



Technical Review: Diabetes Self-Management Education and Training (DSME/T) Outcomes Measures

In 2003, the American Association of Diabetes Educators (AADE) published the Diabetes Self-Management Education Core Outcomes Measures Technical Review. This paper is an update of that review.

This document is composed of six parts: 1) Background, 2) Defining Outcomes, 3) Outcomes Associated with Diabetes Self-Management Education and Training (DSME/T), 4) Assessment for Continuous Quality Improvement (CQI), 5) Self-Care Behavior Outcomes, and 6) Summary and Conclusion. It builds upon the earlier technical review and is further supported by AADE practice documents and seven systematic reviews.¹⁻¹¹ It also complements the “Standards for Outcomes Measurement for Diabetes Self-Management Education and Training” position statement which provides a framework for educators and DSME/T stakeholders to use as a guide in assessing the value and effectiveness of DSME/T.¹¹

Diabetes educators engage in qualitative and quantitative performance and outcomes measurement to determine whether changes that result from DSME/T are actually leading to improvement in health status. AADE has adopted behavior change as the key intermediate outcome of DSME/T.² Seven diabetes self-care behaviors comprise the AADE7 Self-Care Behaviors™ (Being active, Healthy eating, Monitoring, Taking medication, Problem solving, Healthy coping, and Reducing risks) and are key to effective diabetes self-management.² These self-care behaviors and their measurement help establish the core measures of behavioral outcomes associated with DSME/T performance.² Other measures have been defined as important for assessing the outcomes associated with the DSME/T intervention.^{1,11} (Figure 1)

The literature also identifies relevant learning, clinical, health status, satisfaction, and economic outcomes metrics. (Table 1) Diabetes educators can use these measures to determine their effectiveness with individuals and populations, compare their performance with established benchmarks, and establish the unique contribution of DSME/T in the overall context of diabetes care.

BACKGROUND

Outcomes assessment is critical to the successful practice of evidenced-based DSME/T. Diabetes educators engage in outcomes measurement to determine the extent to which changes that result from DSME/T lead to clinical improvement for people with diabetes. Accordingly, AADE works to build the evidence for DSME/T, advance outcomes assessment to improve patient care and better understand the value of DSME/T, and provide tools to help practicing diabetes educators effectively engage in outcomes assessment.

The importance of evaluating DSME/T interventions has been addressed in the literature.¹¹ Moreover, the National Standards for Diabetes Self-Management Education, which were developed and are regularly updated by organizations with an interest in DSME/T (e.g., AADE, American Diabetes Association, American Dietetic Association) highlight the importance of outcomes by defining the process for conducting an evaluation and annual reviews of program- and patient-focused behavioral objectives.¹² The National Standards address the importance of measuring both patient-focused and aggregate outcomes. Standard 9 addresses measurement of the attainment of patient-defined goals and patient-specific outcomes. Standard 10 addresses the need to apply CQI in DSME/T program evaluation.¹²⁻¹⁴

AADE has expanded upon the National Standards for Diabetes Self-Management Education by recommending specific indicators for DSME/T outcomes. Without specificity of indicators, it would be left to the discretion and experience of each diabetes educator to determine what to measure, resulting in considerable variation in defining and reporting specific attributes of effective DSME/T.¹²⁻¹⁸ AADE has also coordinated studies, symposia and literature reviews to answer key questions, such as “Is DSME/T effective?” and “What methods are the best?” In doing so, AADE was able to consider which elements and types of outcomes are relevant for educators and other organizations that are assessing DSME/T interventions.

Diabetes educators are able to advance patient care in their own practices by aggregating data and further building an evidence base. Their efforts also help to identify best practices in DSME/T, which can help drive broad improvements in self-care and diabetes management. Robust analyses begin with questions concerning what treatment, for what population, delivered by whom, under what set of conditions, and ultimately, for what outcome.¹⁵⁻¹⁹ Specific outcomes of DSME/T can be measured consistently at specific time intervals and used to guide or support interventions at an individual level. The aggregation of outcomes involves pooling, collating, and analyzing outcomes from multiple individuals. Subpopulations are formed at every level of aggregation that can, in turn, be pooled into larger populations. For example, population-based outcomes may exist for a specific program service, a specific DSME/T site, or a multisite DSME/T program. Similar to the use of outcomes measures to guide improvements on an individual level, population-based outcomes measurement can be used to monitor and improve DSME/T at a program level.^{18,19} Patient satisfaction with and self-perception of their healthcare experience is also recognized as an important component of outcomes assessment.¹⁵

The need to examine outcomes in diabetes care has been further influenced by reporting requirements of AADE’s Diabetes Education Accreditation Program and the American Diabetes Association’s Education Recognition Program. Both of these accrediting bodies have adopted the National Standards for Diabetes Self-Management Education. The Centers for Medicare and Medicaid Services (CMS), the Agency for HealthCare Research and Quality (AHRQ) and the National Council on Quality Assurance (NCQA) also articulate the importance of outcomes measurement.²⁰⁻²² Such national efforts, however, tend to reference DSME/T as a process measure, assessing whether or not it was performed.

DEFINING OUTCOMES

Outcomes are described as end results, or that which results from the delivery of healthcare services such as DSME/T. According to Donabedian, *outcomes* are defined as “a measurable product and . . . the changed state or condition of an individual as a consequence of health care over time.”²³ Patient health outcomes have been measured for years, with increasing use by researchers and providers who evaluate the best way to improve the performance of providing health care.^{24,25} Donabedian has also defined and categorized structural and process measures.²³⁻²⁸ Process and outcomes measures are addressed in this technical review. Process measures are sometimes used when it is not possible to measure exactly the outcome that one wishes to measure.

Process measures as they relate to DSME/T can be described as what a DSME/T program performs or delivers. Process and outcomes measures both bring about results, and, at least in terms of quality, are interrelated.²³ Many process measures are used as performance measures. The Healthcare Effectiveness Data and Information Set (HEDIS), for example, is a tool used by more than 90 percent of America's healthcare plans to measure performance on important indicators, such as presence or absence of annual eye exams.²⁹ Process measures are often essential to CQI efforts.

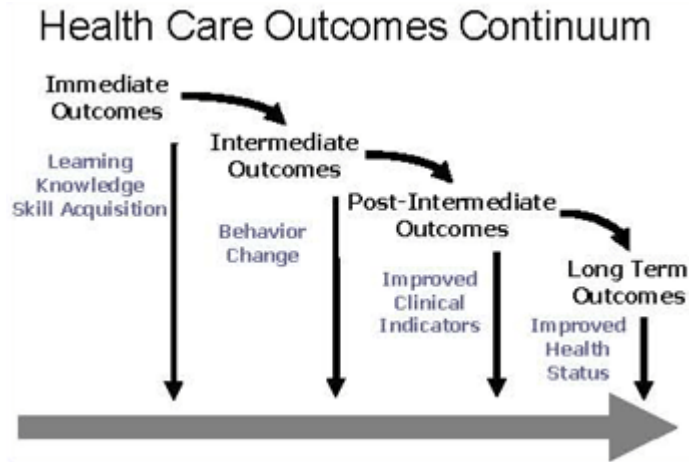
DSME/T builds upon several fields of knowledge, mainly upon education, behavior, and health care. Education includes learning and behavioral outcomes. Health outcomes have traditionally included the longitudinal measurement of both clinical indicators and patient-centered outcomes of satisfaction and well-being. In contrast, economic outcomes are cost factors associated with the health outcome of interest (e.g, cost or utilization) and may include such ratio measures as cost effectiveness and cost benefit.^{30,31} All of these outcomes may be relevant to both patient-specific and population-based evaluation and must be achieved in a cost-effective manner for both the individual and the overall population. Through this systematic and scientific process, the evidence base for DSME/T practice will evolve.

OUTCOMES CONTINUUM

There are multiple types and levels of outcomes for DSME/T. When the system of diabetes education and care is evaluated incrementally, a continuum of outcomes categories emerges. Figure 1 illustrates a simple model of this continuum with feedback loops.^{1,31} Immediate outcomes are those that can be measured at the time of the intervention.³¹ Learning can be assessed by testing or direct observation after the DSME/T intervention.

Intermediate and post-intermediate outcomes result over time, require more than a single measurement, are sensitive to change, and may show a statistical change.¹⁹ Behavior changes result from participant self-management activities and the DSME/T process, and can be measured through self-report. Clinical improvement results from the interaction of DSME/T, participant self-management, and clinical management, and can be measured with laboratory and procedural testing. Long-term outcomes result from multiple variables over an extended time. Behavior change (Intermediate Outcomes) can be systematically measured by the Behavior Score Tools™ which are integral to the Patient Self-Assessment and captured in the AADE7 System™.^{32,33}

Figure 1 Outcomes Continuum for DSME/T



OUTCOMES ASSOCIATED WITH DSME/T

The diabetes educator works collaboratively with the patient to improve overall health status, empowering them to maintain healthy self-management behaviors, which influence functional status and quality of life.³⁴

Learning Outcomes

A goal of DSME/T is to improve overall health status by empowering the person with diabetes to:

- Acquire knowledge (what to do)
- Acquire skills (*how to do it*)
- Develop confidence and motivation to perform the appropriate self-care behaviors (*want to do it*)
- Develop the problem-solving and coping skills to overcome any barriers to self-care behavior (*can do it*)

A central purpose of DSME/T is to help patients make informed decisions and to facilitate their self-care behavior changes.^{34,35} However, there are several more immediate objectives that contribute to the behavior change. The immediate objective of DSME/T is to help participants develop self-care knowledge and skills to achieve self-care behavior goals and, in turn, enhance well-being. Yet, all of these factors are important only to the degree that they facilitate individuals in achieving their diabetes self-care goals.³⁶ Moreover, failure to address all the essential elements of behavior change results in incomplete and ineffective DSME/T.³⁴

Clinical Outcomes

In the overall context of diabetes care, self-care behaviors, along with appropriate therapeutic regimens (if needed), can enhance clinical status, reduce diabetes complications, and improve health status.^{36,37} Educators play an important role in monitoring the patient's clinical status and recommending or referring for appropriate clinical tests or interventions. Practice Guidelines put forth by AADE, the American Association of Clinical Endocrinologists

and the American Diabetes Association (ADA) indicate that a variety of clinical measures relate to DSME/T and are therefore important to outcomes measurement.³⁹⁻⁴¹ Some examples of clinical measures are hemoglobin A1c (A1C), blood pressure, body mass index, lipids, dilated eye exam, and foot exam. See Table 1 for a more extensive list of clinical outcomes that are associated with DSME/T.

Health Status Outcomes

The goal of all diabetes care is improved overall health status. This improvement can result in quality-of-life and economic benefits for people with diabetes as well as for society as a whole. Central to measuring quality improvement is having variables related to quality that are measured consistently, longitudinally, and at appropriate intervals. These quality indicators must also promote changes in practice.

The unit of measurement, the purpose of measurement, and the consumer of the information largely drive outcomes measurement for accountability. Performance measurement for accountability is driven by what is measurable and accessible. Thus, accountability measures are influenced by large accreditation agencies that serve provider organizations or health plans, such as the NCQA and The Joint Commission.^{42,43} DSME/T program accrediting bodies (AADE and ADA) also help to define which health status outcomes are relevant for practicing diabetes educators.⁴⁴ Accordingly, recommended diabetes measures to evaluate and benchmark performance include laboratory measurements that monitor processes and that are widely documented and obtainable, as well as process measures such as whether an annual eye exam occurred.^{44,45} In some instances, these same accountability measurements are used for assessing quality improvement.

Quality of life is a key element of health status.

It has been argued that the subjective quality of life is the ultimate outcome and that health status is important because it affects quality of life.⁴⁵ Evaluating quality of life, however is challenging. It aligns most closely with the healthy coping behavior but is not always a specific element of DSME/T assessment. Testa states, "Researchers study health-related quality of life in people with diabetes for a variety of reasons."⁴⁴ In health care research, the term quality of life has been used broadly to describe health-related constructs, outcomes, measures, scales, and instruments...⁴⁴ While the term has widespread and broad usage, operationally, quality-of-life assessment in health care involves a complex, multidimensional construct that can be measured by evaluating objective levels of health status filtered by the subjective perceptions and expectations of the individual.^{1,44}

The literature presents several diabetes-specific instruments (e.g., ADDQoL, DHP-1/18, DSQOLS, D-39 and QSD-R) that are recognized as valid measures of health-related quality of life.⁴⁵ As they vary somewhat, the educator will consider the relevance of the content of these instruments before application.

Satisfaction Outcomes

Measurement of satisfaction is relevant to DSME/T because satisfied patients demonstrate greater success in diabetes self-management goal achievement and are likely to have higher participation in DSME/T sessions.⁴⁶ A search of the clinical and measurement literature reveals the availability of various instruments (e.g., the Mastery Stress Instrument) that allow

diabetes educators to measure satisfaction among patients in DSME/T programs.⁴⁷ Doing so is important because positive patient satisfaction is positively associated with diabetes education and providers or organizations that achieve more "personal: care."^{48,49} The literature also indicates that patient satisfaction is also associated with a strong theoretical framework and diabetes education sessions that are designed to be culturally appropriate.⁵⁰

Economic Outcomes

The literature presents research that clarifies the economic value of DSME/T.^{37,38,51} Such studies include costing, cost-effectiveness analyses and actuarial methods. While most diabetes educators are unlikely to undertake such rigorous economic analyses, they need to be able to speak knowledgeably about the costs of DSME/T programs and perhaps even defend these costs. Being familiar with and understanding economic outcomes will help them do so. In addition, diabetes educators can use economic metrics such as utilization, retention, and even access to DSME/T as part of CQI studies to enhance delivery of DSME/T within programs. Economic and socioeconomic measures (employed or not, presence or absence of insurance coverage) also help to describe the characteristics of the patient population attending DSME/T classes.

Table 1. Measurable Outcomes for DSME/T

Learning Outcomes

- Diabetes related knowledge
- Diabetes related skills

Behavioral Outcomes

- Goal Setting
- Goal Achievement
- Behavior Scores
- Other (specific to each behavior)

Clinical Outcomes

- Percentage of patients with A1C > 9 percent
- Percentage of patients with A1C < 7 percent
- Percentage of patients with blood pressure < 130/80 mmHg
- Percentage of patients with blood pressure > 140/90 mmHg
- Percentage of patients with LDL cholesterol < 100 mg/dL
- Percentage of patients with LDL cholesterol < 130 mg/dL
- Percentage of patients with annual eye exam
- Percentage of patients with smoking cessation counseling
- Percentage of patients with medical attention for nephropathy
- Percentage of patients with annual foot screen
- Percentage of patients with more appropriate weight or body mass index
- Percentage of patients > 40 years of age on statins
- Percentage of patients with one pneumococcal vaccine at any time in the past
- Percentage of patients with current flu vaccinations
- Percentage of patients on aspirin therapy
- Percentage of patients > 55 years of age on ACE inhibitors or angiotensin receptor blocker medication

- Percentage of patients with self-management goals documented

Health Status Outcomes

- Quality of Life (QoL)
 - Patient perceptions of QoL
- HEDIS Measures

Economic Outcomes

- Cost of DSEM/T provision
 - Cost-effectiveness of the DSME/T Program
 - Comparative effectiveness
- Utilization
 - Decrease in diabetes-related emergency room use
 - Decrease in number of diabetes-related hospitalizations
 - Increased compliance with diabetes-related pharmaceutical regimen
 - Number who complete the program
 - Change in number who have access to diabetes education and remain in the program
 - Number of patients attending classes
 - Number of DSME/T drop outs

Satisfaction Outcomes

- Health care worker satisfaction
- Patient satisfaction with DSME/T
- Patient Perceptions of DSME/T Practice /Program

ASSESSMENT FOR CONTINUOUS QUALITY IMPROVEMENT

CQI is an ongoing effort to improve DSME/T programs. Standard 10 of the 2000 National Standards for Diabetes Self-Management Education explains that “the DSME/T entity will utilize a CQI process to evaluate the effectiveness of the education experience provided, and determine opportunities for improvement.”¹²⁻¹⁵ Applying CQI to daily operations is an important organizational decision because all staff, not just managers, are accountable for the ongoing and CQI of a DSME/T program. Implementing a CQI program for DSME is not only one of the National Standards for DSME but has been adopted by AADE’s Diabetes Education Accreditation Program and ADA’s Education Recognition Program.¹³ Setting targets for educational, behavioral, and clinical outcomes is an important function of quality programs. There are varied CQI methodologies, one of which is shown in the following examples and detailed in Tables 2 and 3.

Table 2. CQI Process Example

1. Identify the problem/opportunity
2. Collect the data (needed to determine the measures/indicators)
3. Analyze the data
4. Identify alternative solutions
5. Develop an implementation plan
6. Implement the plan
7. Evaluate the actions
8. Maintain improvement

Table 3. Outcomes for CQI

Example of Using Aggregate Population Outcomes Data for CQI

Continuous Quality Improvement Aggregate/Population Data						
Opportunity for Improvement	Measurement Indicators, Data Collection	Monitoring Data Analysis	Management			
			Identify Solution(s)	Implement Plan	Evaluate Actions	Maintain Improvement
Although increasing physical activity is chosen as a priority goal by many of the program participants, most express discouragement in achieving their goals.	<ul style="list-style-type: none"> • Priority goal—76% • Goal achievement—44% • Frequency—<2 days/week • Type—walking, 30% • Duration—<30 min • Barriers—time, environment • A1C—7.8% 	CQI team reviewed the data, determined that many participants worked long hours, had long commutes, and typically led sedentary lifestyles	<ul style="list-style-type: none"> • Developed a walking program based on “10 000 Steps Per Day Program” • Provided each participant with a pedometer • Set up a walking club Web site on their organizational Web site 	Implemented a pilot program with 20 participants and followed them for 6 months	At 6 months: average self-reported achievement was 79%; pedometer records indicated that average steps per day per patient were 640; population mean A1C was 6.4%	Program was implemented for all patients; data 1 year later: <ul style="list-style-type: none"> • Goal—74% • Achievement—68% • Frequency—>3x/wk • Type—walking • Duration—<30 minutes • Steps—690/day • Population mean A1C—6.2%

CQI=Continuous quality improvement.

SELF-CARE BEHAVIOR OUTCOMES

Self-Care Behavior—Being Active: Physical Activity (Exercise)

Being active involves body movements that contract skeletal muscle, whereby energy expenditure increases.^{52,53} The terms “exercise,” “physical activity,” and “being active” are often used interchangeably and are considered to be planned, structured, repetitive, and performed with the object of positively impacting physical fitness and/or health outcomes. Regular activity is important for overall fitness, weight management and blood glucose control.⁵³ Being active can help improve body mass index, enhance weight loss, help control lipids and blood pressure and reduce stress.^{4,54-62} With appropriate life style changes that involve exercise, those at risk for type 2 diabetes can reduce that risk, and those with diabetes can improve glycemic control.⁴⁵⁻⁶⁴

Diabetes educators and their patients collaborate to address barriers to being active, such as physical, environmental, psychological and time limitations.⁶³ They also work together to develop an appropriate activity plan that balances food and medication with the activity level.^{62,63} A primary goal of DSME/T is to increase the physical activity of an individual with diabetes; even small changes are considered beneficial and can potentially build self-efficacy in patients who are not confident that they will be able to exercise at a level considered optimal by the guidelines.⁶⁴

Standard Data Elements for Outcomes/Performance Measurement

Baseline knowledge (safety and relationship to food and medications), perceptions of importance, current physical activity (type, duration, frequency, and intensity), and a behavior plan for progression should be measured initially and re-measured at 2 to 4 weeks, and then every 3 to 6 months.⁶⁴ It is also important to measure participants' knowledge of anticipatory behavior, such as adjusting self-monitoring of blood glucose (SMBG) frequency to the duration and intensity of activity. Data can be collected through the self-report method, observation, or physical activity measurement instruments such as a pedometer or other devices relevant to the activity.

Self-Care Behavior—Healthy Eating

Healthy eating involves a complex set of behaviors.^{5,65,66} Decisions are made many times a day regarding what to eat, when to eat, and how much to eat. Many factors affect these decisions, including food availability, family eating patterns, habits, emotions, food preferences, blood glucose control, and knowledge regarding how food affects diabetes control and overall health. Making healthy food choices, understanding portion size and learning the best times to eat are central to managing diabetes.⁶⁷⁻⁷⁰ Skills involved with eating behavior for persons with diabetes can include carbohydrate and fat gram counting, label reading, and measuring foods for portion control.⁷¹ By making appropriate food selections, controlling weight and achieving optimal blood glucose levels, many people with diabetes may be able to manage their condition for a time without medications.^{5,65,66}

The goal of the healthy eating intervention is to assist and facilitate individual lifestyle and eating behavior changes that will lead to improved glycemic control, a reduced risk for complications, and improved health.⁶⁷⁻⁷¹ DSME/T classes can assist people with diabetes in gaining knowledge about the effect of food on blood glucose, sources of carbohydrates and fat, appropriate meal planning and resources to assist in making food choices.^{5,71} Skills taught include reading labels, planning and preparing meals, measuring foods for portion control, fat control and carbohydrate counting.⁷² Barriers such as environmental triggers and emotional, financial and cultural factors are also addressed. Eating is not a behavior unique to diabetes care that must be taught for the first time, unlike some of the diabetes self-care behaviors (e.g., monitoring taking medication). There is ample evidence demonstrating the importance and effectiveness of medical nutrition therapy (MNT) in diabetes management.^{65,73} Following appropriate meal plans can result in decreases in A1C, LDL cholesterol, blood pressure, and weight.⁵

Four specific diet behaviors were identified in the Diabetes Control and Complications Trial (DCCT) as having the most influence on improved glycemic control; these behaviors should therefore be considered as a target of initial behavior change goals for people with type 1 diabetes: 1) adherence to meal plan, 2) appropriate treatment of hypoglycemia, and 3) prompt response to hyperglycemia (more insulin and/or less food), and 4) consistent consumption of a prescribed evening snack, if appropriate.⁷³ Meal planning, carbohydrate counting, portion control and other healthy eating skills are appropriate for people with type 2 and gestational diabetes.⁷²

Standard Data Elements for Outcomes / Performance Measurement

Evaluation of eating behavior is done most often by patient self-report through standard assessment questions (e.g., 24-hour recall and food frequency questionnaire), review of

blood glucose and food records, and skill checks by the educator (using labels, restaurant menus, food models, etc).^{3,4} An individual's type of food choices (including alcohol), the amount of food (or a particular nutrient such as carbohydrate) eaten, the timing of meals, and the effect of food on blood glucose should be measured at baseline, 2 to 4 weeks, and then every 3 to 6 months. It is also important to assess the participant's knowledge of anticipatory behavior, such as how to apply the meal plan in special situations (e.g., sick days, traveling, schedule changes, and dining out), and how to use eating behavior for compensatory situations (e.g., problem solving for changes in a routine, preventing low blood sugar, and balancing exercise and food). Role playing and discussing a variety of real-life scenarios are methods that are used to assess problem-solving behavior.

Self-Care Behavior—Monitoring

Monitoring is defined as observing and checking the progress or quality of something over a period of time.^{6,74} Self-monitoring requires people with diabetes to become involved in self-management of their diabetes and connects them to the outcomes of their measurement activities. Daily self-monitoring of blood glucose provides people with diabetes the information they need to assess how food, physical activity and medications affect their blood glucose levels.^{6,75-82} Monitoring, however, doesn't stop there. People with diabetes also need to regularly check their blood pressure, urine ketones (for those with type 1 diabetes), feet, and weight.⁷⁶

Self-monitoring of blood glucose (SMBG) has been evaluated and is generally, but not uniformly, been recommended as a potentially valuable part of the overall treatment plan.^{6,75-88} Monitoring of blood glucose requires a combination of technical skills and cognitive skills, including the ability to interpret results that allow patients and their healthcare team to evaluate individual response to therapy to assess if glycemic targets are being achieved.⁸²⁻⁸⁴ Diabetes educators advocate for SMBG and other aspects of monitoring and actively engage in teaching these behaviors and skills to people with diabetes.^{72,75} Diabetes education classes instruct patients about equipment choice and selection, timing and frequency of testing, target values, and interpretation and use of results.^{85,86}

Standard Data Elements for Outcomes/Performance Measurement

Baseline assessment of blood glucose monitoring behavior includes method and technique, frequency and schedule of monitoring and number of recommended blood glucose checks not done. Other monitoring (e.g., blood pressure, urine ketones for those with type 1, foot health, eating plans and weight) are also of prime importance.⁸⁷ Individual monitoring behavior should be reassessed within 2 to 4 weeks and every 3 to 6 months thereafter. The individual's goal for desired change also should be assessed, as well as barriers to change including cost, inadequate understanding about health benefits and proper use of results, psychological and physical discomfort, time requirements, physical setting, and complexity of the monitoring procedure. Data can be collected through self-report methods including records or logs, and may be supported by instruments such as glucose meters.

Self-Care Behavior—Taking Medication

Effective drug therapy in combination with healthy lifestyle choices, can lower blood glucose levels, reduce the risk for diabetes complications and produce other clinical benefits.^{7,72,87,88} The goal is for the patient to be knowledgeable about each medication, including its action, side effects, efficacy, toxicity, prescribed dosage, appropriate timing and frequency of

administration, effect of missed and delayed doses and instructions for storage, travel and safety.⁸²

Medications are important to diabetes health outcomes for three major reasons.⁹⁸ First, pharmacotherapy is either imperative or eventually needed to achieve desired glucose treatment goals for most individuals with diabetes.^{7,89-92} In type 1 diabetes, drug therapy is imperative to sustain life as well as to attain glycemic control.^{54,55} In type 2 diabetes, the progression of pathophysiologic defects (insulin resistance and relative or absolute insulin secretory deficiency) eventually necessitates the addition of medication(s) to the diabetes management plan.⁹² In gestational diabetes, the need for medication during the course of pregnancy is not predictable.⁹³ In all instances, pharmacotherapy is intended to augment nonpharmacologic, lifestyle interventions.

Second, healthy eating and physical activity, although important, are difficult to sustain or may be insufficient to manage blood glucose levels. Aggressive (intensive) pharmacotherapy in combination with lifestyle interventions has been shown to lower blood glucose levels and result in clinical benefits, including reduced risk for diabetes complications.⁷³

Third, medication-taking behaviors are particularly important in terms of diabetes health outcomes.⁷ Not taking the prescribed medications or taking them incorrectly can interfere with achieving the expected or desired outcome.⁹² The healthcare literature is replete with studies documenting inappropriate patient medication-taking behaviors and the associated negative effects on therapeutic outcomes.^{7,89,90}

Medication-taking behavior combines cognitive and technical skills associated with taking oral, topical, and/or injected medications.^{89,90} Appropriate medication-taking behaviors include administration at recommended time(s) of day and frequency of doses; correct dose preparation, selection, or calculation; administration technique and skills; and consistency over time.

Standard Data Elements for Outcomes/Performance Measurement

Behavioral changes or outcomes generally expected from DSME/T for taking medication include acquisition of or improvement in knowledge to assure competent, confident, and safe drug use.⁷ People with diabetes and caregivers must be confident and competent in recognizing side effects or drug toxicity, and be prepared to take corrective or preventive actions.⁸⁹ These actions may be as simple as being able to report a drug regimen to a rescue squad or as complex as making insulin adjustments based upon a prescribed supplemental, retroactive, or prospective algorithm. Comparing the patient's blood glucose records (manually recorded or by meter memory printouts) with the dietary, exercise, and medication log is a useful way to assess the patient's application of the dosing scheme as well as the appropriateness of an algorithm or treatment plan.

Other important changes or outcomes require a specific level of skill in the technical aspects of medication administration coupled with consistency of medication administration. For many such skills, the best assessment tool is observing the patient or caregiver perform the procedures. Another critical aspect of medication-taking behavior is the consistency with which a medication is taken and how well the patient administration pattern matches the

prescribed pattern. Reviewing patient self-report diaries, measuring the amount of drug used/unused (e.g., pill counting), or checking refill profiles may all be helpful in determining the percentage of medication taken as well as the consistency and timing of doses per day.

Self-Care Behavior—Problem Solving

Problem solving is a learned behavior that includes generating a set of potential strategies for problem resolution, selecting the most appropriate strategy, applying the strategy, and evaluating the effectiveness of the strategy.⁸⁸ Problem solving is an essential skill for effectively self-managing diabetes and involves more than knowledge or skill acquisition.^{94,95} This skill is continuously put to use because even after decades of living with the disease, stability is never fully attained: the disease is progressive, chronic complications emerge, life situations change and the patient is aging.⁹⁵⁻⁹⁹ In the AADE7 Self-Care Behavior framework, an important focus is on the diabetes problem-solving behavior of recognizing and responding to unanticipated situations of hypoglycemia, hyperglycemia, and sick days.⁸ AADE also recognizes the importance of problem solving in all areas of diabetes self-management including quality of life, support groups, and family therapy especially in youth.^{99,100} Analysis of AADE Diabetes Education Accreditation Program annual reports indicates that problem solving is a behavior that needs to be more frequently tracked and measured by diabetes programs.¹⁰¹

Problem-solving measures have been shown to be effective predictors of dietary, exercise, and medication self-care.⁹⁹ Recent research also suggests that excessively high or low blood glucose levels may influence problem-solving skills, yet at those times the individual with diabetes or their support person must respond appropriately to avoid serious consequences.¹⁰⁰ This emerging body of research indicates that problem-solving skills are critical for helping individuals manage chronic illness treatment regimens.

Standard Data Elements for Outcomes/Performance Measurement

The detailed reasoning involved in decision making is difficult to assess apart from educator experience.¹⁰² Assessment tools that measure the participant's intent to respond to proposed situations and observational measures are helpful in the educator's assessment. Problem solving scenarios provide a measure of behavioral intent but not the actual behavior. Participant self-report about problem management with blood glucose monitoring data may provide objective information regarding the use of food, activity, medication, or ketone testing for resolving problems. Reviewing a log book and meter memory may provide data regarding treatment of high or low blood glucose levels. Medical charts and patient self-report for hospital admissions or emergency room visits for hyperglycemic and hypoglycemic events reveal the frequency or seriousness of those episodes. Other health status measures such as patient self-report of days missed from work, school, or other activities due to diabetes-related issues, especially for out-of-control blood glucose, can be tracked and may provide an indication of problem-solving ability.

Barriers exist to outcomes assessment for problem solving. A systematic review of the problem solving literature emphasized the lack of research in the area of outcomes.⁸ In much of the literature, the intervention is not fully defined, the measurement of problem solving differs, and findings vary. Hence, the effect of problem solving on diabetes outcomes cannot yet be fully clarified.

Self-Care Behavior—Reducing Risks

Reducing risk-factor behaviors for diabetes self-management involves understanding, seeking, and maintaining several preventive healthcare services on a periodic basis, such as annual eye examinations, routine medical follow-up, and dental examinations.⁹ In addition, other self-initiated activities such as foot inspection, appropriate aspirin use, smoking cessation, and immunization are critical behaviors that need greater emphasis during the educational process.^{9,103-105,} Reducing risks in the context of the effective delivery of diabetes education and care has been described in detail in a systematic review and various accreditation agencies.^{9,106,107} Many but not all preventive interventions are in the control of the person with diabetes.¹⁰⁸ Healthcare providers also have a central role to play in achieving the reducing risk behavior.

Standard Data Elements for Outcomes/Performance Measurement

An important part of self-care is learning to understand, seek and regularly obtain an array of preventive services. Short-term collection of outcomes related to risk-reduction behaviors can be achieved through self-report via oral communication, questionnaires, or written maintenance schedules. Data collected through self-report methods may be validated by having individuals demonstrate these activities, and further validated by laboratory or claims data from healthcare organizations. A performance measurement set for adults with diabetes is available,¹⁰⁹ and process measures (e.g., an eye check occurred) are available via electronic medical records.²²

Self-Care Behavior—Healthy Coping

Healthy coping relates to health status and quality of life, which are affected by psychological and social factors.^{10,110} Psychological distress directly affects health and indirectly influences a person's motivation to keep their diabetes in control.^{111,112} Self-care behavior is a function of a person's behavioral intentions, motivations and ability to resolve barriers to self-care.¹¹³ Increased levels of stressors (depression, anxiety, altered social support) can pose barriers to self-care management. Research indicates that these linkages remain even when controlling for the levels of risk factors that may be function of the individual.^{10,110} When motivation is dampened, the commitments required for effective self-care are difficult to maintain.¹¹⁴ When barriers seem insurmountable, good intentions alone cannot sustain the behavior. Coping becomes difficult and a person's ability to self-manage their diabetes deteriorates.^{102,115}

Psychosocial factors are important because they can affect health outcomes both directly (through psychophysiologic pathways) and indirectly (through behavioral pathways). Numerous studies have suggested that psychosocial distress has direct, psychophysiologic effects on health.^{102,114-120} Socioeconomic status, constrained financial resources, poor communication, and family stressors are associated with lower diabetes knowledge and problem solving.¹¹⁴ Psychosocial factors associated with good metabolic control and adherence are internal locus of control, task oriented and problem-focused coping, social support from friends, positive orientation, and use of past experiences to guide coping efforts.¹¹⁸ Moreover, psychological distress, especially depression and poor health status, is significantly higher in people with diabetes than the general population and should be assessed because it can impede self-care behaviors.¹¹⁷⁻¹²²

Standard Data Elements for Outcomes/Performance Measurement

Coping skill measures can be generic or diabetes specific. Social support measures also may be generic or diabetes specific.^{10,121} Outcomes relating to the healthy coping behavior may therefore be evaluated in the context of depression screening and quality of life measures.¹²² Quality of life can, and should, be measured; this can be done by use of a variety of questionnaires.¹²³ Another essential psychosocial dimension is health related beliefs and perceptions related to behavior change (e.g., treatment self-efficacy, readiness/intention to change, and barriers to treatment).¹¹⁴ These factors tend, however, to be domain specific, meaning that the diabetes educator will need to determine their relevance on a case-by-case basis.

SUMMARY AND CONCLUSION

DSME/T is built upon evidenced-based medicine and advanced by ongoing evaluation. Diabetes educators must continue to gather the evidence to support and enhance their practices and modify their interventions in response to the evidence. The ongoing success of DSME/T programs is dependent upon a process of consistently measuring specific indicators (outcomes measurement), the frequency and interval of measuring these indicators (outcomes monitoring), and how these outcomes are used for educational and clinical decision-making (outcomes management).

Because of the complex nature of DSME/T, it draws upon a variety of outcomes metrics, including those that measure educational, behavioral, clinical health status, utilization, cost, and satisfaction. Application of the seven core behavioral outcomes/performance measures to evaluate the effectiveness of DSME/T provides the diabetes care team with the ability to understand what is working and what is not. Effective tools are available with which to assess behavioral, learning, clinical, health status, quality of life, satisfaction and economic outcomes related to services provided by diabetes educators.^{2,22,32,123,124,125} By embracing and employing standard outcome measures for DSME/T the diabetes education profession will be securely established as an essential therapeutic intervention in the care of people with diabetes.

Table 4. GLOSSARY OF TERMS

- Behavioral Outcomes: Measurable changes relating to the AADE7 Self Care Behaviors™ framework, which reflect the best practice of DSME/T by measuring changes in patient behaviors.
- Clinical Outcomes: Measurable changes in an individual's or population's biological markers that are the result of an intervention.
- Continuous Quality Improvement: A continuous process that identifies problems in healthcare delivery, examines solutions to those problems, regularly monitors the solutions to those problems, and regularly monitors the solutions for improvement.
- Cost-benefit: An economic measure and relates specifically to a ratio measuring the costs to administer or deliver an intervention, medication, or service (measured in dollars) to the long-term savings that delivery will provide (measured in dollars).
- Cost-effectiveness: A ratio measure of the costs to administer or deliver an intervention, medication, or service (measured in dollars) to the impact on a health outcome (e.g., clinical indicator, quality of life).
- Cost Outcomes: Economic factors associated with a health outcome of interest; generally reported as ratio measures of cost-effectiveness and cost-benefit.

- Economic Outcomes: Changes in measurable resources, whether these are dollars, people, supplies or services that relate to the care of people who have diabetes.
- Functional Status: The evaluation of how individuals perform typical behaviors without limitations due to health problems.
- Health Outcomes: Changes in the health of an individual or population that are associated with the DSME/T intervention. Includes the measurement of learning, behavioral, clinical, and functional status as well as patient-centered outcomes of satisfaction and well-being.
- Health-status or Health-related Quality of Life: A broad term covering five concepts—duration of life, impairments, functional states, perceptions and social opportunities—that are health related to the extent that disease, injury, treatment, or policy influences them.
- Learning Outcomes: Measurable changes in knowledge and skills possessed by the person with diabetes that are due to the DSME/T intervention.
- Measurement: The process of evaluation and quantification of a healthcare indicator.
- Outcomes: Results arising from the delivery of DSME/T and other healthcare services.
- Outcomes Measurement: The assessment of indicators of health status, satisfaction, survival, and costs as associated with the delivery of healthcare services.
- Outcomes Monitoring: The frequency and interval of measuring outcomes.
- Outcomes Management: The systematic feedback of outcomes measurement and monitoring that helps drive decision making as related to the delivery of an intervention or service.
- Performance: An evaluation of what a healthcare service delivers (process) as well as achieves (outcomes).
- Performance Measurement: An objective evaluation and quantification of a healthcare indicator such as quality; the first step in the process of performance measurement, assessment, and improvement; similar to the outcomes measurement process involving measurement, monitoring, and management.
- Process Measures: What a healthcare service performs or delivers.
- Quality Assurance: Describes and evaluates the level of adherence to quality indicators and healthcare standards.
- Satisfaction Outcomes: Patient perceptions of the services provided by diabetes educators.

Acknowledgement

AADE wishes to thank the 2011 Research Committee for their valuable input to this document and acknowledges the specific contributions of the following individuals: Charlotte Wisnewski, RN PhD BC CDE CNE, Sue Boren, PhD MHA, Margaret Grinslade, NM CDE, Carol Homko, PhD RN CDE, and Jan Kavookjian, PhD MBA. We also recognize the work of the 2011 Professional Practice Committee.

Sources:

*Criteria for rating evidence **

Level-of- Study Design or Information Type

Evidence Rating**

- 1 *Large randomized controlled trial (RCT); Multicenter trial; Large meta-analyses with quality rating, Governmental statistics*
- 2 *Randomized controlled trial that has some design or methodological*

- flaws; Prospective cohort study; Meta-analyses of cohort study; Case control study; Quasi-Experimental study (rigorous pre-post with a control group); Systematic review that is well designed*
- 3 *Methodologically flawed randomized controlled trial; Nonrandomized controlled trial; Observational study; Case series or case report; Review (note Cochrane reviews are systematic reviews that could qualify as Level 2 evidence)*
- 4 *Expert consensus; Expert opinion based on experience; Theory-driven conclusions; Unproven claims; Experience-based information; Opinion Piece*

N/A = not applicable

**This is not an exhaustive list – Readers will need to use their own judgment at times.*

***The evidence rating that has been assigned to each citation is shown at the end of the citation.*

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