indicative of a statistically significant difference in means between the groups. Categorical variables (gender) were reported as frequencies and percentages. Analysis of differences of proportions in gender between groups was measured using a chi squared test.
CHAPTER 4: RESULTS

SUBJECT CHARACTERISTICS

Population demographics and clinical baseline characteristics were obtained for 945 unique adult subjects, and were organized by treatment type: UCM or DCM. Characteristics of both groups are presented in Table 3. The UCM group had 444 subjects and the DCM group had 501 subjects in total.

Gender

There was a statistically significant difference in male to female distribution between groups, with more males in the DCM group. Of the 444 subjects receiving UC, 244 (44%) were male compared with 307 male (61%) subjects in the DCM group (p=0.05). 200 (56%) subjects in UC group were female compared with 194 (39%) in the DCM group.

Age

There was a statistical difference between groups in mean age of subjects. Mean age in the UCM was 50 years, with a standard deviation of 16.3 years, while mean age in DCM was 54.4 years, with a standard deviation of 16.4 years (p=0.001)
### Table 3. Baseline Demographics and Clinical Characteristics of Usual Care and Case Management Diabetes Education Groups

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>Case Management</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>244 (44)</td>
<td>307 (61)</td>
<td>0.05</td>
</tr>
<tr>
<td>Female</td>
<td>200 (56)</td>
<td>194 (39)</td>
<td></td>
</tr>
<tr>
<td><strong>Total (%)</strong></td>
<td>444 (100)</td>
<td>501 (100)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean (SD)</th>
<th>N</th>
<th>Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>444</td>
<td>50.0 (16.3)</td>
<td>501</td>
<td>54.4 (16.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>A1c initial</td>
<td>258</td>
<td>8.7 (2.1)</td>
<td>454</td>
<td>8.5 (1.9)</td>
<td>0.22</td>
</tr>
<tr>
<td>BMI initial</td>
<td>443</td>
<td>31.3 (7.7)</td>
<td>438</td>
<td>32.7 (8.9)</td>
<td>0.01</td>
</tr>
<tr>
<td>LDL initial</td>
<td>208</td>
<td>87 (36)</td>
<td>233</td>
<td>89 (33)</td>
<td>0.65</td>
</tr>
<tr>
<td>HDL initial</td>
<td>227</td>
<td>48 (16)</td>
<td>253</td>
<td>46 (16)</td>
<td>0.17</td>
</tr>
<tr>
<td>TG initial</td>
<td>229</td>
<td>180 (236)</td>
<td>252</td>
<td>188 (33)</td>
<td>0.68</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, Body Mass Index; A1c, Hemoglobin A1c; LDL, Low Density Lipoprotein; HDL, High Density Lipoprotein; TG, Triglyceride; RD, Registered Dietitian
PRIMARY OUTCOMES

A1C

A1C was higher at baseline in the UC group. Baseline A1C at start of UCM was 8.7 with a standard deviation of 2.1 (p=0.001), compared with DCM A1C at baseline which was 8.5 with a standard deviation of 1.9 (p=0.01). Both groups had an improved A1C, demonstrating an overall decrease at 12 months compared to index date. UCM had mean change in A1C of –0.2 compared with DCM group which had a mean change of –0.4 (p = 0.06). Mean endpoint A1C for UCM was 8.4 with standard deviation of 2.2 and DMC A1C was 8.0 with standard deviation of 1.9 (p=0.02).

Figure 2. Change in A1C at 12 Months
**BMI**

Baseline BMI was higher in the DCM group at 32.7 with a standard deviation of 8.9 compared to UCM group with mean BMI of 31.3 with a standard deviation of 7.7 (p=0.01). Mean endpoint BMI in DCM was 32.7 with standard deviation of 2.9 and UCM endpoint BMI was 31.5 with standard deviation of 7.7 (p = 0.04). Change in BMI showed a positive trend in UCM versus a negative trend in the DCM (UCM + 0.2, DCM – 0.04, p = 0.07).

**SECONDARY OUTCOMES**

**HDL**

HDL at baseline was available for 227 of 444 subjects with mean values of 48 and a standard deviation of 16 points (p=0.17). In UC, mean HDL at baseline was 46 with a standard deviation of 16 (p= 0.17). Change in HDL was calculated on 223 of the subjects in total and was 0.1 in UCM versus -0.2 in DCM (p = 0.63).

**LDL**

LDL at baseline was available in 208 of 444 patients in the UC group with and mean value of 87 with a standard deviation of 36 points (p=0.65) compared with DCM baseline LDL which was 88 with a standard deviation of 33 (0.65). Mean endpoint LDL in both groups was 88 (p = 0.18). Change in LDL showed a positive trend in UCM of +1.8 with standard deviation of 17.7 and negative trend in the DCM - 4.2 with a standard deviation of 21.5 (p= 0.002). As shown below, in figure 3, the mean change in LDL showed a significant difference in trends between groups, with a decrease in LDL in the DCM and an increase in LDL in the UCM.
Figure 3. Change in LDL at 12 Months

![Graph showing change in LDL at 12 months]

**Triglycerides**

Baseline TG had a mean value of 88 with a standard deviation of 33 (p = 0.68). Endpoint TG in UCM was available on 228 subjects and had a mean outcome of 178.7 with standard deviation of 232.5. Endpoint mean TG for DCM was available for 481 subjects and had a mean outcome of 179.6 with a standard deviation of 211 (p = 0.96). Change in TG was measured in 229 subjects in the UCM group and found to be –1.3 with standard deviation of 82.0 compared with change in TG calculated for 252 subjects in DCM which was found to be -7.8 with a standard deviation of 143.2 (p = 0.54).

**Total Visits**

Total visits with the RD as well as endocrine MD clinic encounters were measured as an indication of adherence and engagement in the model of care. The DCM had more total visits with the RD, with 5,016 total visits and a mean of 10.0 visits in 12 months compared to a total of 3,281 total visits and a mean of 7.4 visits over 12 months in UCM (p=0.001). DCM also had
more total visits with the MD Clinic, 501 subjects had 5,567 total visits with mean of 11.1 visits per subject. The 455 subjects in UCM had 3,650 total visits with a mean of 8.2 visits per subject (p=.001). The respective mean total visits with Endocrine MD and RD are shown below in figures 4 and 5.

**Figure 4. Total Endocrine MD Encounters at 12 Months**

![Figure 4](image)

**Figure 5. Total RD Encounters at 12 Months**

![Figure 5](image)
Table 4. Primary and Secondary Clinical Outcomes of Usual Care and Case Management Diabetes Education at One Year

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>Case Management</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td><strong>Mean (SD)</strong></td>
<td><strong>N</strong></td>
<td><strong>Mean (SD)</strong></td>
</tr>
<tr>
<td><strong>Primary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1c final</td>
<td>255</td>
<td>8.4 (2.2)</td>
<td>455</td>
</tr>
<tr>
<td>BMI final</td>
<td>443</td>
<td>31.5 (7.7)</td>
<td>439</td>
</tr>
<tr>
<td>A1c change/1yr</td>
<td>244</td>
<td>-0.2 (1.4)</td>
<td>454</td>
</tr>
<tr>
<td>BMI change/1yr</td>
<td>443</td>
<td>0.2 (2.3)</td>
<td>438</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL change/1yr</td>
<td>255</td>
<td>1.8 (17.7)</td>
<td>228</td>
</tr>
<tr>
<td>TG change over 1 year</td>
<td>229</td>
<td>-1.3 (82.0)</td>
<td>252</td>
</tr>
<tr>
<td>HDL change/1yr</td>
<td>253</td>
<td>0.1 (6.3)</td>
<td>253</td>
</tr>
<tr>
<td>LDL final</td>
<td>209</td>
<td>88.7 (37.1)</td>
<td>233</td>
</tr>
<tr>
<td>TG final</td>
<td>229</td>
<td>178.7 (232.5)</td>
<td>481</td>
</tr>
<tr>
<td>HDL final</td>
<td>227</td>
<td>48.4 (16.1)</td>
<td>253</td>
</tr>
<tr>
<td>RD encounters/1yr</td>
<td>3,281</td>
<td>7.4 (5.2)</td>
<td>5,016</td>
</tr>
<tr>
<td>MD Clinic encounters/1yr</td>
<td>3,650</td>
<td>8.2 (5.7)</td>
<td>5,567</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, Body Mass Index; A1c, Hemoglobin A1c; LDL, Low Density Lipoprotein; HDL, High Density Lipoprotein; TG, Triglyceride; RD, Registered Dietitian

In summary, all primary and secondary results are compiled and shown above in Table 4.
CHAPTER 6: DISCUSSION

Studies with similar outcomes measures and populations include those by Franz, Ishani Gilmer and Shea. Versnel proposed a model most similar to our study and projected like outcomes. In the context of current practice and DCM outcomes, we can compare the overall structure of our DCM and outcomes of A1C, BMI, blood lipids and total visits. Tables 5 and 6, respectively, summarize the primary and secondary outcomes of our work to these key publications.

| Table 5. Primary Outcomes of RD DCM Compared with Literature Review of Similar Studies |
|---------------------------------|-----------------|-----------------|----------------|----------------|
|                                 | Endpoint A1C    | Endpoint BMI    | A1C Change     | BMI Change     |
| RD DCM                         | 8.0 (p = .02)   | 32.7(p=.04)     | -0.4 (p=.06)   | -.04 (p=.07)   |
| Franz                          | 7.4             | 32.4            | -0.9           | Not statistically significant |
| Gilmer                         | 7.4             | Not statistically significant | -0.4 | Not statistically significant |
| Ishani                         | 8.6             | 33.5            | -0.4 not statistically significant | Not statistically significant |
| Shea                           | 7.09            | Not Reported    | -29            | Not reported   |

Abbreviations: RD, Registered Dietitian; DCM, Diabetes Case Management; A1C, Hemoglobin A1C; BMI, Body Mass Index

| Table 6. Secondary Outcomes of the RD DCM Compared with Literature Review of Similar Studies |
|---------------------------------|-----------------|----------------|--------------|----------------|
|                                 | Encounters with RD/CM/1 year | Encounters with Endocrine MD/1 year | LDL Change | LDL at End | TG Change | TG at End | HDL Change | HDL at End |
| RD DCM                         | 10 (p=.001)     | 11.1 (p=.001)   | -4.2 (p=.002) | 88.3 (p=.18)  | -7.8 (p=.54) | 179.6 (p=.96) | -0.2 (p=.65) | 46.1 (p=.13) |
| Franz                          | 3               | NSS             | NSS          | NSS          | NSS          | NSS          | NSS         | NSS         |
| Gilmer                         | 0-1             | NR              | -2.2         | 122.4        | -11.3        | 167.8        | 0.0         | 46.2        |
| Ishani                         | 10/year         | NR              | -5.0         | 107.3        | NR           | NR           | NR          | NR          |
| Shea                           | NR              | NR              | -15.0/5 years | 91.3         | NR           | NR           | NR          | NR          |
| Versnel*                       | 12/year         | NR              | NR           | NR           | NR           | NR           | NR          | NR          |

Abbreviations: RD, Registered Dietitian; DCM, Diabetes Case Management; CM, Case Manager; MD, Medical Doctor; LDL, Low Density Lipoprotein; TG, Triglyceride; HDL, High Density Lipoprotein; NSS, Not Statistically Significant; NR, Not Reported; * Projected outcome versus measured outcome
DCM and UCM Structure

The UCM is defined by multiple experts as medical management with quarterly A1C checks, annual blood lipid checks and an undefined amount or frequency of integrated DSMT and medical nutrition therapy. The UCM group in this study is derived from an endocrine clinic practice, which lends itself to having a biased population of higher acuity and worse glycemic control than the literature as a whole represents. Given the likelihood of advanced diabetes status, it is not surprising that subjects in the UCM had approx. 8.2 visits with the MD per year compared with approximately 4 in the UCM. Of note, the IDEAtel randomized control study by Shea et al. studied a population which was likely well matched to our endocrine clinic population as they had a mean of 11.2 years from diagnosis at baseline and therefore may be a study worthwhile of direct comparison. Our study did not have years from diagnosis data available.

In two RN DCM studies showing significant improvements, protocols were published, showing how the RN was to prioritize and manage education and medication titration. In our study, medication titration and education were completed by the RD. It appears that our study achieved similar outcomes as the RN DCM while using a simplified protocol and integrating MNT and medication management.

A1C

A1C has an exponential positive correlation with increased mortality and overall risk of complications, therefore, a decrease in A1C is profoundly beneficial. Our results showed a stronger benefit to lowering A1C in the DCM than with the current standard UCM. Additionally, experts recommend increasing A1C testing frequency from annually to biannually or quarterly in populations which are not controlled. Our results show that 455 subjects received at least biannual A1C testing. Ishani et al. found a mean A1C of 8.0 in CM, 7.8% in UC. Overall improvement of A1C in DCMs varied; Ishani showed a net improvement of -.29% compared to
UCM at 5 years, and an endpoint reduction of -.4%. By comparison, our one year results showed that the RD CDE DCM had similar results to the RN DCM; at one year showed a reduction by -.2% in UCM and -.4% in the DCM.

**BMI**

Ishani et al found that mean BMI in case management was 33.5 and usual care 33.2 which is comparable to our study population, which had a mean BMI of 31.1 in UCM and 32.7 in the DCM group. No DCM studies have reported endpoint BMI or change in BMI. RD studies have used weight loss as a primary outcome. Franz et al. defined a significant outcome as a loss of 2.3 kg in 6 weeks. The study found that subjects receiving MNT alone and did not require diabetes medications sustained weight loss after 6 months, but the subjects who required oral medications had minimal weight loss. Of those using insulin 19% sustained weight loss however this result was not found to be statistically significant. These results demonstrate the progression of diabetes as discussed earlier in the literature and are particularly relevant as a comparison to our study group, which is advanced in severity of disease by virtue of being an endocrine clinic population. Our study demonstrated modest weight loss measured by change in BMI with a result of weight gain over 1 year (+0.2) in the UCM and loss (-0.04) in the DCM, which was approaching statistical significance in a sample size of 438 (p=0.07). This result is striking and significant; weight is rarely measured in the DCM and has shown a trend of gain versus loss however the RD DCM was able to demonstrate sustained overall reduction in BMI at one year.

**Blood Lipids**

Target LDL is 100mg/dl or lower. The only RD study measuring diabetes outcomes from an RD managed intervention similar to the DCM had no significant outcomes in blood cholesterol results, including LDL, HDL and TG. Conversely, our results showed that LDL improved and our results were consistent with outcomes of RN DCM trials. Ishani et al. found a mean LDL at baseline of 107(above goal) and at one year had a modest reduction with a mean of
102.3 (above goal) in the case manager group and a mean of 103 in UC, demonstrating an overall reduction at one year of -5 points\textsuperscript{13}. Similarly, our results showed a reduction of LDL - 4.2 points. The baseline and endpoint LDL in our study was significantly lower, and would be considered in goal range. Our final mean of 88 points is significant because our population started out at goal and continued to improve. This could potentially be explained by differences in medical management per primary care provider however the impact of receiving MNT integrated with the DCM is also a possible advantage of the RD DCM.

Cardiovascular risk increases over time along with intensity of management of blood cholesterol. One study by Shea et al. measured LDL after 5 years of telemedicine case management, finding an improvement of -15 points versus -13 points\textsuperscript{29}. Our results demonstrated a -5 point improvement in LDL at 1 year, which indicates a similar trend.

Target HDL is a measure of healthy cholesterol and is useful in weighing risk of LDL and total cholesterol; the higher the HDL score, the more protective benefits for the patient. Though cardiovascular recommendations advise to review the HDL: total cholesterol ratio, this information was not available in our study population\textsuperscript{38}. HDL dropped in the DCM group which is typical with overall lowering of cholesterol\textsuperscript{6,38}.

Target TG is 150mg/dl or less\textsuperscript{1,6,9,38}. TG is also positively associated with A1C, as glucoes rise, so will TG. Franz et al. found an improvement in TG after 6 months with and RD intervention, however the results were reported to have no statistical significance\textsuperscript{12}. It is not surprising to see elevated TG at baseline in our UCM or DCM population as they are endocrine clinic patients with higher rates of uncontrolled disease and elevated A1C.

**Number of Visits**

Ishani et all reported a mean of 10 case management visits per year. These were conducted as phone calls, with a mean of 15 calls, and 10 being successful\textsuperscript{27}. Though DCM is well documented, this model of care is not standardized and studies have not been repeated.
IDEAtel by Shea, et all is our largest study comparing DCM to UCM however the study failed to report the number of visits with the DCM29. Versnel, et all defined case management as a monthly phone call, and followed subjects over one year resulting in a maximum number of 12 visits with the DCM however the study did not report number of visits with the MD14. In our study, retrospective data showed a mean of 10.0 visits with the DCM RD CDE and 11.1 visits with the MD. DSMT was provided in combination with MNT, which differed from the UCM and from all of the RD DCM studies in the literature.

**Limitations**

This is a retrospective chart review pilot study, which has limitations. The length of time from diagnosis is unknown information in the study; length of diabetes greatly influences patient response to diabetes education interventions. This study is a pilot study and therefore, power calculations were not computed prior to data collection. This study may not be powered to find a statistical difference in blood lipid levels, which have high variability and require a large sample in order to observe a significant finding. Lipid results were not controlled for source or accuracy, and considering that lipid results are often abstracted from annual wellness visits, which vary dramatically in accuracy, there is potential for regression to the mean and type 2 error in our conclusions.

Case management is generally recommended for persons needing additional intensive support beyond what the UCM offers2,8,15. In this study, patients were seen at and endocrinology clinic where the majority of people have had diabetes for years already. Subjects were enrolled at visit one, which could have an impact on motivation level and perception of disease severity.

Lab values are susceptible to variable reliability in a chart review study. Due to inconsistent reporting of lipid values and variability in test results this study may not be powered to detect a significant difference in HDL or TG. A1C is a primary outcome which may be influenced by concomitant conditions such as hypoglycemia, sickle cell trait and end stage renal diseases. Race and ethnicity are pertinent to genetic and cultural factors which may also influence...
efficacy of DCM. It is a limitation that this study does not identify such parameters which may be useful in a stratified analysis and provide insight to the value of DCM in such populations.

Blood pressure control is a component of published DCM interventions and is highly relevant in managing risk of complications from DM. Although RD CDE’s provide known benefits to hypertension management, our study did not include blood pressure values as an outcome. Reliable blood pressure data was unavailable and therefore this study was designed without blood pressure data.

**Strengths**

This study has a large sample size which provides ample data to compare outcomes with current publications of DCM. The study provides a rare occasion to observe clinical outcomes in two models of care with the same population and resources, as it takes place in one clinic with no changes in doctors or medication protocols.
CHAPTER 7: CONCLUSION

This is the first study to document clinical outcomes of a comprehensive RD DCM which provides MNT and DSMT within a DCM. Additionally, this study is first to compare the outcomes of the RD in a UCM to outcomes of an RD directed DCM. Our study provides valuable insight to the baseline population and outcomes of the RD DCM in a clinically complex endocrinology clinic population, which has not previously been demonstrated in the literature. Our most significant finding was a statistically and clinically significant difference in lowering A1C, which showed more benefit in the DCM than with the current standard UCM. This study found that the RD DCM produced results consistent with the published interventions in the UCM and RN case management studies regarding impact on lowering A1C, LDL and BMI. LDL cholesterol was better managed at baseline in the endocrinology clinic population when compared to other studies in the literature, and still showed an improvement after 1 year of the RD DCM. Secondary outcome measures of patient engagement, measured by number of visits, suggest the relationship-based model of DCM increases patient engagement, and this group had better glycemic outcomes than the UCM. Additionally, a significantly higher percentage of men participated in the RD DCM compared to the UCM, signaling a potential difference between gender preference or success in the DCM. Qualitative assessment of gender perceptions and motivations is warranted, given this significant difference. Additional striated outcomes comparisons between genders is also warranted. Consistent with RD studies and RN DCM studies, there was no significant impact on HDL or TG in this study.

The outcomes of this study clearly validate further practice of RD directed DCM in the endocrine clinic setting and suggest it may be a superior model of education for the endocrinology clinic population.

Conclusions
The DCM is a pertinent mode of diabetes education to current and future health care models as a way of improving diabetes outcomes and reducing cost of health care for growing populations with complex diabetes management needs. Given the chronic nature of diabetes and the promising results reported by Shea et al at 5 years post DCM, a longer timeframe study of the RD DCM should be conducted. It is crucial that effective models such as diabetes case management be developed, explored and standardized by RDs in order to optimize efficacy and improve health outcomes for patients with diabetes. The risk of maintaining the status quo in diabetes care is a continued rise in preventable health complications for patients with diabetes, and a rising burden of healthcare costs to all.

CHAPTER 8: BIBLIOGRAPHY


11. Does disease management improve clinical and economic outcomes in patients with chronic

Dietitians in the Management of Non–Insulin-Dependent Diabetes Mellitus: A
Randomized, Controlled Clinical Trial. Journal of the American Dietetic Association.
1995;95(9):1009-1017. doi:10.1016/S0002-8223(95)00276-6

of Medical Nutrition Therapy in Diabetes Management. Diabetes Care. 2002;25(3):608-
613. doi:10.2337/diacare.25.3.608

management for comorbid diabetes type 2 patients; the CasCo study. Design of a


17. Impact of comorbid conditions and race/ethnicity on glycemic control among the US

27, 2019.


37. Role & Function Study Key Findings | Commission for Case Manager Certification (CCMC).
https://ccmcertification.org/about-ccmc/role-function/role-function-study-key-findings.

38. Prospective Randomized Controlled Trial to Evaluate Effectiveness of Registered Dietitian–
Led Diabetes Management on Glycemic and Diet Control in a Primary Care Setting in
Taiwan | Diabetes Care. http://care.diabetesjournals.org/content/33/2/233.long. Accessed
April 27, 2019.

source/practice/practice-resources/position-

40. Nebraska Medicine Clinical Laboratory | Tests.

41. techdocs.pdf.


43. Nebraska Medicine Clinical Laboratory | Tests.