A Multisite Study Demonstrating the Efficacy and Potential Cost Savings of Diabetes Self-Management Education and Medical Nutrition Therapy in the Management of Type 2 Diabetes in Alabama

by

Maria Victoria Salazar

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Approved by

Patricia Marincic, Chair, Associate Professor and Director
Michael Greene, Assistant Professor
Caralise Hunt, Assistant Professor

Abstract

Background

Alabama has one of the highest prevalence rates of Type 2 Diabetes (T2D) impacting greater than 13.5% of the adult population. While diabetes self-management education (DSME) and medical nutrition therapy (MNT) has been shown to promote glycemic control and reduce risk of comorbidities and related healthcare expenditures, access to these services is limited due to poor reimbursement and lack of public policy directives.

Objectives

The project aims were to 1) document outcomes for patients with T2D completing DSME and MNT through 4 American Diabetes Association (ADA)-recognized diabetes education programs in Alabama and 2) identify potential healthcare cost-savings associated with reduction in HbA1c utilizing patient outcomes and mathematical models from published studies.

Methods

A retrospective chart review was conducted of patients with T2D receiving DSME and MNT through four regional ADA-recognized diabetes education programs in Alabama. Baseline, end-of-program, and 1-year follow-up measures were queried for weight, body mass index (BMI), HbA1c, and lipids. Mixed-model analysis of variance was used to determine differences between means for continuous variables; McNemar's test was used to assess frequency of patients reaching glycemic targets.

Results

Significant reductions were observed at end-of-program and 1-year in weight (2.67 kg, P<0.001; 2.25 kg, P = 0.001), BMI (0.93, P < 0.001; 0.76, P = 0.001), HbA1c (1.82%, P<0.001; 1.22%, P<0.001). Patients managed by diet alone had a baseline HbA1c of 6.95% and exhibited a 0.80% reduction in HbA1c; comparatively those managed with diet plus drug therapy had a baseline HbA1c of 9.00% and exhibited a 2.09% reduction in HbA1c at end-of-program.

Conclusions

This study reports actual patient outcomes achieved in the clinical setting. Reductions were observed in key outcome measures weight, BMI and HbA1c. Cost-effective analysis of averting or delaying comorbid disease supports universal reimbursement and patient access to DSME with supplemental individualized MNT.

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List of Abbreviations

T2D: type 2 diabetes

CDC: Centers for Disease Control

ADA: American Diabetes Association

IFG: impaired fasting glucose

IGT: impaired glucose tolerance

OGTT: oral glucose tolerance test

HbA1c: glycosylated hemoglobin

CVD: cardiovascular disease

TG: triglyceride

HDL: high density lipoprotein

LDL: low density lipoprotein

UKPDS: United Kingdom Prospective Diabetes Study

DSME: diabetes self-management education

MNT: medical nutrition therapy

RDN: registered dietitian nutritionist

ALDA: Alabama Dietetic Association

BCBS-AL: Blue Cross and Blue Shield of Alabama

AADE: American Association of Diabetes Educators

AACE: American Association of Clinical Endocrinologists

AND: Academy of Nutrition and Dietetics

NCP: Nutrition Care Process

CHD: coronary heart disease

HTN: hypertension

RCT: randomized control trial

QALY: quality-adjusted life year

ICER: incremental cost-effective ratio

GLM: generalized linear model

RCR: retrospective chart review

OHA: oral hypoglycemic agent

BMI: body mass index

SMBG: self-monitoring blood glucose

ANOVA: analysis of variance

CHAPTER I

INTRODUCTION

Type 2 diabetes (T2D) is a chronic health condition characterized by metabolic disturbances in insulin use and production. Before the disease is diagnosed, insulin resistance occurs when there is a decreased cellular response to insulin, causing a delay in the movement of glucose from the bloodstream into the cell for the body to use as energy. The cell "resists" the insulin, which leads to hyperglycemia. To compensate, the pancreatic β-cells continue to produce insulin, leading to hyperinsulinemia. Hyperinsulinemia in the presence of hyperglycemia eventually leads to pancreatic β-cell failure. β-cell failure in turn leads to decreased glucose uptake by peripheral tissues and an increase in hepatic glucose production resulting in hyperglycemia.

Before T2D is diagnosed, disturbances in glucose metabolism are present. Blood glucose levels are outside of the normal range, but not yet at the level of diagnosis. To emphasize the early prodrome of abnormal glucose levels, the Centers for Disease Control (CDC) and the American Diabetes Association (ADA) defined impaired fasting glucose (IFG) and impaired glucose tolerance (IGT).[1] Impaired fasting glucose describes abnormal fasting blood glucose values during the fasting state and IGT describes the abnormal blood glucose response after a glucose load.[1] The oral glucose tolerance test (OGTT) is also used to describe an abnormal glucose response after a glucose load.[2] Glycosylated hemoglobin (HbA1c), expressed as the percentage of glucose attached to hemoglobin over 3 months, provides a much better indication of long-term glycemic control than blood glucose determinations.[2] Current diagnostic criteria for IFG, IGT, and diabetes, along with glycemic targets for patients with T2D, are shown in Table 1.

Because of the inherent disturbances in glucose metabolism in the presence of insulin resistance, specific glycemic targets have been identified for prevention or delay of long-term comorbid disease. Fasting blood glucose, random blood glucose, OGTT, and HbA1c target goals for diabetes patients are shown in Table 1. The relationship between HbA1c targets and development of comorbidities has been explored extensively. Achieving HbA1c target of < 7% has been shown to reduce microvascular disease, and has been widely accepted as the goal HbA1c for most patients with diabetes.[2] In contrast, an HbA1c level of > 9% is associated with increased risk of comorbidities.[3]

Table 1. Diagnostic Criteria and Target Goals for Patients with Diabetes

	Normal	IFG/IGT	Diabetes	Target Goals
Fasting blood glucose	< 100 mg/dL	100 -125 mg/dL	≥ 126 mg/dL	80 – 130 mg/dL
Random Blood Glucose	< 140 mg/dL	141 – 199 mg/dL	≥ 200 mg/dL	< 180 mg/dL
Oral Glucose Tolerance Test	< 140 mg/dL after 2 hours	141 – 199 mg/dL	≥ 200 mg/dL	< 180 mg/dL
HbA1c%	< 5.7%	5.7 – 6.5%	≥ 6.5%	< 7%

Adapted from www.diabetes.org

Diabetes affects 29 million Americans, 9.3% of the U.S. population, with 1.4 million new cases diagnosed each year representing a healthcare burden of $176 billion in direct medical costs and $69 billion in indirect costs (absenteeism, productivity loss, disability, and premature death). In 2010, diabetes was the seventh leading cause of death in the United States. Alabama has one of the highest diabetes rates in the U.S at 12%,[4] which shows an increase in prevalence

of 45% over the past ten years. Six Alabama counties make the top ten ranking of counties with the highest disease prevalence in the U.S.[4,5]

Diabetes poses a substantial health burden to patients suffering from the disease, as well as a financial burden to the U.S. healthcare system. Direct medical costs for people diagnosed with diabetes are over and above the estimated healthcare costs of people without diabetes.[6] Direct medical costs of diabetes are associated with common long-term complications such as retinopathy, neuropathy, nephropathy, coronary artery disease, peripheral arterial disease, and stroke. Costs include, but are not limited to, emergency room visits, inpatient hospital stays, physician visits, hospital outpatient visits, and medication prescriptions. The highest costs are associated with inpatient hospital stays and medication prescriptions. Length of hospital stays, regardless of admitting diagnosis, are increased in patients with diabetes leading to further increases in healthcare costs.[6]

Complications of diabetes are exacerbated by poor glycemic control and prolonged hyperglycemia. Poor glycemic control causes damage to the small and large vessels in the body leading to micro and macrovascular complications, respectively. Microvascular complications occur when glucose is diverted from tissues requiring insulin for glucose uptake to those that are non-insulin dependent. Damage to the small vessels within these tissues primarily results in decreased blood flow, leading to retinopathy, nephropathy, and neuropathy. Development of retinopathy is related to duration of T2D and glycemic control and is the leading cause of blindness in developed countries. Likewise, 44% of cases of kidney failure are attributed to diabetic nephropathy; treatment consists of long-term dialysis or kidney transplant.[4] Increasing prevalence of chronic kidney disease parallels that of obesity and T2D. Neuropathy, a complex

collection of conditions impacting the gastrointestinal tract, central, and peripheral nervous systems, accounts for significant disability in patients with diabetes.[4]

Poor glycemic control also promotes the development of macrovascular complications, leading to damage of the large blood vessels and promoting the atherosclerotic process of plaque development through complex molecular mechanisms involving glycosylation, oxidative stress, and inflammation.[2] Atherosclerotic cardiovascular disease (CVD) includes a myriad of conditions such as acute coronary syndrome, myocardial infarction, angina, stroke, and peripheral artery diseases, and is the leading cause of morbidity and mortality in T2D. Hypertension and dyslipidemia, common comorbidities of diabetes, further contribute to ASCVD as independent risk factors. Therapeutic interventions and patient education addressing multiple manifestations of diabetes including hypertension and dyslipidemia management have been shown to be effective in decreasing morbidity and mortality. Management of hypertension and dyslipidemia is addressed with lifestyle interventions of diet and physical activity, and medications used to lower blood pressure and normalize lipids. The most common form of dyslipidemia in diabetes, elevated triglycerides (TG) and decreased high-density lipoprotein (HDL), can be addressed with lifestyle interventions to decrease TG levels. Studies addressing medication used to treat this common pattern of dyslipidemia associated with T2D have not produced results demonstrating improvement in cardiometabolic outcomes.[2]

Glycemic control is the key to diabetes management and prevention of comorbidities. The United Kingdom Prospective Diabetes Study (UKPDS), showed that a 1% decrease in HbA1c level correlated to a 37% reduction in risk for microvascular complications and a 21% reduction in the risk of any endpoint or death related to diabetes.[7] The UKPDS was key to the development of comprehensive, evidence-based management strategies and education programs

aimed at what was termed “tight control” at the time. Results and recommendations are well integrated into the current standards of practice.

Comprehensive medical management of diabetes and its comorbidities involves complex regimens that are well articulated in the Standards of Medical Care in Diabetes.[2] However, daily disease management lies with the patient. Multidisciplinary programs offer patients diabetes self-management education (DSME), training, and support; individualized medical nutrition therapy (MNT) is typically provided by a registered dietitian nutritionist (RDN). The standards of practice for management of diabetes have recommended that all patients receive multidisciplinary DSME and MNT, the latter ideally provided by an RDN.[2] Complications of diabetes are four times more likely to develop in people receiving no diabetes education.[8]

Despite existing evidence of the efficacy of diabetes education, the CDC reports that an estimated 6.8% of privately insured, newly diagnosed patients participate in DSME.[9] The lack of physician referrals accounts for some, but not all, of the reported gap in treatment.[10,11] Notably, universal insurance coverage for these services by both private and public payors is deficient and limits patient access to quality care.[10] While DSME is more frequently covered, patients are often confronted with high co-pays. Reimbursement for MNT outside of that designated by Medicare Part B (3 hours of MNT per 12 months) warrants attention. Notably, the RDN is not identified as a preferred provider of DSME and MNT by many private payers, which limits both reimbursement and patient access to care.

The Alabama Dietetic Association (ALDA) has approached Blue Cross Blue Shield of Alabama (BCBSAL), the largest health insurance carrier in the state of Alabama, requesting designation of preferred provider status to gain direct reimbursement for RDNs for provision of DSME and MNT. Despite presentation of data from resources available through the Academy

and published studies, Alabama-specific outcome data was requested before further review of the request would occur.

The present study is built on the pilot study, *Diabetes Self-Management Education and Medical Nutrition Therapy Improve Patient Outcomes: A Pilot Study Documenting the Efficacy of Registered Dietitian Nutritionist Interventions through Retrospective Chart Review*.[12] The aims of this pilot study were to 1) develop methodology for tracking patient outcomes subsequent to RDN interventions, 2) document outcomes for patients with T2D attending an ADA-recognized program, and 3) obtain outcome data to support reimbursement and public policy initiatives to improve patient access to DSME and MNT. One hundred charts of patients with T2D completing DSME and individualized MNT between June 2013-2014 time frame were randomly selected for analysis. A mixed model ANOVA was used to determine differences between means for continuous variables, and the McNemar test and Gamma statistic trend analyses were used to assess frequency of patients reaching glycemic targets. Results demonstrated a weight loss was observed from baseline (94.3±21.1kg) to end-of-program (91.7±21.2) (-1.6±3.9kg, $P<0.001$); weight loss in whites (-5.0±8.4kg) ($P<0.001$) exceeded that of African Americans (-0.8±9.0kg, $P>0.05$). Significant HbA1c reduction was observed from baseline (8.74±2.30%) to end-of-program (6.82±1.37%) (-1.92±2.25%, $P<0.001$) and retained at one-year (6.90±1.16%) ($P<0.001$). Comparatively, 72% of patients reached HbA1c targets (≤7.0%) versus 27% at baseline ($P=0.008$). When stratified by diet alone and diet plus drug therapy, patients exhibited a 1.08±1.20% ($P<0.001$) and 2.36±2.53% ($P<0.001$) reduction in HbA1c respectively. Triglycerides decreased from baseline 181.6±75.5mg/dL (2.0±0.9mmol/L) to 115.8±48.1mg/dL (1.3±0.5mmol/L) ($P=0.023$). HDL increased from 41.4±12.4mg/dL (1.1mmol/L±0.3) to 47.3±12.4mg/dL (1.2±0.3mmol/L) ($P=0.007$). In conclusion, retrospective

chart review was demonstrated to provide an operational model for abstracting existing patient outcome data. In support of universal reimbursement and patient access to DSME with supplemental individualized MNT, reductions were observed in key outcome measures weight, BMI, HbA1c, and TGs.

The present multisite study utilizes this established methodology to examine the reproducibility of our results across four regional diabetes education centers representing the broader demographic characteristics of Alabama. Documenting improvement in patient outcomes is a first step in establishing the efficacy of DSME and MNT programs. However, there is increasing attention to the cost-effectiveness of these interventions. The aims of this present study were to: 1) document outcomes for patients with T2D completing DSME and MNT through 4 ADA-recognized diabetes programs in Alabama, and 2) identify potential healthcare cost-savings associated with reduction in HbA1c utilizing outcomes and mathematical models of published studies.

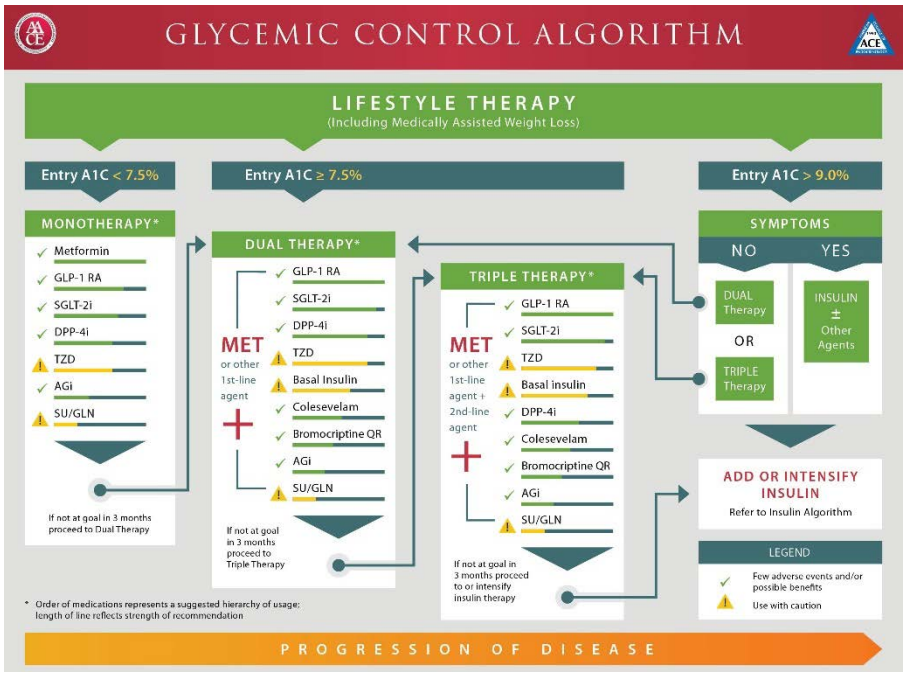
CURRENT STANDARDS OF PRACTICE FOR DSME AND MNT

Diabetes Self-Management Education

T2D is managed by lifestyle changes in nutrition and physical activity patterns, and the addition of pharmacotherapy when glycemic targets cannot be met with diet and exercise alone. It has been established that lifestyle changes require knowledge in diabetes self-management and motivation to make behavior changes. The behavior changes needed for effective management of T2D are identified by the American Association of Diabetes Educators (AADE) and are commonly known as the AADE 7. The seven behaviors known to impact outcomes of patients with diabetes are healthy eating, being active, monitoring, taking medication, problem solving,

reducing risks, and healthy coping.[13] The key to achieving glycemic control is the patient's commitment to lifestyle changes.

Pharmacotherapy in diabetes patients is used in combination with lifestyle changes to achieve glycemic control. The 2016 Consensus Statement from the American Association of Clinical Endocrinologists (AACE)[14] recommends lifestyle therapy as a first line treatment in T2D and highlights the need for continued lifestyle modification even in the presence of pharmacotherapy. The glycemic control algorithm (Figure 1) presents pharmacotherapy management based on HbA1c levels at the time of diagnosis; mono, dual, and triple therapy are used with HbA1c levels <9% without symptoms.[15] Once a patient's HbA1c level exceeds 9% and the patient is experiencing symptoms of diabetes, insulin therapy is added. Many of these medications, while lowering HbA1c levels, aid in reducing the comorbities of T2D, including heart disease and hypertension.[14]



Because of the importance of DSME, the National Standards for Diabetes Self-Management and Support (Table 2) were developed in 1986 and are now revised approximately

every five years based on current literature supporting the educational needs of patients.[16,17] Healthcare providers delivering DSME services in accredited or recognized locations are mandated to meet these standards. Locations not accredited or recognized centers are encouraged to follow these standards as well. Standards provide a foundation for consistent patient management, while allowing flexibility for individual diabetes education centers to provide education based on a needs assessment of their service area and patient population.[2] Current clinical practice guidelines recommend that all people with diabetes participate in DSME programs to achieve and maintain glycemic control for the management of T2D.[2] Furthermore, a joint position statement of ADA, AADE, and the Academy of Nutrition and Dietetics (AND) recommends four critical time points when DSME should be offered: 1) at diagnosis; 2) annually for health maintenance and prevention of complications; 3) when new complicating factors occur; and 4) when transitions in care occur. At least one follow-up encounter is recommended annually to reinforce lifestyle changes and to evaluate and monitor outcomes that indicate the need for changes in MNT or medications.[18]

Medical Nutrition Therapy and the Nutrition Care Process

In addition to DSME, MNT provided by a RDN can further enhance the nutrition education provided to patients with diabetes.[19] MNT provides a working example of the comprehensive services provided by RDNs for the prevention and treatment of disease through nutrition assessment and reassessment, diagnosis, intervention, and monitoring and evaluation. Table 3 summarizes the clinical practice guidelines for comprehensive individualized medical nutrition therapy for T2D.

The focus of the nutrition guidelines is to individualize care provided by the RDN with input from the patient to set short- and long-term goals related to nutrition and glycemic control. For patients managing T2D with lifestyle modification or pharmacotherapy, the goal is to develop a plan to achieve modest weight loss or maintenance while achieving glycemic control. The RDN has the unique education and skill to use the Nutrition Care Process (NCP) to assess the physical, social, psychosocial, and educational background, and the patient's willingness to change in order to develop a nutrition plan that best fits the patient's needs and is most likely to be achievable in the individual's daily life. Patients who are on fixed doses of insulin will benefit from learning basic carbohydrate counting to achieve a consistent carbohydrate intake at each meal. Patients who are on a multiple daily injections or continuous subcutaneous insulin infusion will benefit from advanced carbohydrate counting as insulin is dosed based on the intended intake of carbohydrate at the upcoming meal.

Table 2. National Standards for Diabetes Self-Management Education and Support

Standard 1 – Internal Structure
The providers of DSME will document an organizational structure, mission statement, and goals. For those providers working within a larger organization, that organization will recognize and support quality DSME as an integral component of diabetes care.

Standard 2 – External Input
The providers of DSME will seek ongoing input from external stakeholders and experts to promote quality programs.

Standard 3 – Access
The providers of DSME will determine who to serve, how best to deliver diabetes education, and what resources can provide ongoing support for that population.

Standard 4 – Program Coordination
A coordinator will be designated to oversee the DSME program. The coordinator will have oversight responsibility for the planning, implementation, and evaluation of education services.

Standard 5 – Instructional Staff
One or more instructors will provide DSME. At least one of the instructors responsible for designing and planning DSME will be an RN, RDN, or pharmacist with training and experience pertinent to DSME, or another professional with certification in diabetes care and education. Other health workers can contribute to DSME with appropriate training in diabetes and with supervision and support.

Standard 6 – Curriculum
A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the provision of DSME. The needs of the individual participant will determine which parts of the curriculum will be provided to that individual.

Standard 7 – Individualization
The diabetes self-management, education, and support needs of each participant will be assessed by one or more instructors. The participant and instructors will develop an individualized education together and support plan focused on behavior change.

Standard 8 – Ongoing Support
The participant and instructors will together develop a personalized follow-up plan for ongoing self-management support. The participant's outcomes and goals and the plan for ongoing self-management support will be communicated to other members of the healthcare team.

Standard 9 – Patient Progress
The providers of DSME will monitor whether participants are achieving their personal goals and other outcomes to evaluate the effectiveness of the educational interventions, using appropriate measurable techniques.

Standard 10 – Quality Improvement
The providers of DSME will measure the effectiveness of the education and support and look for ways to improve any identified gaps in service or service quality using a systematic review of process and outcome data.

Adapted from Haas et al., 2013. (16)

Table 3. Nutrition Therapy Recommendations

- An individualized MNT program, preferably provided by a RDN, is recommended for all people with T1D or T2D.
- For people with T1D or those with T2D who are prescribed a flexible insulin therapy program, education on how to use carbohydrate counting to determine mealtime insulin dosing can improve glycemic control.
- For individuals whose daily insulin dosing is fixed, having a consistent pattern of carbohydrate intake with respect to time and amount can result in improved glycemic control and a reduced risk of hypoglycemia.
- An effective approach to glycemia and weight management emphasizing healthy food choices and portion control may be more helpful for those with T2D who are not taking insulin, who have limited health literacy or numeracy, and who are elderly and prone to hypoglycemia.
- Because diabetes nutrition therapy can result in cost savings and improved outcomes, MNT should be adequately reimbursed by insurance and other payers.
- Modest weight loss achievable by the combination of lifestyle modification and the reduction of energy intake benefits overweight or obese adults with T2D and those at risk for diabetes. Interventional programs to facilitate this process are recommended.
- As there is no single ideal dietary distribution of calories among carbohydrates, fats, and proteins for people with diabetes, macronutrient distribution should be individualized while keeping total calorie and metabolic goals in mind.
- Carbohydrate intake from whole grains, vegetables, fruits, legumes, and dairy products, with an emphasis on foods higher in fiber and lower in glycemic load, should be advised over other sources, especially those containing sugars.
- People with diabetes should avoid sugar-sweetened beverages to control weight and should minimize the consumption of sucrose-containing foods that have the capacity to displace healthier, more nutrient-dense food choices.
- In individuals with T2D, ingested protein appears to increase insulin response without increasing plasma glucose concentrations. Therefore, carbohydrate sources high in protein should not be used to treat or prevent hypoglycemia.
- An eating plan emphasizing elements of a Mediterranean-style diet rich in monounsaturated fats may improve glucose metabolism and lower CVD risk and can be an effective alternative to a diet low in total fat but relatively high in carbohydrates.
- Eating foods rich in long-chain omega-3 fatty acids is recommended to prevent or treat CVD; however, evidence does not support a beneficial role for omega-3 dietary supplements.
- There is no clear evidence that dietary supplementation with vitamins, minerals, herbs, or spices can improve diabetes, and there may be safety concerns regarding the long-term use of antioxidant supplements.
- Adults with diabetes who drink alcohol should do so in moderation. No more than one drink per day for adult women and no more than two drinks per day for adult men.
- Alcohol consumption may place people with diabetes at increased risk for delayed hypoglycemia, especially if taking insulin or insulin secretagogues. Education and awareness regarding the recognition and management of delayed hypoglycemia are warranted.
- People with diabetes should limit sodium consumption to, 2,300 mg/day; further restriction may be indicated for those with both diabetes and HTN.

Adapted from ADA Clinical Practice Guidelines, 2016. (8)

EFFICACY IN MANAGING T2D THROUGH DSME AND MNT

During phase one of the present study, a comprehensive review of the literature was conducted exploring the evidence-base specifically the efficacy or DSME and MNT in the management of T2D.[20] Of the 24 studies reviewed, 22 reported significant reductions in HbA1c, statistical significance was taken at the 95% confidence interval.[21–34] Change in HbA1c in the intervention groups ranges from -0.19% to -1.3%, comparatively, control groups ranged from -0.8% to +0.93%. Greater HbA1C reductions were seen in participants with higher levels at baseline.

Direct comparative analysis between studies has been challenging given the heterogeneity of what constitutes DSME across studies; breadth, duration and intensity of the interventions; use of individual providers or multidisciplinary teams; and whether the RDN is the provider of the nutrition education component.[12] A recent meta-analysis exploring the impact of group based DSME alone (21 studies with 2833 participants) revealed a 0.44% (P = 0.0006) and 0.46% (P = 0.0005) reduction in HbA1c at six-months and one-year respectively.[8] The most recent systematic review of the DSME literature included studies specifically addressing the efficacy of DSME against usual care or minimal education; inclusion criteria included studies that specified components of DSME with goals to improve knowledge, skills, and abilities to perform self-management activities; results were more favorable with HbA1c reductions of 0.74%.[20] Comparatively, individualized RDN-administered MNT, based on RCTs, meta-analysis, and systematic review accounts for statistically significant HbA1c reductions of 0.9-1.9%.[23,28,35,36] Total time and number of nutrition visits has been associated with improved patient outcomes.[29,37] The pilot study demonstrated a significant HbA1c reduction from baseline

(8.74±2.30%) to end-of-program (6.82±1.37%) (-1.92±2.25%) (P<0.001) and retained at one-year (6.90±1.16%) (P<0.001); 72% of patients reached HbA1c targets.[12]

COST OF DIABETES

Because of the increasing prevalence in diabetes, researchers have set out to calculate the cost of diabetes in the United States. In 2007, the ADA quantified the economic burden of diabetes caused by increased health resource use and lost productivity and provided a detailed breakdown of the costs attributed to diabetes.[38] This study combined the demographics of the United States population in 2007 with diabetes prevalence rates and other epidemiological data, health care costs, and economic data. Data sources included national surveys (e.g., NHANES) and claims databases, as well as proprietary databases that contained annual medical claims for 16.3 million people. The total estimated cost of diabetes in 2007 was $174 billion, including $116 billion in excess medical expenditures and $58 billion in reduced national productivity. Medical costs attributed to diabetes included $27 billion for care to directly treat diabetes, $58 billion to treat the portion of diabetes-related chronic complications that were attributed to diabetes, and $31 billon in excess general medical costs.[38]

In 2012, the ADA repeated the study to update the costs of diabetes given increasing prevalence rates, health care costs, and economic data. The total estimated cost of diagnosed diabetes in 2012 was $245 billion, including $176 billion in direct medical costs and $69 billion in reduced productivity. This represents a 41% increase in the total estimated cost of diagnosed diabetes from the $174 billion reported in the previous 2007 study. Hospital inpatient care (43% of the total medical cost), antidiabetic agents and diabetes supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%) were the largest components of direct medical

expenditures for patients with diabetes. Though down from the reported expenditure of 50% in 2007, prescription medications to treat complications were also a major component of the direct medical expenditures (18%). The 41% increase in total estimated cost of diagnosed diabetes from 2007 to 2012 highlights the substantial burden that diabetes imposes on society. Patients with diabetes incur average medical expenditures of approximately $13,700 per year, of which $7,900 is related to diabetes. Patients with diabetes have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes. For the cost categories analyzed in both studies, care for patients with diabetes accounts for more than 1 in 5 health care dollars spent in the U.S., and more than half of that expenditure is directly attributable to diabetes itself.[38]

It is also important to note that a large percentage of total medical costs for patients with diabetes were spent on treating micro and macrovascular complications of diabetes. In 2012, about 25% to 53% of the total diabetes-attributed medical expenditures were spent treating complications of diabetes.[6,39] About 57% of the cost of complications was accounted for managing macrovascular complications alone.[39] In 2005, a multivariate analysis of 1,694 adults with diabetes showed that the 3-year costs of patients with diabetes with coronary heart disease (CHD) and hypertension (HTN) were over 300% of those with diabetes in the absence of these two chronic comorbid conditions.[40] In 2011, total Medicare costs for renal replacement therapy such as hemodialysis, peritoneal dialysis, and transplants reached $24.3 billion, $1.5 billion, and $2.9 billion, respectively. As of 2001, diabetes-related amputations were estimated to cost $38,077 each, while costs for foot ulcer care have been estimated at $13,179 per episode.[41] Notably, depression exhibited in patients with diabetes was associated with a 50% increase in

costs.[40] The increasing prevalence in diabetic complications as the disease progresses greatly impacts the total medical expenditure for patients with diabetes while reducing the quality of life.

On the surface, it may appear that the financial burden of diabetes falls primarily on insurers who pay a substantial portion of medical costs. However, the economic burden of diabetes is felt by all. Employers experience productivity loss, and patients with diabetes and their families incur higher out-of-pocket medical costs and reduced earnings or employment opportunities. While the majority (59%) of direct medical cost is for the population aged 65 years and over,[6] the lifetime direct medical costs still pose a significant burden on those younger than 65. For those diagnoses with T2D between ages 25-64 years, the lifetime direct medical cost is about $314,900 and $326,700 for men and women, respectively.[39] Furthermore, approximately 88% of indirect cost is borne by adults under 65 years of age, significantly impacting the working population. Indirect costs of diabetes include increased absenteeism ($5 billion) and reduced productivity while at work ($20.8 billion) for the employed population, reduced productivity for those not in the labor force ($2.7 billion), inability to work as a result of disease-related disability ($21.6 billion), and lost productive capacity due to early mortality ($18.5 billion).

Remarkably, the burden of diabetes and the established epidemic is passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.[6] For the 314 million Americans in 2012, the financial burden of diabetes represents a hidden "tax," averaging over $1,000 per person in the form of higher costs for medical insurance (including higher taxes to cover Medicaid and Medicare entitlements) and reduced national productivity. For a typical American family in 2012 with three members and a median income of $64,000, this diabetes burden equates to 4.8% of income (up from 3.4% in

2007).[39] Additional components of societal burden that cannot be adequately quantified include intangible struggles from pain and suffering, resources from care provided by non-paid caregivers, and the burden associated with undiagnosed diabetes.[6,38,42]

Epidemiological studies forecast that the prevalence of diabetes and its associated costs will rise even further in the future. The diabetic population and the related costs are expected to at least double in the next 25 years; between 2009 and 2034, the number of people with diagnosed and undiagnosed diabetes will increase from 23.7 million to 44.1 million.[43] During the same time period, annual diabetes-related spending is expected to increase from $113 billion to $336 billion (in 2007 dollars). For the Medicare-eligible population, the diabetic population is expected to rise from 8.2 million in 2009 to 14.6 million in 2034; associated spending is estimated to rise from $45 billion to $171 billion.[43] Adding to disease burden, newer estimates suggest that about 592 million people will be living with diabetes by 2035[41] if the prevalence of diabetes increases without interruptions. This increases the predicted direct and indirect costs of diabetes as well, which need to be determined by supplementary studies. Without significant changes in public or private strategies, diabetes and associated incremental cost growth are expected to add a significant strain to an already overburdened health care system.[43]

Given the current economic burden of disease, strategies to optimize disease prevention and progression are paramount. There is surmounting evidence that shows the efficacy of DSME and MNT through improvement on glycemic control and reduction of comorbid disease. These treatment modalities pose the potential to ameliorate some of current economic burden of diabetes. To the end, the current literature review was conducted to explore the cost-effectiveness of DSME and MNT in treating T2D. Academic Search Premier databases PubMed, CINAHL, and MEDLINE were used to conduct a thorough review of the present literature.

Search terms included medical nutrition therapy, diabetes education, cost-effectiveness, and glycemic control, with dates of inclusion of 2005 – 2016. The systematic database search was supplemented with manual searches of citations from relevant systematic reviews and the author's review of the reference lists. Studies were excluded if patients had type 1 diabetes, including pediatric patients, or if cost-effective results were not reported.

MATHEMATICAL MODELS OF COST-EFFECTIVENESS

Decision making in medicine relies heavily on clinical studies, preferably randomized control trials (RCTs). Although the evidence obtained from such research is invaluable in guiding the development of new healthcare interventions, clinical trials seldom observe health outcomes over long periods and less frequently consider the long-term economic impacts of the interventions. In the face of these problems, clinicians and policy makers have traditionally had to rely on their judgement, as demonstrated by wide variations in practice patterns, conflicts in guidelines, and high rates of inappropriate care.[44] Factors such as these may in part contribute to the lack of physician referral and reimbursement for DSME and MNT. Decision makers are increasingly turning to mathematical modeling as an acceptable technological tool that can provide more informed answers to questions that have not been, or will not be, answered by clinical trials.[44,45] Even though mathematical models cannot perfectly represent reality, models may be used to integrate evidence from clinical trials to make inferences about future economic, quality of life, and health outcomes and to provide data for decision making when long-term information is not available.[46,47]

However, several features of diabetes pose challenges for models. First, the complications of diabetes may take years or even decades to occur, so models must have long-

term trajectories and include mortality as a competing risk. Second, diabetes affects multiple organ systems, resulting in many types of complications. These complications not only share common risk factors, but also are linked in that one complication may affect the likelihood of developing others (e.g., HTN and CVD). Third, patients with diabetes typically receive many different treatments concurrently, affecting a diverse range of outcomes (e.g., ACE inhibitors can prevent CVD and renal disease). Therefore, diabetes models must include a wide range of complications and treatment effects. Some complications, such as myocardial infarction, may be rapidly fatal, whereas others, such as blindness, greatly reduce a person's quality of life but not necessarily life expectancy. Models should include both the quality and length of a person's life. There can also be a long delay between the onset of T2D and clinical diagnosis; thus, models should be able to make this distinction.[44] With these challenges in mind, a variety of mathematical models have been proposed to understand different aspects of diabetes such as epidemiology of diabetes and its complications, cost of diabetes and cost-effectiveness of interventions dealing with diabetes.[48] Therefore, the different types of mathematical models found in the literature all have advantages and disadvantages to modeling diabetes and diabetes-related costs.

Mathematical modeling of healthcare economics includes defined measures that help decision makers determine the cost-effectiveness of a certain intervention. Chronic diseases, like diabetes, and interventions to treat the disease impact patient health outcomes, and thus, the overall quality of life. To describe the effectiveness an intervention has on both the quality and quantity of life lived in the face of a disease, the outcomes are expressed in terms of quality adjusted life years (QALYs). QALYs are calculated by multiplying the quality of life value for each health state of a disease by the time in the state, and then summing for all the health states

across a period of time or person's lifetime.[49] Thus, the QALY is a measure of the value of health outcomes produced by a certain intervention. The incremental cost incurred by a certain intervention divided by the QALYs gained in a specific period of time is the incremental cost-effectiveness ratio (ICER).[49] The ICER summarizes the cost-effectiveness of a healthcare intervention by allocating monetary units to the outcomes produced by a certain intervention. Measuring individual ICERs is only the first step in determining whether the funding of a specific healthcare intervention is an efficient use of scarce resources. Such a determination would require comparing the ICER for a specific intervention with those of other healthcare interventions. Each individual ratio is of no use by itself; it must be compared with the ratios associated with other interventions.[50] ICERs can be used by decision makers in resource allocation and establish a willingness-to-pay value for healthcare interventions.

Establishing that an intervention is cost-effective is still problematic since the threshold for cost-effectiveness is controversial.[51] A threshold value is often set by policy makers, who may decide that only interventions with an ICER below a certain threshold are cost-effective and therefore should be funded.[52] Laupacis and colleagues have proposed a system to rate interventions based on the likely magnitude of the net benefit associated with their application (cost per QALY). They argue that interventions that cost less than $20,000 per QALY are an appropriate way to use resources and those that cost $20,000 to $100,000 per QALY are probably appropriate, but those that cost greater than $100,000 per QALY may not be a good use of resources.[47,52] However, US researchers and policy makers frequently employ $50,000 US/QALY as the threshold ICER.[51–56]

Generalized Linear Model

The generalized linear model (GLM) is a broad statistical method that can be used to find linear relationships between a predictor variable, such as DSME, and response variables, like changes in HbA1c and cost-savings.[57] Out of all the models discussed in this literature review, GLMs are the easiest and most accessible for researchers to use. They require a simple working knowledge of statistics and a validated statistical software program. Thus, the use of GLMs to study health outcomes and associated costs is popular. However, GLMs do come with limitations. Because GLMs are based implicitly on assuming a particular distributional form, there is a loss of precision in specific situations were skewness is common and inevitable.[57] For example, because patients with uncontrolled HbA1c tend to have higher prevalence of diabetic comorbidities, medical expenditures are substantially higher than those with controlled HbA1c. The graphic representation of HbA1c to medical expenditure is thus skewed to the left, which ultimately distorts the interpretation of the relationship between HbA1c and medical expenditure.[58] In general, more complex approaches to the GLM that consider the specific features of the data might lead to gains in precision and to more informative estimates, but could run a risk of misfitting or overfitting the data.[57]

Cost-effective/Cost-utility Analysis

The most common and oldest form of economic evaluation is cost-effectiveness analysis. The cost-utility analysis is a subset of cost-effective analysis where a measure of the quality of life is included in the analysis, and the two terms are often used interchangeably.[49] As stated above, cost-effectiveness analysis of a health care intervention requires a comparison of that

intervention with alternative interventions in a given disease state. With regard to DSME, the alternative methods are often defined as “standard care”.[50]

Cost-effective analysis is advantageous to decision makers because it allows comparisons across healthcare interventions of greatest potential benefit to patients and sets priorities across distinct interventions aimed at different groups of patients. Furthermore, cost-effective analysis is commonly used in conjunction with a marginal analysis, which is the examination of the additional benefits of an intervention compared to the additional costs incurred by the same intervention. Those interventions that yield lower marginal costs for each additional QALY produced are considered more efficient to pursue.[59] Using this method gives decision makers extra information that is usually simple and clear to understand while comparing interventions. However, it is often difficult to compare the results of one cost-effectiveness analysis with another because of heterogeneity in methodology, types of costs included, outcomes, and population groups and related baseline risk. There may also be differences in healthcare systems, incentives to healthcare professionals and institutions, clinical practices, population values, availability and accessibility of technologies, and currency purchasing power that influence the overall cost-effectiveness of the intervention of interest.[51]

Markov Model

In a healthcare context, Markov models are particularly suited to modelling chronic disease.[60] In Markov models, the disease in question is divided into distinct states and transition probabilities are assigned for movement between these states over a discrete time period. By attaching the estimates of resource use and health outcomes to each disease state, it is possible to estimate the long-term costs and outcomes associated with a disease and a particular healthcare

intervention.[49,60–63] Thus, Markov models simulate transitions from one disease state to another (e.g., from IGT to T2D) as chance events[62] and provide a means of modelling clinical problems in which the risk is continuous over time, events may occur more than once, and the utility of an outcome is dependent on when it occurs.[63]

The intuitive way in which Markov models can handle both costs and outcomes make them a powerful tool for economic evaluation of chronic disease. The fundamental difference between Markov models and other economic models in medical decision-making is that decision makers are interested in both the resource and health outcome consequences of healthcare interventions. The way in which Markov models handle both costs and outcomes of an intervention simultaneously is one of their strengths.[60,61] These models are useful for predicting the long-term health and cost consequences of an intervention for which there is only short-term data. This is particularly true with diabetes, for which the complications and their costs are most likely to occur years after the primary intervention was initiated. In such situations, clinical trials and long-term evaluations are very expensive, infeasible, and cannot produce timely results or policy recommendations. Thus, results from Markov models can provide decision makers with good estimates of the impacts of novel interventions.[60,64] Markov models are also dynamic and probabilistic as they can address problems in which events and decisions are occurring randomly over time.[60,61]

One of the biggest limitations of the Markov models is the unstandardized definitions of disease states and the quantity of disease states between studies. To better describe diabetes-related complications and its associated costs, the disease states need to be defined within the Markov models.[49] The transition probabilities also present problems. In medicine, they are not simple chance events, but the result of very complex biological phenomena and our attempts to

manage them.[61] The use of discrete time intervals, usually annual, also creates problems as almost nothing of real clinical significance happens at annual intervals.[61] The Markov modelling approach could be very flexible but relies on sufficient data to allow robust modelling and estimation. They also generally require substantial expertise, both in statistical modelling and in computation.[57]

Archimedes Model

In attempts to address the limitations of the Markov models, the Archimedes model was built.[65] The Archimedes model is a mathematical representation of the anatomy, pathophysiology, signs, symptoms, behaviors, tests, treatments, logistics, resources, and outcomes associated with type 1 and type 2 diabetes, as well as several other diseases and conditions, like CHD, congestive heart failure, asthma, stroke, hypertension, and obesity.[45,66] The model uses an object-oriented approach and differential equations to recreate a level of detail corresponding to that in patient charts, medical textbooks, clinical practice guidelines, and clinical trials.[45,48,65,67] It is written at a deep level of detail to accurately portray biological phenomena such that the Archimedes model does not calculate the risk of an outcome, like a myocardial infarction, but rather models the occlusion of specific coronary arteries in specific locations.[48,65] The Archimedes model is designed to be comprehensive and includes not only biological details from individual patients, but also other important aspects of a health care system, such as health care personnel, facilities, equipment, logistics, supplies, policies and procedures, regulations, utilities, costs, and quality of life.[45,48,65] Unlike the Markov model, the Archimedes model has no disease states, and continuously calculates all pertinent biological variables and their interactions as part of a simulated physiology, enabling the model to analyze

detailed practice guidelines, disease management interventions, intervention outcomes, and the development of comorbidities.[45,48,65,67] This design characteristic addresses interventions, such as diet and exercise, that affect multiple biological variables and conditions, interactions between treatments, and syndromes that affect multiple organ systems in their continuous nature.[65] While the design objective of the model is to simulate what happens in a real healthcare system at the deep level of detail at which people plan and make decisions, the key innovation in the development of the Archimedes model is that interventions and healthcare policies can be tested before they are implemented.[65,67,68] Validation of the Archimedes model against clinical trials has been published, providing details of 74 validation exercises involving 18 trials.[45]

Archimedes attempts to integrate the various systems of medicine and healthcare together in a model that allows decision makers to make informed decisions based on future predictions simulated by existing information. However, the widespread benefits of systems medicine cannot be realized due to common barriers in practice and research. First, the current understanding of the human body will need to be elaborated in fine detail. In diabetes, the in-depth knowledge of how diet, inflammation, genetics, environment, and lifestyle factors interrelate and influence each other's behavior is not fully realized. Second, theoretical and experimental methods should be effectively integrated.[66] Evaluating the cost-effectiveness of accredited DSME and MNT programs cannot be realized if they are not included in the cost-effective studies. Third, complex analysis is inherently a long-term, broad-based investment. To those accustomed to immediate, predictable results, this may present as the greatest barrier, causing many to doubt whether the benefits of DSME and MNT merit further financial commitment.[66] Fourth, as a model is made more accurate, its complexity increases. This, in turn, reduces its understandability to decision

makers.[51] Last, it is important to note that the Archimedes model is a proprietary model from Kaiser Permanente®, which makes it less accessible to researchers.[46]

COST-EFFECTIVENESS OF DSME AND MNT

In order to further explore the relationship between improved patient outcomes and healthcare cost-savings associated with provision of DSME and MNT, we have conducted a review of literature of studies linking patient outcomes to cost-effectiveness (Table 4). In exploring the published literature, two of the most integral objectives of DSME and MNT, glycemic control and comorbidity prevention and reduction, have been identified as key outcome variables for study. Health policy and reimbursement for DSME and MNT are driven by results of these cost-effective analyses. Determining that an intervention is cost-effective necessitates setting a threshold for cost-effectiveness and provider willingness to pay. Studies typically express incremental changes in HbA1c and/or classify patients at baseline and post intervention based on reaching glycemic targets (≤ 7) and risks; HbA1c cutoffs for risk vary between reported studies.

Table 4. Studies Linking Glycemic Control and Cost-effectiveness					
Author, year of publication	Participants	Design	Intervention	Results: Glycemic control	Results: Cost-effectiveness
Banister 2004	N = 70 Baseline HbA1c: 9.70% ± 2.40%	Study design: quasi-experimental cohort trial Mathematical model: GLM	DSME	-1.5% HbA1c End HbA1c: 8.20% ± 2.00%	$185 saved per person per year for each point reduction in HbA1c.
Christensen 2004	N = 155 Baseline HbA1c: 7.16% ± 1.35%	Study design: quasi-experimental cohort trial Mathematical model: GLM	Cooperative Extension Service nutrition program focused on food portioning skills	-0.73% HbA1c End HbA1c: 6.43% ± 1.11%	Hospitalization cost savings: $94,010 per year for this cohort of patients
Shetty 2005	N = 6,780	Study design: RCR Mathematical model: GLM	DSME	HbA1c ≤7%: n = 3,121 HbA1c >7%: n = 3,659	Total predicted cost for HbA1c >7% group during a 1-year period was $1,540 per patient, 32% higher than the total predicted cost ($1,171) for the HbA1c ≤7% group
Balamurugan 2006	N = 212 Baseline HbA1c: 8.00% ± 2.55%	Study Design: quasi-experimental cohort trial Mathematical model: GLM	DSME	-0.45% HbA1c End HbA1c: 7.55% ± 1.68%	Over 3 years, the estimated cost savings in was $415 per program completer.
Oglesby 2006	N = 10,780 HbA1c ≤7%: n = 6,069 HbA1c >7% and ≤9%: n = 3,586 HbA1c >9%: n = 1,125	Study design: longitudinal of healthcare administrative data Mathematical model: GLM	No intervention implemented	N/A	Direct medical costs were 16% lower for patients with HbA1c ≤7% than for those with HbA1c >7% and ≤9% ($1,505 vs. $1,801), and 20% lower for those with HbA1c ≤7% than for those with HbA1c >9% ($1,505 vs. $1,871)

Author, year of publication	Participants	Design	Intervention	Results: Glycemic control	Results: Cost-effectiveness
Valentine 2006	N = 1000	Study design: simulation of NHANES data Mathematical model: Markov	Assumed hypothetical intervention *Scenario 1*: HbA1c reduction of from 9.5% to 8.0% vs. no reduction (remain at HbA1c of 9.5%). *Scenario 2*: HbA1c reduction of from 8.0% - 7.0% vs. no reduction (remain at HbA1c of 8.0%). *Scenario 3*: HbA1c reduction of 7.0% to 6.5% vs. no reduction (remain at HbA1c of 7.0%).	N/A	Scenario 1: total lifetime complications costs of $72,629 per patient reduced to $67,420, a saving of $5,209 per patient. Scenario 2: further reduction of total cost of complications to $64,322, a saving of $3,099. Scenario 3: reducing HbA1c to 6.5% decreased total lifetime complication costs to $62,684, saving $1,637 per patient compared with no HbA1c change.
Robbins 2008	N = 18,404	Study design: RCR Mathematical model: GLM	DSME and MNT	HbA1c not reported	DSME was associated with $11,571 less in hospital charges per person. Each MNT visit was associated with a $6,503 reduction in total hospital charges.
Brownson 2009	N = 1273	Study design: RCR Mathematical model: Markov	Various diabetes education programs through the Robert Wood Johnson Foundation	-0.5% HbA1c	ICER: $39,563/QALY in 3-year period

Author, year of publication	Participants	Design	Intervention	Results: Glycemic control	Results: Cost-effectiveness
Menzin 2010	N = 9,887 Baseline HbA1c <7%: n = 5,649 Baseline HbA1c 7-8%: n = 2,747 Baseline HbA1c 8-9%: n = 1,002 Baseline HbA1c 9-10%: n = 312 Baseline HbA1c ≥10%: n = 177	Study design: RCR Mathematical model: GLM	No intervention implemented	End HbA1c <7%: n = 3,046 End HbA1c 7-8%: n = 1,787 End HbA1c 8-9%: n = 740 End HbA1c 9-10%: n = 180 End HbA1c ≥10%: n = 121	HbA1c of < 7%: hospitalization costs were $2,792 per patient per year. HbA1c of ≥10%: hospitalization costs were $6,759 per patient per year
Brown 2012	N = 30 *Intervention group* Baseline HbA1c: 9.55% ± 2.53% *Control group* Baseline HbA1c: 10.50% ± 2.39%	Study design: RCT Mathematical model: Archimedes	Lifestyle modification program led by community health workers (CHWs)	*Intervention group* -3.26% HbA1c End HbA1c: 6.29% ± 0.40% *Control group* -1.95% HbA1c End HbA1c: 8.55% ± 1.33%	ICER: $10,995 - $33,319/ QALY in a 20-year period
Schechter 2012	N = 444 Baseline HbA1c (both groups): 9.2% *Telephone group* Baseline HbA1c ≥7.5%: n = 228 *Print group* Baseline HbA1c ≥7.5%: n = 216	Study design: RCT Mathematical model: cost-effective analysis	Telephonic diabetes education program	-0.42% mean HbA1c difference between telephone and print groups *Telephone group* End HbA1c ≤7%: n = 201 *Print group* End HbA1c ≤7%: n = 205; 5.1%	ICER: $490.58/QALY per HbA1c point improvement and $2,617.35/QALY per person over a 1-year achieving goal HbA1c. Cost per percentage point reduction in HbA1c: $487.75 Cost per person achieving the HbA1c goal of <7%: $2,312.88

Author, year of publication	Participants	Design	Intervention	Results: Glycemic control	Results: Cost-effectiveness
Juarez 2013	N = 1,304 Baseline HbA1c <7%: n = 450 Baseline HbA1c ≥7%: n = 854	Study design: RCR Mathematical model: GLM	DSME	End HbA1c <7% for 3 years: n = 169 End HbA1c ≥7% for at least 1 year: n = 349	HbA1c levels of <7%: total cost care decreased by $2,207 per patient for 3 years. HbA1c ≥7%: total cost of care increased by $3,006 per patient for 3 years.
Sullivan 2013	N = 34,953 *C/E group* Baseline HbA1c: 8.3% *Non-C/E group* Baseline HbA1c: 8.2%	Study design: RCR Mathematical model: GLM	Various diabetes education and nutrition programs; includes DSME and MNT	*C/E group* -1.1% HbA1c End HbA1c: 7.2% *Non-C/E group* -0.5% HbA1c End HbA1c: 7.7%	Overall costs in the C/E group were $15,194 vs $13,164 in the non-C/E group. Diabetes-related health care costs were higher in the C/E group ($5,157) compared with the non-C/E group ($4,375).
Prezio 2014	N = 180 Baseline HbA1c (both groups): 9.70% ± 1.70%	Study design: RCT Mathematical model: Archimedes	Diabetes education intervention led by community health workers	*Intervention group* -1.89% HbA1c End HbA1c: 7.61% ± 0.04% *Control group* -1.15% HbA1c End HbA1c: 8.55% ± 0.05%	ICER: $355/QALY per intervention participant per year

Cost-effectiveness of glycemic control

Because of the impact of glycemic control on the development of comorbidities, reduction in HbA1c decreases diabetes-related medical costs. Using a GLM, a $415 cost-savings in diabetes-related costs per program completer over a 3-year period was estimated after the implementation of a DSME program for 157 Medicaid patients with a mean reduction in HbA1c of 0.45%.[69] Markov modeling has been used to project the long-term clinical and cost outcomes associated with improvements in glycemic control based on scenarios with incremental

reductions in HbA1c (scenario 1, reduction in HbA1c from 9.5% to 8.0%; scenario 2, reduction in HbA1c from 8.0% to 7.0%; and scenario 3, reduction in HbA1c from 7.0% to 6.5%) verses no reduction.[70] Reductions in HbA1c decreased the cumulative incidence of complications, and thus increased the potential cost savings. The most substantial cost savings were projected in scenario 1 (9.5–8.0%) where the mean total lifetime costs of $72,629 (±$2,497) per patient were reduced to $67,420 (±$2,583) with the hypothetical intervention, a saving of $5,209 per patient. In scenario 2, the hypothetical intervention further reduced the total cost of complications to $64,322 (±$2,498), corresponding to a saving of $3,099. In scenario 3, reducing HbA1c to 6.5% decreased total lifetime complication costs to $62,684 (±$2,333), saving $1,637 per patient compared with no HbA1c change.[70] Likewise, an ICER of $355/QALY gained was estimated for a diabetes education and management intervention with 180 uninsured participants. Participants who received the intervention had significantly higher reduction in HbA1c (9.50% to 7.61%; -1.89%) compared to those who did not receive care (9.50% to 8.55%; -0.95%) ($P<0.001$).[71]

Estimations of cost-benefit of incremental reductions in HbA1c have been explored specific to the provision of DSME and MNT. An early cost-utility analysis of 179 patients, from 3 states (Minnesota, Florida, and Colorado) with T2D receiving diabetes education and individualized nutrition interventions provided by an RDN according to practice guidelines resulted in a 0.93% (±1.63%) reduction in HbA1c ($P<0.01$) as compared to patients receiving basic care (0.69% ±1.67%). The ICER was 21% lower in the treatment group.[72] An Archimedes model was used to forecast disease outcomes expressed in QALYs gained, and lifetime costs associated with attaining selected HbA1c levels through a community-based intervention in low-income Hispanic adults.[56] HbA1c reductions were observed in patients treated by diet alone of 1.95% (10.50% ± 2.39% to 8.55% ± 1.33%) and for diet plus drug therapy of 3.26% (9.55% ±

2.53% to 6.29% ± 0.40%). The ICER for the intervention ranged from $10,995 to $33,319/ QALY gained when compared with usual care; highest cost-effectiveness was observed for adults with HbA1c >9%. In the state of New York, a 1% reduction in HbA1c has been reported to result in a conservative health care cost savings estimate of $1,200/year per patient for Medicaid fee-for-service beneficiaries with diabetes who engaged in DSME and RDN-administered MNT.[73] Cost-effective modeling supports achievement of sustained glycemic control through DSME and MNT as the cornerstone of diabetes management.

In addition to incremental reductions in HbA1c, categorical grouping of patients relative to HbA1c targets and risks has been useful in assessing cost savings and healthcare utilization. Among 2.1 million patients with diabetes in the United States, those reaching glycemic targets (HbA1c ≤7%) exhibited direct diabetes-related medical costs that were 16% lower than those with fair glycemic control (HbA1c ≥7% and ≤9%) and 20% lower than those with poor glycemic control (HbA1c >9%).[74] Retrospective analysis of 1,304 patients with poor (HbA1c ≥7%) and target initial glycemic control (HbA1c <7%) followed over a 3-year period revealed significant improvements in total cost of care for patients with sustained glycemic control. Costs decreased by $2,207 with HbA1c < 7% and increased by $3,006 with HbA1C ≥7%; this cost differential represents and effective cost savings of $5,214 (95% CI, $10,163 to $264) per patient reaching and sustaining glycemic control.[75] Much of this cost has been attributed to increased hospitalizations mostly due to diabetes related comorbidities. Estimated cost of diabetes-related hospitalizations per patient at target HbA1c < 7% were $2,792 as compared to $6,759 among those with HbA1c ≥10%.[76] Overall, patients with HbA1c > 7% have been reported to have total healthcare costs that are 32% higher than those with sustained HbA1c in the target range ($P<0.001$).[77]

In assessing healthcare cost savings associated with reduction in HbA1c, the cost of provision of services must also be considered. Diabetes self-management training followed by individualized consultations from an RDN provided in a community setting have been demonstrated to improve patient outcomes at modest cost.[78] Mean HbA1c improved from 9.7±2.4% to 8.2±2.0% (P<0.001); 61% of patients experienced positive medication outcomes. The diabetes education program cost was about $280 per person per year and included diabetes testing supplies, but not the cost of medications. Based on outcomes of a 1.5% reduction in HbA1c, the program cost was $185 for each point reduction in HbA1c. Even though there are costs to implement and manage diabetes education interventions, patients that receive DSME and MNT generally incur lower inpatient and emergency department costs, indicating that these patients are able to manage their diabetes in the primary care setting and not drive up medical costs associated with acute care.[79,80] With each educational visit with an RDN associated with an estimated $6,503 less in total hospital charges per patient in a 5-year period, the evidence suggests that many hospitalizations and related charges could be avoided in the long term if patients with diabetes had access to DSME and MNT.[80]

Cost-effectiveness and Comorbidity Treatment

The effect that glycemic control has on the development of micro and macrovascular comorbidities also impacts the cost of diabetes-related medical costs. For each myocardial infarction averted, the average costs in 2005 US$ saved are $15,900 for a nonfatal event and $11,300 for a fatal event. Averting a coronary artery bypass graft saves approximately $18,300, and preventing a stroke saves nearly $10,000.[69] In 2011, diabetes was listed as the primary cause in 44% of all new cases of kidney failure in the United States, and in the same year, the total

Medicare costs for kidney treatments such as hemodialysis, peritoneal dialysis, and transplants reached $24.3 billion, $1.5 billion, and $2.9 billion, respectively.[41] In 2014 US$, patients with diabetes who also had CHD and HTN had average medical costs 300% higher than those with diabetes only ($46,897 v. $14,233, P<0.05). Depression was also associated with a $10,358 increase in costs ($31,967 v. $21,609, P<0.05).[40] It is important to note that while most clinicians attempt to improve diabetes care have focused primarily on improving HbA1c[81], it seems that this strategy only makes clinical and economic sense when median HbA1c is high (HbA1c >9%). While there is a strong linear relationship between HbA1c and chronic comorbid conditions, once median HbA1c improves to <7%, focusing on primary and secondary prevention of comorbidities may provide more clinical benefits at less cost on a population basis.[82] A simulation study using a GLM to model the relationship between improvement in target HbA1c goals, development of comorbidities, and cost-savings in commercial and Medicaid populations illustrates this strategy.[83] With improved control of HbA1c already at target level, reductions in the probability of complications ranged from 43% to 67% in the commercial population (n = 392) and 28% to 49% in the Medicare population (n = 466). Cost-savings from reduced complications ranged from $67 to $105 per patient per month in the commercial population and $99 to $158 in the Medicare population, yielding a reduction of about 10% in total costs.[83]

DSME and MNT vs. diabetes prevention

While it may appear more cost-effective to focus resources on reducing the overall prevalence of diabetes and pre-diabetes through diabetes prevention programs, this does not seem to be the case.[53,56,84,85] A 30-year Archimedes model simulation shows the DPP lifestyle

intervention to be neither cost-effective nor cost-saving.[86] Notably, in a comprehensive review of the evidence-base of the cost-effectiveness of prevention of diabetes, annual direct medical costs increased from $1,400 to $4,600 (2008 US$) as an individual progressed from impaired glucose tolerance to uncomplicated diabetes to diabetes requiring pharmacologic treatment to diabetes with complications and comorbidities.[52] Furthermore, MNT could be even more cost-saving than a DPP lifestyle intervention because of the effective use of services and resources tailored to the individual to obtain optimal outcomes.[86] Even though this application of the evidence would suggest directing limited healthcare dollars to those in higher risk categories in the current US health care model, it raises ethical concerns regarding the duty to treat all patients with diabetes at various stages of the disease progression.

Program costs for DSME and MNT are a fraction of the costs of managing diabetes complications due to disease progression.[78,87] Direct medical cost of complications of diabetes in 2012 US$ for major macrovascular disease averaged $56,445 for a myocardial infarction, $42,118 for ischemic stroke, $23,758 for heart failure, and 21,406 ischemic heart disease per event year.[88] For microvascular complications, annual costs per event year are $71,714 for end stage renal disease and $2,862 for blindness. The event-year cost was $9,041 for lower extremity amputations.[88] A year of DSME and testing supplies costs 38% less than one emergency department admission.[78]

Limitations of Cost-Benefit Analysis of DSME and MNT

The heterogeneity of study design, population, and variability in diabetes education interventions pose similar challenges in assessing cost savings as they did biomedical outcomes.[12,87] Many of the studies that explored the cost-effectiveness of DSME provided broad

definitions of DSME, and therefore may not accurately depict the cost-effectiveness of the DSME programs currently covered by many public and private insurers. Duncan et al conducted two longitudinal studies that analyzed insurance claims for patients with diabetes participating in commercial and Medicare Advantage insurance plans with formal diabetes education through ADA-recognized or AADE-accredited programs. In both studies, investigators observed discernible cost-savings associated with patients who had participated in DSME; there was a dose-benefit response in that patients receiving more time and/or a greater number of visits exhibited better glycemic control and adherence to treatment regimens, lower cost, and decreased utilization of services. These cost-savings were largely attributable to decreased inpatient costs.[79] More data from studies that specifically address DSME with RDN-provided MNT according to the standards of practice applied in real-world settings are needed to further evaluate cost-effectiveness of these programs. Likewise, many of the studies failed to use the HbA1c levels for glycemic target and risk; an HbA1c level of <7% is the accepted goal target for most patients with diabetes[2] while an HbA1c level of >9% is associated with increased risk of comorbidities.[3] Cost-effectiveness studies included in this literature review used variable HbA1c cutoffs and targets. Additional research using ADA standard targets and risks is warranted.

The ICER considers the difference in costs and the difference in benefits of two interventions. A threshold value is often set by policy makers, who may decide that only interventions with an ICER below the designated threshold are cost-effective and therefore warrant funding. However, it is important to note that cost-effectiveness of lifestyle interventions differs among countries because of country-specific interventions and health care costs. While no standard definition exists for the evaluation of interventions, in the US, interventions that cost less than $50,000/QALY are considered an efficient use of resources and

worth recommending.[51–56] Other countries have different evaluations of this measure depending on their specific system of health care management, financial views, and health care laws.[53,55] Therefore, health care cost-effective results from studies conducted outside of the US healthcare system need to be evaluated with the acknowledgement of differences in health care management, public policy, and culture.

Among studies that have found the costs of diabetes education to exceed potential savings or have found no impact on overall costs, investigators have often suggested that the results may be due to the limited timeframe of analysis and that DSME is likely cost-effective or cost-saving in the long-term.[64,89] The costs associated with sustaining glycemic control, including but not limited to DSME, MNT, additional physician visits, and medications including insulins, are immediate, but the benefits may take years to realize. Even so, it is likely these costs will continue to be lower in subsequent years if patients maintain glycemic control.[75] Evaluation of the cost-effectiveness of treatments, specifically DSME and MNT, require long-term discernment to best analyze the ultimate impact on patient outcomes and cost saving over the course of this progressive chronic disease.

It is also important to note that cost-effective analysis does not address the distribution of costs and the benefits of interventions, such as DSME and MNT, to society as a whole. Because of the difficulty of appraising the costs of higher insurance premiums, taxes, reduced earning and employment opportunities, and reduced standard of living,[90] indirect costs related to diabetes were not measured or accounted for in the studies reviewed. The societal or personal willingness to pay, social and legal aspects, or ethical issues associated with delivering or withholding each intervention are important in formulating public policy and business strategies.[54] All of these

aspects are important in considering the total worth of DSME and MNT, which are not taken into account in traditional cost-effective analyses.

SUMMARY

Despite existing evidence, CDC reports that an estimated 6.8% of privately insured newly diagnosed patients participate in DSME. Access to DSME and MNT are limited by inconsistent insurance coverage. This study provides the Alabama specific patient outcome data requested by BCBS-AL for RDNs to be considered preferred providers. By obtaining preferred provider status and therefor reimbursement for DSME and MNT provided by RDNs, more patients would have access to these services. Furthermore, demonstration of positive outcomes could be utilized to support the provision of these services to adult Medicaid patients in Alabama who currently receive no diabetes education. This project builds on our pilot initiative with two major aims: 1) to document outcomes for patients with T2D completing DSME and MNT through 4 ADA-recognized diabetes education programs in Alabama and 2) identify potential healthcare cost-savings associated with reduction in HbA1c utilizing patient outcomes and mathematical models from published studies.

CHAPTER II

METHODS

Study Design

Retrospective chart review (RCR) was used to extract patient outcome data from medical records at four regional ADA-recognized diabetes education centers subsequent to provision of DSME and MNT. The RCR employed previously established methodology for abstracting patient outcome data; interrater reliability was established (Cohen's kappa = 1).[12] Given the high interrater reliability, duplication was not performed. The protocol was approved under Expedited Review by the Institutional Review Boards of Auburn University and the participating medical centers in Auburn-Opelika, Dothan, Huntsville, and Montgomery, Alabama.

Population and Intervention

The population included adult patients diagnosed with T2D completing comprehensive ADA-recognized education programs at four regional diabetes education centers throughout Alabama (Auburn-Opelika, Dothan, Huntsville, and Montgomery). Charts of patients beginning each program between June 2013 and June 2014 and completing all scheduled visits were identified as eligible for review; patients with chronic kidney disease on dialysis were excluded from the study. A randomized sample of 100 medical records was queried from each site; after exclusions 388 charts were included in the multisite analysis. A suitable control group was not identified; each patient served as his or her own control.

Each of the four comprehensive diabetes education programs is offered in compliance with the *National Standards for Diabetes Self-Management Education and Support*, which serves as the framework for the ADA Education Recognition requirements.[16,91] Core content

areas included diabetes disease process; treatment options, incorporating nutritional management and physical activity into lifestyle; using medications safely and for maximum therapeutic effectiveness; monitoring blood glucose and other parameters, and interpreting and using the results for self-management decision making; preventing, detecting, and treating acute and chronic complications; developing personal strategies to address psychosocial issues and concerns; and developing personal strategies to promote health and behavior change.[2,16] Each program provided DSME incorporating nutrition education and individualized RDN-provided MNT; RDNs provided the nutritional management components of DSME. While programs varied with regard to choice of curriculum, length, total number of hours of DSME and MNT, and individual or group sessions, all programs were administered in compliance with standards. Table 5 provides a summary of the specific characteristics of the education programs from each of the four participating regional ADA-recognized diabetes education centers in Alabama.

Table 5. Summary of American Diabetes Association – Recognized Diabetes Education Programs and Four Regional Diabetes Education Centers in Alabama				
Site	**Auburn-Opelika**	**Dothan**	**Huntsville**	**Montgomery**
Program Length (follow-up)	6 months (6 months)	12 months (12 months)	6 months (every 6 months c/ PCP referral)	6 months (6 months)
Curriculum	Conversation Map	Healthways	Life with Diabetes (ADA 5th Ed.)	Self-developed curriculum
DSME	1-hour individual (multidisciplinary) 3 - 2 1/2 hour group (multidisciplinary) 1 - 1 1/2 hour group at 6 months (multidisciplinary) **Total DSME 10 hrs**	2 - 3.5 hour group (multidisciplinary) Day 1: RN (initial assessment, behavior change, diabetes overview, treatment, control, acute complications, foot care) Day 2: RDN (nutrition, physical activity, and chronic complications) **Total DSME 7 hrs**	2 - 4 hour group 2-4 weeks apart (RDN or RN) **Total DSME 9.5 hrs**	30 min individual assessment (RDN or RN) 3-hour group (RDN) 3-hour group (RN) Individual education provided if patient unable to participate in class (2-3 hours with RN/RDN or CDE; 30-60 minute follow-up 2 weeks) **Total DSME 6.5 hrs**
MNT	1-hour individual MNT (2 weeks after last DSME class) 1/2 hour individualized MNT (3 months after last DSME class)	Telephone follow-up to assess need; if need referred for: 1-1 1/2 hour face-to-face individualized MNT for meal planning or CHO counting	30 minute individual MNT 6 months after DSME to assess goals and information presented in DSME *30 minute individual follow-up at 1 year after DSME for Medicare patients only*	30 minute individual MNT 2-3 weeks after DSME to assess glycemic control/food diary and goals 6 month phone follow-up *6 month 1 hour group class for Medicare patients only*
Measures				
A1c%	Baseline, 3 months, 6 months	Baseline, 3 months, 6 months, 12 months	Baseline, Every 6 months	Baseline, 6 months
SMBG	At each follow-up	At each follow-up, if available	At each follow-up	At each follow-up
Weight	Baseline, 2 weeks, 3 month, 6 month	Baseline (follow-up weights are self-reported)	Baseline, 1 month, Every 6 months	Baseline, 2 weeks, 6 months

Outcome Measures

Demographic information was queried for age, sex, race; length of diagnosis and comorbid disease; smoking and alcohol use; learning barriers; and primary insurance.

Prescription medication use for diabetes and common comorbid disease was documented at baseline and follow-up and included oral hypoglycemic agents (OHA), insulin, other injectables, blood pressure medications, and statins. Key outcomes measures included: anthropometrics (weight and BMI); glycemic control (HbA1c, SMBG averages, and frequency of hypoglycemia); serum lipids (total cholesterol, LDL, HDL, and triglycerides); blood pressure; and number of hospitalizations. Anthropometric data was available at baseline, following DSME, following MNT (end-of-program), and at 1-year. HbA1c was available at baseline, end-of-program, and at 1-year. Patients were grouped into categories of HbA1c targets ($\leq 7\%$)[2] and those with poor control, HbA1c $\geq 9\%$.[92] Baseline and follow-up lipids were available in a small subset of the sample population. Primary care providers were contacted to obtain missing data where feasible.

Statistical Analysis

Descriptive statistics were used to present the demographic characteristics of the population and to classify patients at baseline, end-of-program, and 1-year follow-up with regard to glycemic targets. A mixed-model analysis of variance (ANOVA) was used to compare changes in continuous variables, anthropometric measures and HbA1c, across the treatment period and at 1-year. Mixed model ANOVA accounts for missing data inherent in the RCR. The McNemar test was performed to assess relative frequencies of patients reaching glycemic targets and at risk. Anthropometric measures and HbA1c were stratified by sex, race, and length of diagnosis to address potential confounders and effect modifiers. In order to further discriminate the full effect of DSME and MNT, HbA1c was stratified by diet alone and diet plus pharmacotherapy. Power analysis from the pilot study revealed that the minimum number of

subjects to achieve 80% power was 12, 52, and 56 for HbA1c, weight, and BMI respectively.[12] Significance testing was conducted at the 95% confidence interval (alpha = 0.05).

RESULTS

Demographic characteristics for the combined multisite study population are presented in Table 6a. For patients with insurance coverage for DSME; 96% received services administered by BCBS (BCBS-AL and Medicare). The diabetes education programs are administered such that both DSME and MNT are reimbursed for Medicare beneficiaries. There is no state coverage for DSME or MNT for adult Medicaid patients with a diagnosis of T2D in Alabama; 13 Medicaid-eligible patients received DSME and MNT through a scholarship program offered through one of the sites. Approximately 63% of the patient population had a recent diagnosis of T2D within the preceding year. Greater than 85% of the population had at least one diagnosed comorbid condition; hypertension, dyslipidemia, and obesity were most common. Demographic characteristics of each individual site are presented in Tables 6b-e.

Table 6a. All Sites: Population Demographics of Patients with T2DM receiving DSME and MNT					
n = 388	**Frequency**	**%**		**Frequency**	**%**
Sex			**Comorbidities**		
Female	219	55.87	Amputations	1	0.26
Male	168	42.86	CHD	11	2.81
Ethnicity			CVA	14	3.57
African American	121	30.87	Depression	31	7.91
White (non-Hispanic)	262	66.84	Dyslipidemia	157	40.05
Asian	8	2.04	Hypertension	274	69.90
Hispanic-Latino American	1	0.26	Kidney Disease	10	2.55
Insurance			Neuropathy	52	13.27
BCBS/other	209	53.32	Non-healing Wounds	0	0.00
Medicare	166	42.35	Retinopathy	20	5.10
Medicaid/none	17	4.34	Obesity	89	22.70
Years Diagnosed			OSA	44	11.22
< 1 year	245	62.50			
1 - 5 years	43	10.97	**Number of Comorbidities**		
6 - 10 years	32	8.16	None	54	13.78
> 10 years	70	17.86	One	126	32.14
Barriers			Two	146	37.24
Physical	3	0.77	Three	39	9.95
Hearing	44	11.22	Four	18	4.59
Vision	58	14.80	Five	7	1.79
Low Literacy	11	2.81	Six	2	0.51
Language	1	0.26			

Table 6b. Auburn-Opelika: Population Demographics of Patients with T2DM receiving DSME and MNT					
n = 88	**Frequency**	**%**		**Frequency**	**%**
Sex			**Comorbidities**		
Female	52	59.09	Amputations	0	0
Male	36	41.91	CHD	6	6.82
Ethnicity			CVA	9	10.23
African American	31	35.23	Depression	14	15.91
White (non-Hispanic)	56	63.64	Dyslipidemia	51	57.95
Asian	1	1.14	Hypertension	65	73.86
Insurance			Kidney Disease	3	3.41
BCBS/other	35	39.77	Neuropathy	16	18.18
Medicare	40	45.45	Non-healing Wounds	0	0
Medicaid/none	13	14.77	Retinopathy	17	19.32
Years Diagnosed			Obesity	49	57.64
< 1 year	52	59.77	OSA	14	15.91
1 - 5 years	9	10.34			
6 - 10 years	9	10.34	**Number of Comorbidities**		
> 10 years	17	19.54	None	8	9.09
Barriers			One	16	18.18
Physical	2	2.38	Two	38	43.18
Hearing	10	11.90	Three	10	11.36
Vision	5	5.95	Four	9	10.23
Low Literacy	4	4.76	Five	5	5.68
Language	0	0	Six	2	2.27

Table 6c. Dothan: Population Demographics of Patients with T2DM receiving DSME and MNT					
n = 100	**Frequency**	**%**		**Frequency**	**%**
Sex			**Comorbidities**		
Female	53	53.00	Amputations	0	0.00
Male	47	47.00	CHD	3	3.00
Ethnicity			CVA	4	4.00
African American	27	27.00	Depression	14	14.00
White (non-Hispanic)	73	73.00	Dyslipidemia	24	24.00
Insurance			Hypertension	68	68.00
BCBS/other	53	53.00	Kidney Disease	3	3.00
Medicare	47	47.00	Neuropathy	19	19.00
Medicaid/none	0	0.00	Non-healing Wounds	0	0.00
Years Diagnosed			Retinopathy	2	2.00
< 1 year	51	51.00	Obesity	23	23.00
1 - 5 years	15	15.00	OSA	24	24.00
6 - 10 years	11	11.00			
> 10 years	23	23.00	**Number of Comorbidities**		
Barriers			None	9	9.00
Physical	0	0.00	One	34	34.00
Hearing	14	14.00	Two	33	33.00
Vision	6	6.00	Three	14	14.00
Low Literacy	4	4.00	Four	8	8.00
Language	0	0.00	Five	2	2.00

Table 6d. Huntsville: Population Demographics of Patients with T2DM receiving DSME and MNT					
n = 102	**Frequency**	**%**		**Frequency**	**%**
Sex			**Comorbidities**		
Female	56	57.73	Amputations	0	0.00
Male	41	42.27	CHD	2	1.98
Ethnicity			CVA	1	0.98
African American	27	26.47	Depression	0	0.00
White (non-Hispanic)	72	70.59	Dyslipidemia	61	59.80
Asian	3	2.94	Hypertension	71	69.61
Insurance			Kidney Disease	2	1.96
BCBS/other	62	60.78	Neuropathy	3	2.94
Medicare	39	38.24	Non-healing Wounds	0	0.00
Medicaid/none	1	0.98	Retinopathy	0	0.00
Years Diagnosed			Obesity	13	12.75
< 1 year	67	66.34	OSA	1	0.98
1 - 5 years	10	9.90			
6 - 10 years	6	5.94	**Number of Comorbidities**		
> 10 years	18	17.82	None	15	14.71
Barriers			One	28	27.45
Physical	1	0.98	Two	51	50.00
Hearing	11	10.78	Three	8	7.84
Vision	39	38.24			
Low Literacy	3	2.94			
Language	0	0.00			
Diabetes Medications					
None	29	28.43			
OHA	65	63.73			
Injectable	4	3.92			
Insulin	21	20.59			
OHA + Injectable	4	3.92			
OHA + insulin	14	13.73			
Injectable + insulin	2	1.96			

Table 6e. Montgomery: Population Demographics of Patients with T2DM receiving DSME and MNT					
n = 102	**Frequency**	**%**		**Frequency**	**%**
Sex			**Comorbidities**		
Female	58	56.86	Amputations	1	0.98
Male	44	43.14	CHD	0	0.00
Ethnicity			CVA	0	0.00
African American	36	35.29	Depression	3	2.94
White (non-Hispanic)	61	59.80	Dyslipidemia	21	20.59
Asian	4	3.92	Hypertension	70	68.63
Hispanic-Latino American	1	0.98	Kidney Disease	2	1.96
Insurance			Neuropathy	14	13.73
BCBS/other	59	57.84	Non-healing Wounds	0	0.00
Medicare	40	39.22	Retinopathy	1	0.98
Medicaid/none	3	2.94	Obesity	4	3.92
Years Diagnosed			OSA	5	4.90
< 1 year	75	73.53			
1 - 5 years	9	8.82	**Number of Comorbidities**		
6 - 10 years	6	5.88	None	22	21.57
> 10 years	12	11.76	One	48	47.06
Barriers			Two	24	23.53
Physical	0	0.00	Three	7	6.86
Hearing	9	8.82	Four	1	0.98
Vision	8	7.84			
Low Literacy	0	0.00			
Language	1	0.98			

Table 7a provides a summary of patient outcomes across dependent variables of BMI, weight, and HbA1c from pooled data from all four sites. Tables 7b-e provide data from each of the four individual sites. Baseline BMI ranged from 21.41 to 59.72 kg/m^2. There was a statistically significant reduction in BMI and weight from baseline following DSME. Further significant weight loss was observed following MNT (end-of-program). Weights were available for a small subset of the patient sample (n = 63) at the one-year follow up; though lower than any interval of the study, were highly variable and did not reflect significant additional loss over end-of-program. 30% of patients exhibited ≥5% weight loss; of those 46% were managed by diet

alone and 26% were managed by diet plus drug therapy. When stratified by race, AAs had higher baseline BMI and weight than whites; both groups exhibited similar weight loss patterns across the treatment period and at 1-year follow-up. Given the retrospective nature of the chart review, data regarding interval follow-up weights were incomplete at some of the regional sites. Gaps in available data are represented on data tables for each of the four regional sites (Tables 7b-e). Statistical analysis was unattainable at selected time points for individual sites.

Significant reduction in HbA1c was observed following DSME and MNT; reductions over baseline were maintained at one-year follow-up (Table 7a). Notably, 32% of the patient population had an HbA1c at the target of $\leq 7.0\%$ at baseline as compared to 62% of patients reaching target following DSME and MNT ($P < 0.001$). Conversely, 32% of patients exhibited baseline HbA1c $\geq 9\%$ compared to fewer than 7% ($P < 0.001$) and 4% ($P < 0.001$) at end-of-program and at one-year, respectively (Table 8). When stratified by race, both whites and AAs exhibited significant reductions in HbA1c; however, baseline HbA1c was higher in AAs and AAs exhibited greater reduction in HbA1c as compared to whites.

Table 7a. All Sites: BMI, Weight, and HbA1c in Patients with T2DM receiving DSME and MNT							
Outcome n = 388	**Baseline (n)**	**DSME (n)**	**P-value**	**MNT (end of program) (n)**	**P-value**	**1-year (n)**	**P-value**
Body Mass Index							
BMI kg/m^2	33.65 ± 7.14 (284)	32.70 ± 6.43 (188)	P = 0.003[1]	32.57 ± 7.12 (271)	P < 0.001[1] P < 0.001[2]	32.57 ± 6.77 (63)	P = 0.000[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline)	_	-0.39 ± 1.01 (184)	P = 0.003[1]	-0.93 ± 1.91 (268)	P < 0.001[1]	-0.76 ± 1.93 (62)	P = 0.000[1]
BMI kg/m^2 - White	33.80 ± 6.86 (186)	33.15 ± 6.56 (118)	P = 0.012[1]	32.69 ± 7.04 (173)	P < 0.001[1] P < 0.001[2]	32.69 ± 6.69 (46)	P < 0.002[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline) - White	_	-0.46 ± 0.72 (117)	P = 0.012[1]	-1.10 ± 1.83 (172)	P < 0.001[1]	-0.70 ± 1.85 (46)	P < 0.002[1]
BMI kg/m^2 - AA	34.07 ± 7.45 (89)	32.38 ± 6.07 (64)	P = 0.023[1]	32.93 ± 7.25 (89)	P < 0.001[1] P > 0.05[2]	33.08 ± 6.50 (16)	P < 0.008[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline) - AA	_	-0.41 ± 0.98 (61)	P = 0.023[1]	-0.74 ± 1.68 (86)	P < 0.001[1]	-1.01 ± 2.27 (15)	P < 0.008[1]
Weight							
Weight (kg)	96.77 ± 22.71 (287)	94.04 ± 20.60 (191)	P = 0.003[1]	93.73 ± 22.67 (274)	P < 0.001[1] P < 0.001[2]	92.92 ± 20.98 (63)	P = 0.000[1] P > 0.05[2] P > 0.05[3]
Mean Change in Weight (from baseline)	_	-1.13 ± 3.01 (187)	P = 0.003[1]	-2.67 ± 5.54 (271)	P < 0.001[1]	-2.25 ± 5.45 (62)	P = 0.000[1]
Weight (kg) - White	98.81 ± 22.73 (188)	96.74 ± 21.39 (120)	P = 0.009[1]	95.49 ± 23.02 (175)	P < 0.001[1] P < 0.001[2]	94.49 ± 21.22 (46)	P = 0.001[1] P > 0.05[2] P > 0.05[3]
Mean Change in Weight (from baseline) - White	_	-1.39 ± 2.14 (119)	P = 0.009[1]	-3.23 ± 5.31 (174)	P < 0.001[1]	-2.11 ± 5.38 (46)	P = 0.001[1]
Weight (kg) - AA	95.20 ± 21.44 (90)	90.65 ± 18.10 (65)	P = 0.022[1]	92.49 ± 21.33 (90)	P = 0.000[1] P = 0.041[2]	90.28 ± 19.84 (16)	P = 0.007[1] P > 0.05[2] P > 0.05[3]
Mean Change in Weight (from baseline) – AA	_	-1.14 ± 2.53 (62)	P = 0.022[1]	-2.10 ± 4.59 (87)	P = 0.000[1]	-2.79 ± 5.98 (15)	P = 0.007[1]

Glycemic Control - HbA1c							
HbA1c%	8.59 ± 2.36 (388)	_	_	6.81 ± 1.37 (353)	P < 0.001[1]	6.98 ± 1.33 (181)	P < 0.001[1] P > 0.05[3]
Change in HbA1c (from baseline)	_	_	_	-1.82 ± 2.23 (350)	P < 0.001[1]	-1.22 ± 2.15 (216)	P < 0.001[1]
HbA1c% - White	8.41 ± 2.18 (259)	_	_	6.70 ± 1.24 (236)	P < 0.001[1]	6.85 ± 1.20 (134)	P < 0.001[1] P > 0.05[3]
Change in HbA1c - White (from baseline)	_	_	_	-1.73 ± 2.13 (233)	P < 0.001[1]	-1.38 ± 2.30 (132)	P < 0.001[1]
HbA1c% - AA	8.94 ± 2.61 (120)	_	_	6.99 ± 1.52 (110)	P < 0.001[1]	7.31 ± 1.60 (44)	P < 0.001[1] P > 0.05[3]
Change in HbA1c - AA (from baseline)	_	_	_	-2.01 ± 2.47 (110)	P < 0.001[1]	-1.69 ± 2.19 (43)	P < 0.001[1]
HbA1c% - Diet alone	6.95 ± 1.12 (68)	_	_	6.19 ± 0.66 (60)	P < 0.001[1]	6.23 ± 0.46 (39)	P < 0.001[1] P > 0.05[3]
Change in HbA1c% - Diet alone (from baseline)	_	_	_	-0.80 ± 0.91 (60)	P < 0.001[1]	-0.95 ± 1.35 (34)	P < 0.001[1]
HbA1c% - Diet plus drug therapy	9.00 ± 2.44 (295)	_	_	6.95 ± 1.48 (268)	P < 0.001[1]	7.19 ± 1.44 (131)	P < 0.001[1] P > 0.05[3]
Change in HbA1c – Diet plus drug therapy (from baseline)	_	_	_	-2.09 ± 2.40 (266)	P < 0.001[1]	-1.74 ± 2.62 (107)	P < 0.001[1]

[1]Reflects significance over baseline
[2]Reflects significance over weight two DSME
[3]Reflects significance over end-of-program
Significance taken at the 95% confidence interval P < 0.05

Table 7b. Auburn-Opelika: BMI, Weight, and HbA1c in Patients with T2DM receiving DSME and MNT							
Outcome n = 88	**Baseline (n)**	**DSME (n)**	**P-value**	**MNT (end of program) (n)**	**P-value**	**1-year (n)**	**P-value**
Body Mass Index							
BMI kg/m^2	32.89 ± 6.85 (84)	32.27 ± 6.80 (84)	P = 0.002[1]	31.83 ± 6.78 (85)	P < 0.001[1] P > 0.05[2]	30.70 ± 5.69 (33)	P > 0.05[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline)	_	-0.42 ± 1.01 (88)	P = 0.002[1]	-0.54 ± 1.40 (81)	P < 0.001[1]	-0.42 ± 2.10 (32)	P > 0.05[1]
BMI kg/m^2 - White	33.26 ± 6.47 (55)	33.70 ± 6.75 (53)	P = 0.005[1]	32.19 ± 6.92 (54)	P < 0.001[1] P > 0.05[2]	31.24 ± 5.57 (24)	P > 0.05[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline) - White	_	-0.47 ± 0.86 (56)	P = 0.005[1]	-0.76 ± 1.34 (53)	P < 0.001[1] P > 0.05[2]	-0.43 ± 1.99 (24)	P > 0.05[1]
BMI kg/m^2 - AA	32.65 ± 7.28 (28)	31.95 ± 6.65 (30)	P > 0.05[1]	31.62 ± 6.27 (30)	P > 0.05[1] P > 0.05[2]	30.60 ± 4.98 (8)	P > 0.05[1] P > 0.05[2] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline) - AA	_	-0.39 ± 1.34 (27)	P > 0.05[1]	-0.10 ± 1.46 (27)	P > 0.05[1]	-0.41 ± 2.78 (7)	P > 0.05[1]
Weight							
Weight (kg)	94.34 ± 21.06 (84)	92.64 ± 20.90 (84)	P < 0.001[1]	91.68 ± 21.17 (85)	P < 0.001[1] P > 0.05[2]	88.60 ± 17.04 (33)	P > 0.05[1] P > 0.05[2] P > 0.05[3]
Mean Change in Weight (from baseline)	_	-1.21 ± 2.78 (88)	P < 0.001[1]	-1.58 ± 3.99 (81)	P < 0.001[1]	-1.33 ± 5.87 (32)	P > 0.05[1]
Weight (kg) - White	96.95 ± 20.90 (55)	95.35 ± 21.41 (53)	P = 0.004[1]	93.88 ± 22.05 (54)	P < 0.001[1] P > 0.05[2]	96.89 ± 15.55 (24)	P > 0.05[1] P > 0.05[2] P > 0.05[3]
Mean Change in Weight (from baseline) - White	_	-1.41 ± 2.57 (56)	P = 0.004[1]	-2.27 ± 3.86 (53)	P < 0.001[1]	-1.37 ± 5.69 (24)	P > 0.05[1]
Weight (kg) - AA	90.31± 20.57 (28)	88.81 ± 19.24 (30)	P > 0.05[1]	88.69 ± 19.02 (30)	P > 0.05[1] P > 0.05[2]	84.96 ± 20.16 (8)	P > 0.05[1] P > 0.05[2] P >0.05[3]
Mean Change in Weight (from baseline) – AA	_	-1.02 ± 3.40 (27)	P > 0.05[1]	-0.25 ± 4.04 (27)	P > 0.05[1]	-1.32 ± 7.34 (7)	P > 0.05[1]

Glycemic Control - HbA1c							
HbA1c%	8.74 ± 2.30 (88)	_	_	6.82 ± 1.37 (88)	P < 0.001[1]	6.90 ± 1.16 (49)	P < 0.001[1] P > 0.05[3]
Change in HbA1c (from baseline)	_	_	_	-1.92 ± 2.25 (88)	P < 0.001[1]	-1.33 ± 1.67 (49)	P < 0.001[1]
HbA1c% - White	8.10 ± 1.78 (56)	_	_	6.59 ± 1.04 (56)	P < 0.001[1]	6.67 ± 0.75 (38)	P < 0.001[1] P > 0.05[3]
Change in HbA1c - White (from baseline)	_	_	_	-1.51 ± 1.67 (56)	P < 0.001[1]	-1.26 ± 1.81 (38)	P < 0.001[1]
HbA1c% - AA	9.82 ± 2.73 (31)	_	_	7.18 ± 1.76 (31)	P < 0.001[1]	7.62 ± 1.92 (10)	P = 0.009[1] P > 0.05[3]
Change in HbA1c - AA (from baseline)	_	_	_	-2.64 ± 2.94 (31)	P < 0.001[1]	-1.49 ± 1.11 (10)	P = 0.009[1]
HbA1c% - Diet alone	7.70 ± 1.63 (23)	_	_	6.39 ± 0.59 (23)	P < 0.001[1]	6.54 ± 0.97 (16)	P < 0.001[1] P > 0.05[3]
Change in HbA1c% - Diet alone (from baseline)	_	_	_	-1.31 ± 1.37 (23)	P < 0.001[1]	-1.27 ± 1.34 (9)	P < 0.001[1]
HbA1c% - Diet plus drug therapy	9.32 ± 2.47 (52)	_	_	6.96 ± 1.63 (52)	P < 0.001[1]	7.05 ± 1.30 (28)	P < 0.001[1] P > 0.05[3]
Change in HbA1c – Diet plus drug therapy (from baseline)	_	_	_	-2.36 ± 2.53 (52)	P < 0.001[1]	-1.28 ± 1.19 (6)	P < 0.001[1]

[1]Reflects significance over baseline
[2]Reflects significance over weight two DSME
[3]Reflects significance over end-of-program
Significance taken at the 95% confidence interval P < 0.05)

Table 7c. Dothan - HbA1c in Patients with T2DM receiving DSME and MNT

Outcome n = 100	**Baseline (n)**	**DSME (n)**	**P-value**	**MNT (end-of program) (n)**	**P-value**	**1-year (n)**	**P-value**
HbA1c%	8.74 ± 2.70 (97)	_	_	7.09 ± 1.47 (81)	$P < 0.001^1$	7.20 ± 1.53 (86)	$P < 0.001^1$ $P > 0.05^3$
Change in HbA1c (from baseline)	_	_	_	-1.75 ± 2.64 (79)	$P < 0.001^1$	-1.63 ± 2.70 (83)	$P < 0.001^1$
HbA1c% - White	8.64 ± 2.59 (71)	_	_	6.99 ± 1.32 (62)	$P < 0.001^1$	7.09 ± 1.45 (63)	$P < 0.001^1$ $P > 0.05^2$
Change in HbA1c - White (from baseline)	_	_	_	-1.69 ± 2.63 (60)	$P < 0.001^1$	-1.60 ± 2.74 (61)	$P < 0.001^1$
HbA1c% - AA	8.98 ± 3.00 (26)	_	_	7.41 ± 1.87 (19)	$P = 0.001^1$	7.49 ± 1.71 (23)	$P = 0.002^1$ $P > 0.05^2$
Change in HbA1c - AA (from baseline)	_	_	_	-1.94 ± 2.75 (19)	$P = 0.001^1$	-1.72 ± 2.65 (22)	$P = 0.002^1$
HbA1c% - Diet alone	6.51 ± 0.33 (9)	_	_	6.25 ± 0.55 (8)	$P > 0.05^1$	6.14 ± 0.50 (11)	$P = 0.014^1$ $P > 0.05^2$
Change in HbA1c – Diet alone (from baseline)	_	_	_	-0.39 ± 0.29 (7)	$P > 0.05^1$	-0.42 ± 0.54 (9)	$P = 0.014^1$
HbA1c% - Diet plus drug therapy	8.99 ± 2.73 (87)	_	_	7.18 ± 1.51 (73)	$P < 0.001^1$	7.36 ± 1.57 (74)	$P < 0.001^1$ $P > 0.05^2$
Change in HbA1c – Diet plus drug therapy (from baseline)	_	_	_	-1.88 ± 2.73 (72)	$P < 0.001^1$	-1.80 ± 2.83 (73)	$P < 0.001^1$

[1]Reflects significance over baseline
[2]Reflects significance over end-of-program

Table 7d. Huntsville: BMI, Weight, and HbA1c in Patients with T2DM receiving DSME and MNT							
Outcome n = 101	**Baseline (n)**	**DSME (n)**	**P-value**	**MNT (end of program) (n)**	**P-value**	**1-year (n)**	**P-value**
Body Mass Index							
BMI kg/m^2	35.00 ± 8.12 (101)	_	_	34.49 ± 8.33 (88)	P < 0.001[1]	34.63 ± 7.35 (30)	P < 0.001[1] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline)	_	_	_	-0.68 ± 1.14 (88)	P < 0.001[1]	-1.13 ± 1.69 (30)	P < 0.001[1]
BMI kg/m^2 - White	34.66 ± 7.72 (72)	_	_	34.19 ± 7.94 (61)	P < 0.001[1]	34.29 ± 7.55 (22)	P < 0.001[1] P > 0.05[3]
Mean Change BMI kg/m^2 (from baseline) - White	_	_	_	-0.72 ± 1.15 (61)	P < 0.001[1]	-0.98 ± 1.68 (22)	P < 0.001[1]
BMI kg/m^2 - AA	37.02 ± 8.96 (26)	_	_	36.43 ± 9.05 (24)	P > 0.05[1]	35.57 ± 7.18 (8)	P < 0.001[1]
Mean Change BMI kg/m^2 (from baseline) - AA	_	_	_	-0.55 ± 1.15 (24)	P > 0.05[1]	-1.54 ± 1.73 (8)	P < 0.001[1]
Weight							
Weight (kg) -	101.12 ± 26.09 (101)	_	_	99.48 ± 26.48 (88)	P < 0.001[1]	97.67 ± 24.00 (30)	P < 0.001[1] P > 0.05[3]
Mean Change in Weight (from baseline)	_	_	_	-1.92 ± 3.33 (88)	P < 0.001[1]	-3.23 ± 4.87 (30)	P < 0.001[1]
Weight (kg) - White	101.82 ± 25.96 (72)	_	_	100.20 ± 26.10 (61)	P < 0.001[1]	98.42 ± 25.87 (22)	P < 0.001[1] P > 0.05[3]
Mean Change in Weight (from baseline) - White	_	_	_	-2.11 ± 3.51 (61)	P < 0.001[1]	-2.91 ± 5.03 (22)	P < 0.001[1]
Weight (kg) - AA	103.51 ± 25.14 (26)	_	_	102.38 ± 25.99 (24)	P > 0.05[1]	95.61 ± 19.29 (8)	P < 0.001[1] P = 0.017[3]
Mean Change in Weight (from baseline) - AA	_	_	_	-1.43 ± 2.97 (24)	P > 0.05[1]	-4.09 ± 4.61 (8)	P < 0.001[1]

Glycemic Control – HbA1c							
HbA1c%	8.14 ± 1.94 (101)	_	_	6.82 ± 1.19 (82)	P < 0.001[1]	6.58 ± 0.92 (42)	P < 0.001[1] P > 0.05[3]
Change in HbA1c (from baseline)	_	_	_	-1.46 ± 1.74 (82)	P < 0.001[1]	-1.33 ± 1.92 (42)	P < 0.001[1]
HbA1c% - White	8.13 ± 1.96 (71)	_	_	6.81 ± 1.23 (57)	P < 0.001[1]	6.63 ± 1.02 (31)	P < 0.001[1] P > 0.05[3]
Change in HbA1c - White (from baseline)	_	_	_	-1.50 ± 1.91 (57)	P < 0.001[1]	-1.12 ± 1.92 (31)	P < 0.001[1]
HbA1c% - AA	8.33 ± 1.94 (27)	_	_	6.88 ± 1.13 (24)	P < 0.001[1]	6.46 ± 0.56 (10)	P < 0.001[1] P > 0.05[3]
Change in HbA1c - AA (from baseline)	_	_	_	-1.40 ± 1.33 (24)	P < 0.001[1]	-2.08 ± 1.94 (10)	P < 0.001[1]
HbA1c% - Diet alone	6.92 ± 1.33 (30)	_	_	6.28 ± 0.88 (24)	P < 0.004[1]	6.25 ± 0.37 (17)	P < 0.001[1] P > 0.05[3]
Change in HbA1c – Diet alone (from baseline)	_	_	_	-0.71 ± 0.90 (24)	P < 0.004[1]	-0.99 ± 1.61 (17)	P < 0.001[1]
HbA1c% - Diet plus drug therapy	8.65 ± 1.93 (71)	_	_	7.05 ± 1.23 (58)	P < 0.001[1]	6.80 ± 1.10 (25)	P < 0.001[1] P > 0.05[3]
Change in HbA1c – Diet plus drug therapy (from baseline)	_	_	_	-1.77 ± 1.91 (58)	P < 0.001[1]	-1.56 ± 2.11 (25)	P < 0.001[1]

[1]Reflects significance over baseline
[2]Reflects significance over weight two DSME
[3]Reflects significance over end-of-program

Table 7e. Montgomery: BMI, Weight, and HbA1c in Patients with T2DM receiving DSME and MNT							
Outcome n = 101	**Baseline (n)**	**DSME (n)**	**P-value**	**MNT (end-of program) (n)**	**P-value**	**1-year (n)**	**P-value**
Body Mass Index							
BMI kg/m^2	31.93 ± 8.20 (102)	32.64 ± 5.87 (98)	P > 0.05[1]	31.49 ± 5.86 (98)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change BMI kg/m^2 (from baseline)	_	-0.31 ± 0.96 (98)	P > 0.05[1]	-1.48 ± 2.60 (98)	P < 0.001[1]	_	_
BMI kg/m^2 - White	32.17 ± 8.44 (61)	32.87 ± 6.08 (59)	P > 0.05[1]	31.59 ± 5.92 (58)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change BMI kg/m^2 (from baseline) - White	_	-0.37 ± 0.42 (61)	P > 0.05[1]	-1.81 ± 2.50 (58)	P < 0.001[1]	_	_
BMI kg/m^2 - AA	33.01 ± 5.76 (35)	32.75 ± 5.58 (34)	P > 0.05[1]	31.64 ± 5.93 (35)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change BMI kg/m^2 (from baseline) - AA	_	-0.43 ± 0.58 (34)	P > 0.05[1]	-1.37 ± 1.93 (35)	P < 0.001[1]	_	_
Weight							
Weight (kg)	94.46 ± 19.82 (102)	93.73 ± 19.21 (101)	P > 0.05[1]	90.46 ± 19.33 (101)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change in Weight (from baseline)	_	-0.89 ± 3.02 (102)	P > 0.05[1]	-4.23 ± 7.52 (101)	P < 0.001[1]	_	_
Weight (kg) - White	97.94 ± 20.05 (61)	95.77 ± 19.96 (61)	P > 0.05[1]	92.15 ± 19.90 (60)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change in Weight (from baseline) - White	_	-1.17 ± 1.22 (61)	P > 0.05[1]	-5.21 ± 7.13 (60)	P < 0.001[1]	_	_
Weight (kg) - AA	93.01 ± 17.75 (36)	92.24 ± 17.19 (35)	P > 0.05[1]	89.07 ± 17.95 (36)	P < 0.001[1] P < 0.001[2]	_	_
Mean Change in Weight (from baseline) - AA	_	-1.23 ± 1.63 (35)	P > 0.05[1]	-3.94 ± 5.23 (36)	P < 0.001[1]	_	_

Glycemic Control – HbA1c							
HbA1c%	8.75 ± 2.42 (102)	_	_	6.64 ± 1.25 (101)	P = 0.000[1]	_	_
Change in HbA1c (from baseline)	_	_	_	-2.07 ± 2.21 (102)	P = 0.000[1]	_	_
HbA1c% - White	8.75 ± 2.19 (61)	_	_	6.51 ± 0.99 (60)	P = 0.000[1]	_	_
Change in HbA1c - White (from baseline)	_	_	_	-2.22 ± 2.12 (60)	P = 0.000[1]	_	_
HbA1c% - AA	8.59 ± 2.54 (36)	_	_	6.68 ± 1.30 (36)	P = 0.000[1]	_	_
Change in HbA1c - AA (from baseline)	_	_	_	-1.92 ± 2.44 (36)	P = 0.000[1]	_	_
HbA1c% - Diet alone	7.00 ± 0.79 (17)	_	_	6.04 ± 0.47 (17)	P = 0.000[1]	_	_
Change in HbA1c – Diet alone (from baseline)	_	_	_	-0.96 ± 0.21 (17)	P = 0.000[1]	_	_
HbA1c% - Diet plus drug therapy	9.10 ± 2.49 (85)	_	_	6.77 ± 1.32 (84)	P = 0.000[1]	_	_
Change in HbA1c – Diet plus drug therapy (from baseline)	_	_	_	-2.30 ± 2.33 (85)	P = 0.000[1]	_	_

[1]Reflects significance over baseline
[2]Reflects significance over weight two DSME

Table 8. All Sites: HbA1c Outcomes by Target (< 7%) and Risk (> 9%)								
HbA1c%	**Baseline**		**End-of Program**			**1-Year**		
	Frequency	**%**	**Frequency**	**%**	**P-Value**	**Frequency**	**%**	**P-Value**
Auburn - Opelika								
< 7	24	27.27	63	71.59	$P < 0.008^1$	33	37.50	$P < 0.001^2$
> 9	29	32.95	4	4.55	$P < 0.01^1$	3	3.41	$P < 0.009^2$
Dothan								
< 7	34	34.00	46	46.00	$P < 0.001^1$	49	49.00	$P = 0.001^2$
> 9	29	29.00	8	8.00	$P = 0.008^1$	11	11.00	$P = 0.019^2$
Huntsville								
< 7	37	36.27	53	51.96	$P = 0.000^1$	34	33.33	$P = 0.078^2$
> 9	26	25.49	8	7.84	$P = 0.001^1$	2	1.96	$P = 0.309^2$
Montgomery								
< 7	30	29.41	79	77.45	$P = 0.002^1$	-	-	-
> 9	37	36.27	6	5.88	$P = 0.002^1$	-	-	-
ALL Programs								
< 7	125	31.89	241	61.48	$P < 0.001^1$	116	29.59	$P < 0.001^2$
> 9	121	30.87	26	6.63	$P < 0.001^1$	16	4.08	$P = 0.000^2$

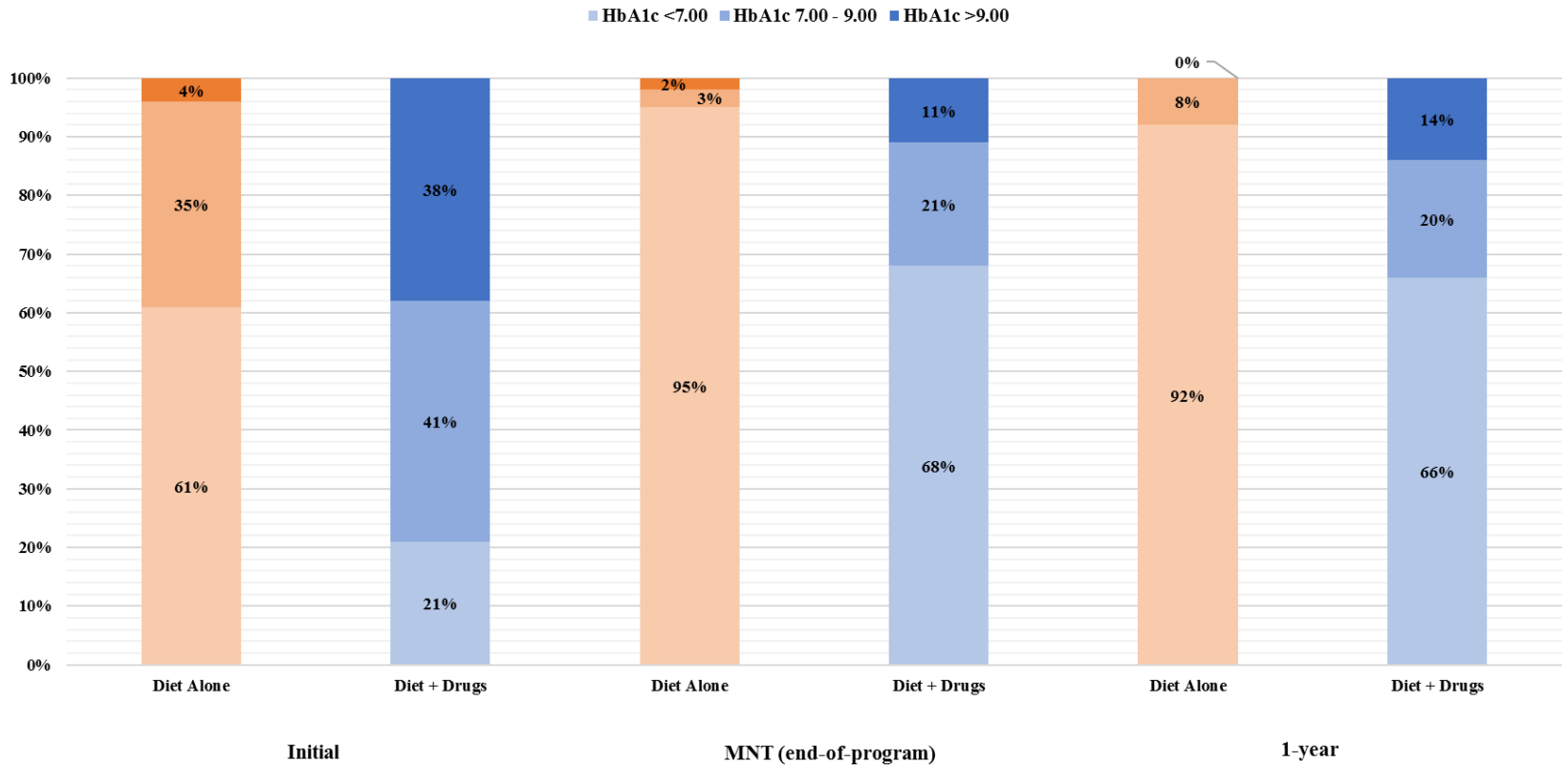
Baseline SBGM data was extrapolated from A1C for newly diagnosed patients lacking data.
P^1- Significance over baseline
P^2- Significance end-of-program

In order to further discriminate HbA1c outcomes attributed to DSME with RDN-provided nutritional education and individualized MNT, HbA1c outcomes were stratified based on disease managed by diet alone and diet plus adjunct drug therapy. As expected, patients managed by diet plus drug therapy exhibited higher HbA1c levels at baseline (9.00% ± 2.44%) compared to those managed by diet alone (6.95% ± 1.12%) and exhibited greater HbA1c reduction over the treatment period (-2.09 ± 2.40; P<0.001). HbA1c reduction of -0.80 ± 0.91 (P<0.001) was observed with diet alone, with further reduction over baseline of -0.95 ± 1.35

($P<0.001$) at one year. Figure 1 further discriminates disease managed by diet alone and diet plus drug therapy specifically based on patient reaching HbA1c targets and at risk.

There were no apparent trends in blood pressure across the treatment period and information regarding new prescriptions or changes, if any, to the antihypertensive regimen was incomplete. Data regarding frequency of hypoglycemia was incomplete as well. Hospitalizations data was not fully accessible from records queried; these diabetes centers service patients who may seek hospitalization at a number of other regional hospitals. Full statistical analysis was deferred regarding these variables. Presentation and assessment of outcomes regarding lipids will be discussed in a subsequent manuscript.

Figure 2. Percentage of Patients Managed by Diet Alone or Diet plus Drug Therapy Reaching HbA1c Targets



DISCUSSION

The majority of patients presenting with T2D are overweight or obese; prevalence of obesity in the states with the top ten highest rates of diabetes varies from 28.8 to 35.6% of the adult population.[93] The paradox of weight management in T2D is that improved glycemic control, reduced glycosuria, and insulin therapy can result in weight gain. In a recent systematic review and meta-analysis of RCTs exploring lifestyle interventions for overweight and obese patients with T2D, 17 study groups reported weight loss of < 5% with no significant benefit to HbA1c, lipids, or blood pressure.[94] Two study groups, the Mediterranean-style diet and the Look AHEAD trial, reported weight loss of > 5% at 12 months and subsequent HbA1c reductions of 1.2% and 0.6%, respectively. RDNs provided the nutrition counseling in both of these trials. The overall conclusion emphasized that a weight loss of > 5% appeared to be necessary for beneficial effects on HbA1c, lipids, and blood pressure. In a recent report of an ADA-recognized DSME program offered in a primary care setting, patients receiving DSME exhibited significant weight loss; however, the greatest effect was observed in those who received individualized RDN or RN provided services (> 2 kg: $P<0.05$). Statistically significant weight loss was observed in the present study across the treatment period, however, changes in weight were highly variable between patients. Notably, 30% of patients reached ADA target weight loss recommendations of 5-7%; 46% of patients reaching goal were treated by diet alone.[95] Further reduction post MNT and at one-year follow-up for all participants suggests added benefit of individualized RDN-provided MNT over that observed with DSME alone. The role of the RDN as members of the education team appears to be an important factor in improving patient outcomes.[96]

HbA1c is the hallmark of glycemic control. A 1% decrease in HbA1c level correlates to a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of any endpoint or death related to diabetes.[7] A recent meta-analysis exploring the impact of group based DSME alone (21 studies with 2833 participants) revealed a 0.44% (P = 0.0006) and 0.46% (P = 0.0005) reduction in HbA1c at six-months and one-year respectively.[97] The most recent systematic review of the DSME literature included studies specifically addressing the efficacy of DSME against usual care or minimal education; inclusion criteria encompassed studies that specified components of DSME with goals to improve knowledge, skills, and abilities to perform self-management activities; results were more favorable with HbA1c reductions of 0.74%.[98] Effectiveness of MNT with DSME with integrated nutrition modules provided by an RDN, with or without supplemental individualized MNT, and standalone MNT has been reported to result in significant reductions in HbA1c ranging from 0.7 - 1.9%; usual care showed reductions of less than 0.2%.[99] Comparatively, individualized RDN-administered MNT, based on RCTs, meta-analysis, and systematic review accounts for statistically significant HbA1c reductions of 0.9-1.9%.[22,31,35,99] Total time and number of nutrition visits has been associated with improved patient outcomes.[8,80]

There is much variability within the studies reviewed which include, but are not limited to, years diagnosed, baseline HbA1c, and use and documentation of pharmacotherapy as an adjuvant to MNT. The latter poses significant error to overall outcomes if diet alone is not discriminated from combined diet and drug therapy. The present study clearly discriminated HbA1c outcomes for patients managed by diet alone and those receiving diet plus drug therapy. While both groups exhibited significant reductions in HbA1c, consistent with other reported DSME and MNT outcomes,[98] patients receiving combination therapy had higher baseline HbA1c

(9.00%±2.44%) (P<0.001) and exhibited greater reductions in HbA1c (2.09%±2.40%) (P<0.001). HbA1c reductions of 0.5-1.5% are reported for use of oral hypoglycemic agents alone.[2] In the present study, the mean baseline HbA1c of 6.95% ± 1.12% for patients managed by diet alone was already at the ADA goal HbA1c of <7%. Nonetheless, significant reductions were seen across the treatment period of 0.80 ± 0.91%; further reductions were observed at one year evincing the added benefit of individualized RDN-provided MNT.

The target HbA1c level of < 7% is the widely accepted goal for most patients with diabetes.[2] HbA1c > 9% is associated with increased risk of comorbidities.[3] Greater response to treatment, in both weight loss and reduction in HbA1c has previously been reported with newly diagnosed patients;[12] baseline HbA1c was higher in our population than many studies reviewed within.[21,23,25,26,28,32,100] Consistent with that observation, provision of DSME and MNT resulted in a lower frequency of patients categorized in the high risk (HbA1c >9%) as compared to fair (HbA1c ≥7% and ≤9%) and low risk disease states (HbA1c <7%). It has recently been argued that patients with HbA1c > 9% benefit the most from DSME based on a greater reduction in HbA1c, and that treatment at lower HbA1c could occur later.[98] This seems counterintuitive given the effectiveness of the established evidence base supporting the diabetes prevention programs.[47,52–54,65,84–86,101,102] Notably, in a comprehensive review of the evidence of the cost-effectiveness of prevention of diabetes, annual direct medical costs increased from $1,400 to $4,600 (2008 US$) as an individual progressed from impaired glucose tolerance to uncomplicated diabetes to diabetes requiring pharmacologic treatment to diabetes with complications and comorbidities.[52] Delaying DSME and MNT for treatment of this progressive disease may further exacerbate metabolic derangements, increase prevalence of comorbidities, and subsequently have deleterious effects on patient outcomes increasing healthcare costs.[12]

Patients who have received nutrition education and counseling are more likely to attain glycemic control than those who do not receive these services.[89,97] Conversely, complications are four-fold more likely to develop in people receiving no diabetes education;[8] and subsequently lead to decreased quality of life and increased healthcare costs. Patients managed by diet alone who receive no DSME or MNT are essentially receiving inadequate treatment for T2D.[12] Reported patient outcomes from the present multisite study provide additional support for routine physician referral, access to, and reimbursement for comprehensive services delivered through ADA-recognized education programs offered in compliance with established evidence-based practice standards to attain glycemic control.[2]

Cost-effective Analysis of DSME and MNT

In order to further explore the relationship between improved patient outcomes and healthcare cost-savings associated with provision of DSME and MNT, we have conducted a literature review of studies linking patient outcomes to cost savings. Cost effectiveness of health care interventions requires a comparison between the intervention and alternative methods of care;[50] with regard to DSME and MNT, the alternative method is often defined as usual or standard care. Allocating funds is typically based on estimation of the extra cost of providing the benefit versus improved clinical outcomes resulting in cost savings. Studies looking specifically at cost-effective ratios of a particular intervention may place a greater emphasis on cost savings associated with improved clinical outcomes rather than the outcomes themselves. With regard to diabetes, patients with higher HbA1c levels would be expected to show greater improvement post intervention than those already near targets. Healthcare policy and payment systems must consider both populations.

Health policy and reimbursement for services (e.g., DSME and MNT) are driven by results of cost-effective analyses. Determining that an intervention is cost-effective necessitates setting a threshold for cost-effectiveness and provider willingness to pay. The outcomes are generally expressed in terms of the quality of life years by multiplying the quality of life value for each health state by the time in the state, and subsequently summing for all the health states across a given period of time or a person's lifetime.[49] One can forecast diabetes outcomes, expressed in QALYs gained, and lifetime costs associated with maintaining HbA1c levels at the recommended target.[56] The ICER is the ratio between the difference in costs and the difference in benefits of two interventions.[52] The ICER is commonly expressed as the costs incurred divided by QALYs gained in a period of time. A threshold of less than or equal to 50,000 US$/QALY is often identified as the ICER in which it is cost-effective to treat.[51,54]

In exploring the published literature that integrates patient outcomes with estimates of cost-effectiveness, two of the most integral objectives of DSME and MNT, glycemic control and comorbidity prevention and reduction, have been identified as key outcome variables for study. HbA1c ≤7% is the evidence-based ADA target for most adult patients with diabetes and is associated with reduced onset or progression of micro- and macrovascular complications.[2] A 1% decrease in HbA1c level correlated to a 37% reduction in risk for microvascular complications and a 21% reduction in the risk of any endpoint or death related to diabetes.[7] Studies typically express incremental changes in HbA1c and/or classify patients at baseline and post intervention based on reaching glycemic targets (≤7%) and risks; HbA1c cutoffs for risk vary between reported studies.

Because of the impact of glycemic control on the development of comorbidities, reduction in HbA1c decreases diabetes-related medical costs. Markov modeling has been used to

project the long-term clinical and cost outcomes associated with improvements in glycemic control based on scenarios with incremental reductions in HbA1c (scenario 1, reduction in HbA1c from 9.5% to 8.0%; scenario 2, reduction in HbA1c from 8.0% to 7.0%; and scenario 3, reduction in HbA1c from 7.0% to 6.5%) verses no reduction.[70] Stepwise reductions in HbA1c delayed time to diabetes-related complications and reduced cumulative incidence of complications, which ultimately resulted in potential cost-savings. The most substantial cost savings were projected in scenario 1 (9.5–8.0%) where mean total lifetime costs of $72,629 (±$2,497) per patient were reduced to $67,420 (±$2,583) with the hypothetical intervention, a saving of $5209 per patient. In scenario 2, the hypothetical intervention further reduced the total cost of complications to $64,322 (±$2,498), corresponding to a saving of $3099. In scenario 3, reducing HbA1c to 6.5% decreased total lifetime complication costs to $62,684 (±$2,333), saving $1637 per patient compared with no HbA1c change.[70]

Estimations of the cost-benefit of incremental reductions in HbA1c have been explored specific to the provision of DSME and MNT. An early cost-utility analysis of 179 patients, from 3 states (Minnesota, Florida, and Colorado) with T2D receiving diabetes education and individualized nutrition interventions provided by an RDN according to practice guidelines resulted in a 0.93% (±1.63%) reduction in HbA1c ($P<0.01$) as compared to patients receiving basic care (0.69% ±1.67%). The ICER was 21% lower in the treatment group.[72] Brown and colleagues employed the Archimedes model to forecast disease outcomes expressed in QALYs gained, and lifetime costs associated with attaining selected HbA1c levels through a community-based intervention in low-income Hispanic adults.[56] HbA1c reductions were observed in patients treated by diet alone of 1.95% (10.50% ± 2.39% to 8.55% ± 1.33%; $P<0.001$) and for diet plus drug therapy of 3.26% (9.55% ± 2.53% to 6.29% ± 0.40%; $P<0.001$). The ICER for the

intervention ranged from $10,995 to $33,319/QALY gained when compared with usual care; highest cost-effectiveness was observed for adults with HbA1c >9%. In the state of New York, a 1% reduction in A1C has been reported to result in a conservative health care cost savings estimate of $1,200/year per patient for Medicaid fee-for-service beneficiaries with diabetes who engaged in DSME and RDN-administered MNT.[73] Cost-effective modeling supports achievement of sustained glycemic control through DSME and MNT as the cornerstone of diabetes management.

In assessing healthcare cost savings associated with reduction in HbA1c, the cost of provision of services must also be considered. Diabetes self-management training followed by individualized consultations from an RDN provided in a community setting have been demonstrated to improve patient outcomes at modest cost.[78] Mean HbA1c improved from 9.7±2.4% to 8.2±2.0% (-1.5% HbA1c; $P<0.001$); 61% of patients experienced positive medication outcomes. The diabetes education program cost was about $280 per person per year and included diabetes testing supplies, but not the cost of medications. Based on outcomes of a 1.5% reduction in HbA1c, the program cost was $185 for each point reduction in HbA1c. In the present study, costs of the comprehensive ADA-recognized diabetes education programs averaged $700. Using the aforementioned scheme and the observed 1.8% reduction in HbA1c subsequent to DSME and MNT a 1% reduction in HbA1c was associated with a $389 cost for these services.

In addition to incremental reductions in HbA1c, categorical grouping of patients relative to HbA1c targets and risks has been useful in assessing cost savings and healthcare utilization. Among 2.1 million patients with diabetes in the United States, those reaching glycemic targets (HbA1c ≤7%) exhibited direct diabetes-related medical costs that were 16% lower than those

with fair glycemic control (HbA1c ≥7% and ≤9%) and 20% lower than those with poor glycemic control (HbA1c >9%).[74] Retrospective analysis of 1,304 patients with poor (HbA1c ≥7%) and target initial glycemic control (HbA1c <7%) followed over a 3-year period revealed significant improvements in total cost of care for patients with sustained glycemic control. Costs decreased by $2,207 with HbA1c < 7% and increased by $3,006 with HbA1C ≥7%; this cost differential represents and effective cost savings of $5,000 per patient reaching and sustaining glycemic control.[75] Much of this cost has been attributed to increased hospitalizations mostly due to diabetes-related comorbidities. Estimated cost of diabetes-related hospitalizations per patient at target HbA1c < 7% were $2,792 as compared to $6,759 among those with HbA1c ≥10%.[76] Overall, patients with HbA1c > 7% have been reported to have total healthcare costs that are 32% higher than those with sustained HbA1c in the target range.[77] In the present study, only 32% of patients were at the target HbA1c <7.0% at baseline and 68% had baseline HbA1c >7%. Notably 31% had baseline HbA1c values exceeding 9.0%. Subsequent to DSME and MNT, 62% of patients reached HbA1c targets (P<0.001); only 7% and 4% remained at risk (HbA1c > 9%) at end-of-program and one-year respectively suggesting significant potential healthcare cost savings subsequent to DSME and RDN-provided individualized MNT. Even though there are costs to implement and manage diabetes education programs, evidence suggests that DSME and MNT are ultimately cost-effective.[54,79,80,103] While patients who have had diabetes education and counseling are more likely to have higher outpatient and pharmacy charges, these patients generally incur lower inpatient and emergency department costs, indicating that patients receiving DSME and MNT are able to manage their diabetes in the primary care setting and not drive up medical costs associated with acute care.[79,80] With each educational visit with an RDN associated with an estimated $6,503 less in total hospital charges per patient in a 5-year period,

the data suggests that many hospitalizations and related charges could be avoided in the long term if patients diagnosed with diabetes had access to DSME and MNT.[80]

While most clinicians who attempt to improve diabetes care have focused primarily on improving HbA1c,[81] this strategy makes clinical and economic sense when median HbA1c is high (HbA1c >9%). While there is a strong linear relationship between HbA1c and chronic comorbid conditions, once median HbA1c improves to <7%, primary and secondary prevention of comorbidities may provide more clinical benefits at less cost on a population basis.[82] Recently, CVD has been regarded as a strong predictor of future costs in diabetes. Hyperglycemia, along with hypertension and dyslipidemia, is a risk factor that contributes directly to atherosclerosis and therefore to CVD. Consequently, the focus of DSME and MNT on managing comorbidities in patients with diabetes is likely to result in improved quality of life and lower long-term costs.[40,104] For each myocardial infarction averted, the average costs saved are $15,900 for a nonfatal event and $11,300 for a fatal event. Averting a coronary artery bypass graft saves approximately $18,300, and preventing a stroke saves nearly $10,000.[69] Additionally, diabetes was listed as the primary cause in 44% of all new cases of kidney failure in the United States in 2011. In the same year, total Medicare costs for kidney treatments such as hemodialysis, peritoneal dialysis, and transplants reached $24.3 billion, $1.5 billion, and $2.9 billion, respectively. Similarly, in 2010, U.S. doctors performed 73,000 non-traumatic lower-limb amputations on adults diagnosed with diabetes. In 2001, diabetes-related amputations were estimated to cost $38,077 each, while costs for foot ulcer care have been estimated at $13,179 per episode.[41]

While it may appear more cost-effective to focus resources on reducing the overall prevalence of diabetes and pre-diabetes through diabetes prevention programs, this does not

seem to be the case.[53,56,84,85] It is more cost-effective to concentrate on sustaining glycemic control in patients whose HbA1c levels are poorly controlled (>9%) than patients who have fair (≥7% and ≤9%) and target glycemic control (<7%).[56,84] Even though this application of the evidence would suggest directing limited healthcare dollars to those in higher risk categories in the current US health care model, it raises ethical concerns regarding the duty to treat all patients with diabetes at various stages of the disease progression.

Program costs for DSME and MNT are a fraction of the costs of managing diabetes complications due to disease progression.[78,87] Direct medical cost of complications of diabetes in 2012 US$ for major macrovascular disease averaged $56,445 for a myocardial infarction, $42,118 for ischemic stroke, $23,758 for heart failure, and 21,406 ischemic heart disease per event year.[88] For microvascular complications, annual costs per event year are $71,714 for end stage renal disease and $2,862 for blindness. The event-year cost was $9,041 for lower extremity amputations.[88] A year of DSMT and testing supplies bas been estimated to cost 38% less than one emergency department admission.[78]

Limitations of Cost-Benefit Analysis of DSME and MNT

The heterogeneity of study design, population, and variability in diabetes education interventions pose similar challenges in assessing cost savings as they did biomedical outcomes.[12,87] It is important to note that many of the studies that explored the cost-effectiveness of DSME provided broad definitions of DSME, and therefore may not accurately depict the cost-effectiveness of the DSME programs currently covered by many public and private insurers. Duncan et al. conducted two longitudinal studies that analyzed insurance claims for diabetes patients participating in commercial and Medicare Advantage insurance plans with formal

diabetes education through ADA-recognized or AADE-accredited programs. In both studies, investigators observed discernible cost-savings associated with patients who had participated in DSME; there was a dose-benefit response in that patients receiving more time and/or a greater number of visits exhibited better glycemic control and adherence to treatment regimens, lower cost, and decreased utilization of services. These cost-savings were largely attributable to decreased inpatient costs.[79] More data from studies that specifically address DSME with individualized RDN-administered MNT according to the standards of practice applied in real-world settings are needed to further evaluate cost-effectiveness of these programs.

The ICER accounts for the difference in costs and the difference in benefits of two interventions. A threshold value is often set by policy makers, who may decide that only interventions with an ICER below the threshold are cost-effective and therefore warrant funding. However, it is important to note that cost-effectiveness of lifestyle interventions differs among countries because of country-specific interventions and health care costs. While no standard definition exists for the evaluation of interventions, in the US, interventions that cost less than $50,000/QALY are considered an efficient use of resources and worth recommending.[51–56] Other countries have different evaluations of this measure depending on their specific system of health care management, financial views, and health care laws.[53,55] Therefore, health care cost-effective results from studies conducted outside of the US healthcare system need to be evaluated with the acknowledgement of differences in health care management, public policy, and culture.

Among studies that have found the costs of diabetes education to exceed potential savings or have found no impact on overall costs, investigators have often suggested that the results may be due to the limited timeframe of analysis and that DSME is likely cost-effective or cost-saving in the long-term.[64,89] The costs associated with sustaining glycemic control include

but are not limited to DSME, MNT, additional physician visits, and medications including insulins. While these costs are immediate, the benefits may take years to realize. Even so, it is likely these costs will continue to be lower in subsequent years if patients maintain glycemic control.[75] Evaluation of the cost-effectiveness of treatments, specifically DSME and MNT, require long-term discernment to best analyze the ultimate impact on patient outcomes and cost-saving over the course of this progressive chronic disease.

While it appears that the financial burden of diabetes falls primarily on insurers who pay a substantial portion of medical costs, indirect costs are passed along to all of society. Employers experience productivity loss and patients with diabetes and their families suffer higher medical costs and reduced earnings and employment opportunities. Society at large is impacted in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.[6,90] Cost-effective analysis does not address the distribution of costs and the benefits of interventions such as DSME and MNT across these variables. The societal or personal willingness to pay, social and legal aspects, or ethical issues associated with each intervention are important in formulating public policy and business strategies.[54] All of these aspects are important in considering the total worth of DSME and MNT, which are not taken into account in cost-effective analysis.

Barriers impacting Access to DSME and MNT

Despite the efficacy of DSME and MNT for the management of T2D, CDC reports that an estimated 6.8% of privately insured, newly diagnosed patients with diabetes participate in DSME[9] with only 58% of patients with diabetes ever receiving diabetes education.[92] The Joint Position Statement of the American Diabetes Association and the Academy of Nutrition and

Dietetics identifies several factors resulting in underutilization of these services; current reimbursement models and requirement for physician referral are noted as key barriers.[18]

While reimbursement for DSME is common among private insurance providers, not all public insurance providers reimburse for DSME. Most public and private insurance plans in the United States are legally required to provide coverage for DSME.[10] As previously noted, Medicare Part B outlines provisions for both DSME and MNT, when provided through ADA or AADE recognized programs.[2] However, Medicaid reimbursement for DSME varies by state and specific provisions for RDN-provided individualized MNT, if any, are not clearly defined.

According to recent tracking efforts by the National Conference of State Legislatures, 44 states and the District of Columbia currently require private plans to provide coverage for self-management training.[105] When state and private insurance plans do not provide coverage for DSME and MNT, the costs fall on the patients and subsequently prevents patients from accessing quality care.[11] Uninsured and adult Medicaid beneficiaries, may not get the quality of care needed to sustain effective self-management practices placing these vulnerable adults at increased risk of devastating and costly complications of diabetes despite known benefits. Patients who lack access to stable primary care often seek care through emergency departments and other acute care settings driving up cost of disease management.[106] The public health challenge is further exacerbated by disparately high disease burden among those in low socioeconomic strata.[69]

Another common barrier is lack of physician referral. Both patients and diabetes educators report that physicians often to do not refer patients to DSME, and if a referral is made, there may not be enough emphasis made on the importance of DSME.[11] Physicians have reported their own reasons and perceptions for not referring patients to DSME, which include

doubting the quality of the DSME provided, not including enough of a real-world focus on diabetes self-care, not personalizing care to the patients' needs, and using medical jargon that ultimately confuses patients. However, the vast majority of the evidence on DSME does not support these perceptions.[11]

With regard to patient perspectives, most patients are unaware of the need or availability of DSME and MNT, and therefore do not seek these services. Some patients do not believe that DSME could be helpful or prefer to get DSME from their physician rather than from a diabetes educator. Logistic difficulties were reported to be common, including distant locations or lack of transportation and inconvenient times of service for working people. The ideal point of care identified by the patient is often at the physician's office, but DSME is rarely available at the site of most patients' physician.[11]

It is important that both physicians and patients to understand the benefits of multidisciplinary DSME and RDN-administered individualized MNT provided per the standards of practice.[2] RDNs should take an active role in ensuring that providers in their regional referral networks are aware of the services offered through their clinics. The RCR methodology presented within the present study can be used to obtain outcome data from individual programs to demonstrate efficacy and market DSME and RDN services.

Study Limitations and Future Directions

The RCR has a limitation in that not all data points are available for all patients across each time period. The mixed model ANOVA utilized within provides a means of accounting for missing data. Since this study was conducted in Alabama, results may not be applicable to other states. Alabama has one of the highest rates of obesity and diabetes. Notably our sample

population is higher in African Americans than the US as a whole; health disparity is evinced in higher baseline HbA1c in our African American population.

Cost savings reported from outcome studies and mathematical models are imperfect when extrapolated across varied treatment programs. While reduction in HbA1c, comorbid disease, and hospitalizations provide the foundation for determination of cost savings, most models are heterogeneous in variables studied. Models reported estimated healthcare costs and savings, but do not include indirect costs and potential savings related to such variables as quality of life, insurance premiums, wages, and productivity. US dollars are reported at the time of the respective studies and do not reflect current 2017 costs for disease management, hospitalizations and treatment of acute and chronic complications of diabetes, and therefore underestimate costs to the health system associated with disease burden.

CONCLUSIONS

This RCR of 388 patients who received DSME with integrated nutrition education and RDN-provided individualized or group MNT through ADA-recognized education programs reports positive outcomes for all endpoints (weight, BMI, and HbA1c) that are consistent with or exceed those previously described in observational studies and RCTs that can be achieved in the real-life setting. Significant reductions in HbA1c were observed for both patients managed by diet alone and diet plus drug therapy and sustained at one year. Reduction in HbA1c is associated with a decrease in chronic comorbid disease and hospital admissions and ultimately reductions in healthcare costs. Given national figures and high rates of obesity, diabetes, kidney disease, and other chronic comorbid conditions,[107] these results demonstrate a critical role of the RDN; specifically, the importance of the RDN as a member of the multidisciplinary team providing

DSME and the preferred provider of patient-centered individualized MNT to support both improved health outcomes and cost reduction.

The reviewed literature assessed that DSME and MNT can save direct medical costs related to diabetes. Because DSME and MNT directly impacts glycemic control and comorbidity prevention and reduction, positive patient outcomes result in cost savings seen in patients with access to these services. To better assess the cost-effectiveness of DSME and MNT, future studies must be consistent in study design, analysis, and population, and narrowly define DSME and MNT to evidence-based, ADA-recognized or AADE-accredited diabetes education programs. Long-term simulations that model the cost-effectiveness of DSME and MNT must also account for the indirect costs of diabetes and its associated comorbidities to fully comprehend the costs and burden of the disease. Results of these cost-effective analyses direct health policy and reimbursement for DSME and MNT.

The present study provided a means to extract outcome data in support of the request from BCBS-Alabama in a timely and cost-effective manner. Educating employers, insurers, and primary care providers of the benefits and availability of effective RDN-provided services in local healthcare systems, as evidenced in the present study, could increase reimbursement, referral and ultimately patient access to care. In the present climate of outcome driven research and cost-benefit analysis, such data obtained using RCR from individual programs to multisite and national studies can inform health policy decisions and position the RDN in current and emerging healthcare models for the treatment and prevention of chronic disease.

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