PARTICIPATION OF PHARMACISTS IN DIABETES SELF MANAGEMENT EDUCATION AND TRAINING (DSME/T) PROGRAMS IN UNITED STATES- A MIXED METHODS RESEARCH STUDY

By
Tanvee Mahesh Thakur

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ABSTRACT

Objectives: To explore the participation of pharmacists in diabetes self-management education/training (DSME/T) programs as care providers and educators, and explore the relationship between community pharmacies and DSME/T programs.

Study design: Sequential exploratory mixed methods design. Six in-depth interviews of program coordinators and intensive literature review were used to inform the development of a survey instrument. Survey was constructed from themes generated from interviews and critical literature review, pilot tested, then distributed via U.S. mail to all AADE DSME/T program coordinators. Survey responses were entered, quality assurance checked and analyzed within SPSS to describe, compare and relate findings.

Primary findings: Qualitative themes: (a) Due to their expert knowledge, pharmacists are desired by patients and DSME/T coordinators as educators in DSME/T programs, (b) Pharmacists are often unable to complete the 1,000 direct patient care hours [pre-requisite for Certified Diabetes Educator (CDE) accreditation] due to their professional workload, and (c) DSME/T clinics and community pharmacists do not recognize each other’s importance. Survey results: Overall the response rate from DSME/T program coordinators was 71.7% (532/742). Three hundred fifty two of the respondents were CDEs and 102 were pharmacists, 42% had pharmacists on their advisory board, 36% had a pharmacist involved in their program and 83% of the programs with a pharmacist involved in education had the pharmacist teach classes. Co-coordinators clearly believed pharmacist care is beneficial to patients (Median: 95 of 100 point scale) when asked to rate pharmacist how beneficial pharmacists were on semantic differential scale. Out of
the 342 program coordinators reporting no pharmacist involvement, 56% think pharmacists bring additional benefit to the patient, and 25% plan to involve a pharmacist in their program. Sixty four per cent of coordinators feel community pharmacy care in addition to their DSME/T program would enhance patient care. Though 56% of all program coordinators reported that their program was known to local community pharmacies, only 32% are aware of community pharmacists referring patients to their programs.

Conclusions: Through the eyes of DSME/T coordinators, this study revealed a comprehensive description of pharmacist participation in DSME/T programs and insights to their views about community pharmacy relationships. Future engagement of pharmacists in chronic disease management will be informed by this study.
PREFACE

Poster presented in the following national meetings:

1. **Tanvee Thakur**, Kimberly Galt, Mark Siracuse, Kevin Fuji, James Bramble; Pharmacists and Diabetes Self-Management Education/ Training programs, for Academy Health Annual Research Meeting, New Orleans, LA, June 2017 (Accepted).


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2. Thakur Tanvee, ‘Participation of pharmacists In Diabetes Self-Management Education (DSME/T) programs- A mixed methods research study’; St Albert’s Science Day, Creighton University, Omaha, NE, 2016.
Dedicated to my parents Mahesh Thakur and Priti Thakur and to my younger brother Omkar Thakur.
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CHAPTER 1

INTRODUCTION

Chapter 1 (Introduction) provides a brief overview of how this thesis is organized. This study introduces us to the problem of diabetes and explores how pharmacists are involved in diabetes care. Documented literature reports improved clinical parameters like hemoglobin A1C levels and lipid profiles of patients having pharmacists as diabetes management educators. Diabetes Self-Management Education and Training (DSME/T) programs are used as a comprehensive strategy to address management of diabetes in the United States. Literature also exists about the effects of DSME/T programs on patient demographics like age, gender, ethnicity, etc. But a gap exists in our knowledge and understanding about pharmacist participation as educators and care providers in DSME/T programs in the United States. Specifically, we explore the engagement of pharmacists as educators in these interdisciplinary programs, as well as, the extent of involvement of DSME/T programs with community pharmacists who serve their patients prescription and self-care needs but are not educators in DSME/T.

Chapter 2 (Literature review) provides a comprehensive literature review. First, the problem of diabetes, its prevalence, and the sequelae of unmanaged diabetes are reviewed. Then the structure, interprofessional involvement, and pharmacist engagement in DSME/T programs is presented. Published evidence about enhanced patient care and health outcomes with pharmacists as educators in diabetes self-management is reviewed. This chapter concludes by describing the gap in knowledge that remains, thus supporting the need for this study.
Chapter 3 (Research Methodology) describes the research methods for this study. First the study purpose statement is provided, followed by the research question guiding the study. Next, the research design, a sequential exploratory mixed methods approach is described. Study population identification and enrollment efforts through collaboration with the American Association of Diabetes Educators (AADE) are described. The representation of DSME/T coordinators of both the American Diabetes Association (ADA) and AADE through AADE members is examined and justified. Research instrument development, a written survey, through the conduct of qualitative interviews and use of the published literature is described in detail. Pilot testing, data collection, and developing the database for analysis are presented. Data analysis processes, including qualitative, quantitative and mixed analysis are presented.

Chapter 4 (Results) presents results for this study in the order of qualitative phase, quantitative phase and then mixed methods phase. The results for the qualitative phase are in the form of propositions which are broad ideas developed from the interviews conducted. The results for the quantitative phase are from analyzing the primary database developed from the survey responses. The quantitative phase results are depicted as numbers, charts and graphs derived from analyzing the primary database developed. Mixed methods results are an integration and comparison of the results for the qualitative and quantitative phase.

Chapter 5 (Conclusions) presents the interpretation, discussion and implications from this study. The conclusions also follow the pattern of qualitative phase conclusions followed by the conclusions of the quantitative and mixed phases. In the results we discuss the direct findings obtained through this study. Results for different segments are
compared and contrasted to establish patterns and logical reasoning for issues central to this study. We discuss the implication or reason behind each finding and an effort to decipher the underlying implications for the results is made in the conclusions.

**Chapter 6 (Discussion)** presents the implications of this study through a broader perspective. Larger ideas about practice, policy for pharmacists in diabetes management and education process and future study prospects are addressed through this chapter. This study has its own set of limitations which are addressed in this chapter. Also the relevance of this study to the country of study, the United States, as well as a global scenario and how these results can be extrapolated to other countries with similar diabetes management programs is discussed.
CHAPTER 2

LITERATURE REVIEW

Introduction to the chapter

In this chapter, we will discuss the existing literature that informs us about the problem of diabetes, DSME/T programs, pharmacist participation and address the literature gap in our knowledge about pharmacist participation in DSME/T programs in the United States of America (USA). This chapter presents the literature that (a) introduces us to and defines of key terms, (b) describes the nature of diabetes and its impact on people’s health, (c) identifies the strategies for improving management of diabetes, (d) focuses our understanding specifically on the strategy of DSME/T programs, (e) describes what is known about the relationship of patient care and health outcomes when pharmacists are involved as educators in diabetes self-management, and (f) describes the gap in our knowledge about how pharmacists participate in DSME/T programs; and the relationship between DSME/T programs and local community pharmacists who commonly care for patients with diabetes. The chapter concludes by describing the need for theory, the purpose of the project, and the research question posed in this thesis.

Definition of terms

Diabetes mellitus is described as a metabolic disease in which the body’s inability to produce any or enough insulin causes elevated levels of glucose in the blood. Diabetes is caused by an inability of pancreas to produce insulin or the body cells not
responding to the insulin produced by the pancreas. There are three types of Diabetes Mellitus:

**Type 1 Diabetes Mellitus (DM)** results from the pancreas's failure to produce enough insulin. This is referred to as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes".

**Type 2 DM** begins with insulin resistance, a condition in which cells fail to respond to insulin properly. This form is also known as "non-insulin-dependent diabetes mellitus" (NIDDM) or "adult-onset diabetes".

**Gestational diabetes** is the third form of diabetes mellitus and occurs in pregnant women without a history of diabetes as they develop high blood-sugar levels.

**Prediabetes** is a stage when blood glucose levels in a person are higher than normal but not yet high enough to be diagnosed as diabetes.

Symptoms of high blood sugar include frequent urination, increased thirst, and increased hunger. If not controlled, diabetes can cause many complications. Acute complications can include diabetic ketoacidosis, non-ketotic hyperosmolar coma, or death. Serious long-term complications include heart disease, stroke, chronic kidney failure, foot ulcers, and damage to the eyes.

Prevention and control include healthy lifestyle, healthy diet, regular physical exercise and weight management. It has been observed that self-management of the disease by patients leads to better control and management of disease. Patients can check their blood sugar levels and keep them in control, learn to self-administer insulin, and take diabetes management classes to learn self-management techniques.
AADE advises the following 7 self-care behaviors (American Association of Diabetes Educators, 2017a):

1. Healthy Eating
2. Being Active
3. Monitoring
4. Taking Medication
5. Problem Solving
6. Reducing Risks
7. Healthy Coping

ADA suggests guidelines in the following topic areas for managing diabetes (American Diabetes Association, January 2017):

1. Promoting Health and Reducing Disparities in Populations
2. Classification and Diagnosis of Diabetes
3. Comprehensive Medical Evaluation and Assessment of Comorbidities
4. Lifestyle Management
5. Prevention or Delay of Type 2 Diabetes
6. Glycemic Targets
7. Obesity Management for the Treatment of Type 2 Diabetes
8. Pharmacologic Approaches to Glycemic Treatment
9. Cardiovascular Disease and Risk Management
10. Microvascular Complications and Foot Care
11. Children and Adolescents
Diabetes self-management education and training (DSME/T) is a collaborative process through which people with diabetes gain the knowledge and skills needed to modify their behavior and successfully self-manage the disease and its related conditions (National Institute of Chronic Disease Directors, 2012).

Diabetes program coordinators are program managers who are the authority to report to for the health care providers engaged in a DSME/T program. They maintain patient records and serve as a point of contact for the affiliated organization (Haas et al., 2014).

Diabetes educators are health care professionals who have appropriate credentials and experience consistent with the particular profession's scope of practice and are trained in diabetes care. They are part of a team which educates patients about self-managing diabetes and work in clinics, hospitals or retail pharmacies.

A pharmacist is a member of the health care team directly involved with patient care. Pharmacists undergo clinical doctoral level education to understand the biochemical mechanisms and actions of drugs, drug uses, therapeutic roles, side effects, potential drug interactions, and monitoring parameters. Pharmacists are licensed after successful completion of a national board examination and state legal examination (National Association of Board of Pharmacy, 2017).

Community pharmacists are pharmacists who work in retail settings and their responsibilities include: checking and dispensing prescription drugs, providing advice on
drug selection and usage to doctors and other health professionals, and counseling patients in health promotion, disease prevention and the proper use of medicines.

A **Certified Diabetes Educator (CDE)** is a health professional who possesses comprehensive knowledge of and experience in prediabetes, diabetes prevention, and management. The CDE educates and supports people affected by diabetes to understand and manage the condition. (National Certification Board for Diabetes Educators, 2017)

**Board Certified- Advanced Diabetes Management (BC- ADM).** The person holding the BC-ADM credential skillfully manages complex patient needs and assists patients with their therapeutic problem-solving (American Association of Diabetes Educators, 2017b). Within their scope of practice, healthcare professionals who hold the BC-ADM certification, (a) Adjust medications, (b) Treat and monitor acute and chronic complications and other comorbidities, (c) Counsel patients on lifestyle modifications, (d) Address psychosocial issues, and, (e) Participate in research and mentoring.

**Nature of Diabetes and Impact on Health**

As of 2014, an estimated 422 million people had diabetes around the world, with type 2 diabetes making up about 90% of the cases. This represents 8.3% of the adult population, with equal rates in both women and men. From 2012, approximately 1.5 million deaths each year occurred due to diabetes. (WHO diabetes report, 2016)

As of 2014, 29.1 million people in United States had diabetes. This constituted 9.3% of the total population of United States. Out of these 29.1 million, 21 million people were diagnosed with diabetes while the other 8.1 million were undiagnosed. The global
economic cost of diabetes was estimated to be US $612 billion in 2014. (National Diabetes Statistic Report, 2014)

A few clinical parameters are used to determine the onset of diabetes and should be checked regularly to detect the onset of diabetes as early as possible. The following standards are as suggested by the ADA for hemoglobin A1C (HgbA1C), Fasting Plasma Glucose (FPG), and Oral Glucose Tolerance Test (OGTT).

- **Hemoglobin A1C**

  The A1C test measures your average blood glucose for the past 2 to 3 months. Hemoglobin A1C values less than 5.7% are considered normal. When they reach the range of between 5.7% and 6.4%, the person is considered to have prediabetes. Diabetes is diagnosed at an A1C of greater than or equal to 6.5%.

- **Fasting Plasma Glucose (FPG)**

  This test checks your fasting blood glucose levels. Fasting blood glucose levels are considered normal when they are less than 100 mg/dl. When they reach the range between 100 mg/dl and 125 mg/dl, the person is considered to have prediabetes. Diabetes is diagnosed at fasting blood glucose of greater than or equal to 126 mg/dl.

- **Oral Glucose Tolerance Test (also called the OGTT)**

  The OGTT is a two-hour test that checks your blood glucose levels before and two hours after you consume a glucose beverage. It tells the doctor how your body processes glucose. The OGTT is considered normal when it is less than 140 mg/dl. When it reaches
the range between 140 mg/dl and 199 mg/dl, the person is considered to have prediabetes. Diabetes is diagnosed at 2 hour blood glucose of greater than or equal to 200 mg/dl.

In 2003–2006, after adjusting for population age differences, cardiovascular disease death rates were about 1.7 times higher among adults aged 18 years or older with diagnosed diabetes than among adults without diagnosed diabetes. In 2010, hospitalization rates for heart attack were 1.8 times higher and hospitalization rates for stroke were 1.5 times higher among adults aged 20 years or older with diagnosed diabetes than among adults without diagnosed diabetes. Diabetes was listed as the primary cause of kidney failure in 44% of all new cases in 2011. From 2009–2012, 71% of adults over the age of 18 years with diabetes had blood pressure greater than or equal to 140/90 millimeters of mercury, 65% had blood Low Density Lipoprotein (LDL) cholesterol greater than or equal to 100 mg/dl. (National Diabetes Statistic Report, 2014)

**Strategies for Improving Management of Diabetes**

Early detection and treatment of complications caused by diabetes can prevent progression, so monitoring with dilated eye exams, urine tests, and foot exams is essential. Because the risk of cardiovascular disease is increased in diabetes and prediabetes, blood pressure and lipid management, along with smoking cessation, are especially important. By working together, people with diagnosed diabetes, their support network, and their health care providers can reduce the occurrence of these and other complications. This next section looks at various studies have been conducted on diabetes self-management programs and outcomes.
Diabetes self-management Education and Training (DSME/T) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes. The DSME/T program is based at a clinic, hospital or other health care facility, including pharmacies. Health care providers like physicians, nurses, pharmacists, dieticians, exercise specialists are educators in this program. Each program has an advisory board which makes decisions about the program. The DSME/T services are reimbursed under Medicare part B. (Medicare.gov, 2016). Patients are offered both individual assessment and group classes as part of the DSME/T services. Medicare reimburses for one hour of initial individual assessment followed by nine hours of group education for 12 months after a patient is diagnosed with diabetes.

Individual assessment allows providers to examine the patient on individual basis, look over their health records, discuss issues like family history, financial and emotional support, diet and exercise, medication regimen and level of awareness on the part of the patient. The group education classes cover discussions about types of diabetes, medications, exercise, diet and healthful eating, behaviors and attitudes for coping with this disease. These programs are reimbursed under Medicare Part B only if they are certified as active diabetes programs by the ADA or AADE.

**Strategy of DSME/T Programs for Improving Management of Diabetes**

A national strategy to improve the management of diabetes is DSME/T programs. There is literature available on the varying effect of DSME/T programs on patient demographics.
Gender effect

Studies show that women respond better to diabetes education than their male counterparts. In a study conducted by Mathew et al, women were reported to use more socially interactive resources, like education classes and support groups whereas men relied more on self-directed learning but also described wanting more guidance to help navigate the healthcare system (Mathew, Gucciardi, De Melo, & Barata, 2012).

Age effect

In a behavioral study conducted on elderly adults, it was seen that elderly people respond better to diabetes education than youths (Beverly, Sitnikov l, Ganda, Caballero, & Weinger, 2013). The WHO quality of life questionnaire was used in determining the effect of diabetes education in elderly females to elderly males. Elderly females show considerable response to diabetes management training in attaining goals and adapting self-care behaviors when compared to elderly men.

Ethnicity based effects

Studies have also shown different races to respond variably in achieving intensive glycated hemoglobin goal. One of the studies demonstrated the difference in Hispanic and Non- Hispanic whites when given equal access to comprehensive diabetes care (Getaneh et al., 2012). The study reported that, to achieve glycated hemoglobin goal, compared to Puerto Ricans, Mexicans were more likely [Hazard Ratio (HR) = 1.38, Confidence Interval (CI): 0.90–2.10] and Dominicans (natives from Dominican Republic) as likely (HR = 1.01, CI: 0.66–1.54). The hazard ratio (HR) is the ratio of the
hazard rates corresponding to the conditions. Participants born in the United States achieved their glycated hemoglobin goal at a higher rate than those born in other countries. Puerto Ricans (OR = 0.47, CI: 0.31–0.71), and Dominicans (OR = 0.41, CI: 0.26–0.66) were less likely than non-Hispanic whites to achieve glycated hemoglobin goals, whereas the difference between non-Hispanic whites and Mexicans was not statistically significant.

Another study provided a useful framework for development of culturally relevant diabetes education facilities for African Americans (Cherrington et al., 2012). One of the systematic, meta-analysis and meta-regression studies addresses the fact that DSME/T programs targeted to racial/ethnic minority groups can produce a positive effect on diabetes knowledge and on self-management behavior, ultimately improving glycemic control (Ricci-Cabello et al., 2014).

**Geographic area based effects**

A review study conducted by Ricci-Cabello et al. assessed the effectiveness of quality improvement strategies designed to improve diabetes care in rural areas and identify characteristics associated with greater success. A meta-analysis of 20 randomized controlled trials (3,094 patients) out of 37 studies indicated that the programs produced a reduction in glycated hemoglobin of -0.31% (95% CI -0.48% to -0.14%). Meta-regressions showed larger reduction in glycated hemoglobin in individual and face to face delivered interventions, as well as in those involving peer educators, including cognitive reframing techniques, and a lower number of teaching methods (Ricci-Cabello, Ruiz-Perez, Rojas-García, Pastor, & Gonçalves, 2013).
Mode of education effects

Studies were also conducted on the mode of education for patients—group classes and individual classes. It was observed that individual education for patients with sub-optimally controlled diabetes is more effective than group classes (Sperl-Hillen et al., 2011).

Pharmacists in community pharmacy practice

One of the areas of interest in this study involves referrals to and from community pharmacies. A few studies have been conducted in these areas which are available in the literature. A study by Mansell et al. conducted in Canada discusses the advantages of having community pharmacists educate patients from the patient’s perspective (Mansell & Perepelkin, 2011). Convenience sampling was used in this study and patients reacted positively to community pharmacists educating them. Another study in Belgium was conducted on the community pharmacist participation. In this study, a randomized controlled trial was conducted over 6 months showed significant decrease in the hemoglobin A1C levels for patients. This diabetes education program also resulted in improved self-management and better knowledge of diabetes (Mehuys et al., 2011). Another study conducted in Texas with similar criteria, did not report exactly the same results as that of the other two studies mentioned before. This longitudinal pre/post cohort study that took place in nine community and four workplace pharmacies did not show a significant change in hemoglobin A1C levels in the patients. However statistically significant reductions were observed in fasting plasma glucose, triglycerides, and
diastolic blood pressure (Oyetayo, James, Martinez, Roberson, & Talbert, 2011). A study conducted in Australia on the roles of community pharmacists in diabetes management education measured the effectiveness by number of goals set and attained by the patients and by the improvement in clinical outcomes (Mitchell et al., 2011). These studies involving pharmacotherapeutic intervention by the community pharmacists have demonstrated positive results both from provider and patient perspectives in various countries.

**Pharmacists’ participation in diabetes management education programs**

Pharmacists can play a major role as educators in diabetes self-management education and training for patients due to their expert knowledge in medications, drug interactions and proper dosing. The results of 2012 AADE National Diabetes Education Practice Survey states that nurses and dietitians continued to comprise the majority of diabetes educators in 2012. However a modest increase from 4% to 5% occurred in the respondents identified as pharmacists from 2010 to 2012 (Martin, Warren, & Lipman, 2013).

**National standards for DSME/T.** National Standards for DSME/T in United States state ten standard areas set down by a task force set up by ADA and AADE for diabetes education in 2006 (Haas et al., 2014). These areas of program and care provision are:

1. **Organization-** The DSME/T entity has documentation of its organizational structure, mission statement, and goals and will recognize and support quality DSME/T as an integral component of diabetes care.
2. Advisory board- The DSME/T entity appoints an advisory group to promote quality. This group includes representatives from the health professions, people with diabetes, the community, and other stakeholders.

3. Resources- The DSME/T entity determines the diabetes educational needs of the target population(s) and identify resources necessary to meet these needs.

4. Coordination- A coordinator is designated to oversee the planning, implementation, and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education and in program management.

5. Educators- DSME/T is provided by one or more instructors. The instructors have recent educational and experiential preparation in education and diabetes management or are certified diabetes educator (CDE).

6. Curriculum- A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, serves as the framework for the DSME/T entity.

7. Individual patient assessment- An individual assessment and education plan is developed collaboratively by the participant and instructor(s) to direct the selection of appropriate educational interventions and self-management support strategies.

8. Patient progress- A personalized follow-up plan for ongoing self-management support is developed collaboratively by the participant and instructor.

9. Outcomes and follow up- The DSME/T entity measures attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.
10. Effectiveness- The DSME/T entity measures the effectiveness of the education process and determines opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities' process and outcome data (Haas et al., 2014).

According to these standards, pharmacist involvement as educators has increased over last few years. Still registered nurses and registered dietitians both serve as the key primary instructors for diabetes education and as members of the multidisciplinary team responsible for designing the curriculum and assisting in the delivery of DSME/T. Conversely pharmacists are seldom seen as instructors or care-givers in diabetes self-management programs (Haas et al., 2014).

The American Association Diabetes Education’s (AADE) National Diabetes Education Practice Survey conducted in 2013 demonstrates the current trends, opportunities and improvements in diabetes education in the USA (Martin et al., 2013). A literature review study by Martin et al. portrays expanded opportunities and roles for diabetes educators in the future and a wide scope for the profession of a certified diabetes educator (Martin & Lipman, 2013).

Drabs (2009) examined the American Diabetes Association (ADA) and American College of Endocrinology (ACE)/American Association of Clinical Endocrinologists (AACE) diabetes guidelines. In the guidelines he identified key areas for increased pharmacist involvement for more effective implementation of target glycemic goals set for patients in his review study of the ADA/ AACE guidelines (Drab, 2009). This study identifies pharmacists as ideal instructors to educate patients about the importance of self-management, the availability of new technologies and delivery
devices, and the need to achieve glycosylated hemoglobin (A1C) targets. Interdisciplinary provider participation is essential in good patient care and education in these programs. Each health care provider can contribute their expertise and knowledge in their capacity to the process of education. Pharmacists are proficient in medication and drug interactions. Community and clinical pharmacists were proven beneficial in literature when involved in process of diabetes education and training.

**Enhanced clinical outcomes with pharmacists as educators**

A recently published systemic review of 118 research papers from search engines covering MEDLINE, CINAHL, EMBASE, ERIC, and PsycINFO with pharmacist intervention in diabetes self-management reported 61.9% significant changes in hemoglobin A1C. Overall mean reduction in hemoglobin A1C was 0.74 mg/dL and 0.17 mg/dL for intervention and control groups and an average absolute reduction in hemoglobin A1C of 0.57 mg/dL was observed (Chrvala, Sherr, & Lipman, 2015).

Hasali et al. identified twenty-seven studies that demonstrated the effects of a pharmacist's intervention on hemoglobin A1C. These interventions were successful in reducing hemoglobin A1C in patients by improving patient lipid profiles, cardiovascular outcomes, and body mass indexes (BMIs), and in reducing other complications associated with the disease. It was also reported that economic profitability for diabetes management clinics increased with pharmacists as instructors (Hassali, Nazir, Saleem, & Masood, 2015). One study reported significant improvement in patients' clinical outcomes and that all patients, even those with tremendous barriers to appropriate diabetes care benefit from patient-centered, interdisciplinary health care teams that include pharmacists. This study was conducted on 1,836 patients.
disproportionately affected by diabetes, representing diverse ethnicities, insurance status, and social and economic backgrounds (Blum, Watson, Skelton, Manolakis, & Brock, 2014).

A study was conducted with 101 patients with diabetes enrolled in pharmacist-conducted MTM program in Toledo, Ohio. Participants scheduled consultations with a pharmacist at predetermined intervals. Overall health outcomes, such as clinical markers, health-related quality of life (HRQoL), disease knowledge, and social and process measures were documented during these visits and assessed for improvement. All these parameters showed improvement (Pinto, Kumar, Partha, & Bechtol, 2014). A study conducted in Hawaii on 190 employed diabetes patients, almost one third of them being Asians and other one third being Hawaiian natives reported positive results in clinical parameters for patients after pharmacist interventions in treatment schedule. This shows that having pharmacists involved in education of diabetes patients has positive impact on patient groups with different ethnicities as well (Nishita, Cardazone, Uehara, & Tom, 2013).

The positive role of community pharmacists in teaching patients diabetes management skills was demonstrated by a qualitative study conducted by interviewing 24 participants who were Maltese immigrants in Sydney and who were diagnosed with diabetes. Patient’s perspective about involving community pharmacists was explored in this study. The patients expressed gratitude and appreciation towards community pharmacists who helped them keep diabetes in control through self-management (Barbara & Krass, 2013). Another team conducted a study by adding a pharmacist to the primary care team of physicians for educating patients against diabetes and this group was
compared with a control group which did not have a pharmacist. Clinically significant reductions in HbA1C levels, LDL-C, and blood pressure values and in occurrence of coronary heart disease and stroke rates were observed (Ip et al., 2013). Pharmacists who are certified as diabetes educators or disease managers can be a great resource for primary care providers and other allied health professionals in helping patients manage diabetes (Cohen, 2012).

A retrospective study was conducted in outpatient clinics at Shands Jacksonville Medical Center. The primary end point for this study was an absolute change in Hemoglobin A1C versus baseline and a secondary end point was a change in cholesterol and blood pressure and number of patients achieving ADA goals. The group with pharmacist intervention showed a greater percentage positive change in hemoglobin A1C, though no difference was found in end points of cholesterol and blood pressure (Pepper, Mallory, Coker, Chaki, & Sando, 2012). Another paper reported positive patient response and satisfaction about diabetes education they received. This study also reported improved clinical parameters for patients in their pharmacist led education program. This study also observed the patient’s clinical parameters 12 months and 24 months after pharmacist intervention and reported results for both. The intervention group decreased its Hemoglobin A1C values significantly more than the control group in the short-term follow-up between 0 and 6 months after baseline ($p=0.05$). Individuals in the intervention group showed being more satisfied with one’s own knowledge about diabetes ($P=0.008$), exercising more in order to affect blood-glucose levels ($p=0.015$), and being able to predict current blood-glucose levels before measuring it ($p=0.048$) as compared to individuals in the control group (Sarkadi & Rosenqvist, 2004). The Asheville project was
implemented for diabetes and other chronic diseases. Through the Asheville Project, employees with diabetes received intensive education through the Mission-St. Joseph’s Diabetes and Health Education Center in Asheville, North Carolina. These clinics simultaneously teamed with community pharmacists who made sure that patients were using their medications correctly. This project has been an inspirational model for involving pharmacists in diabetes education (Cranor & Christensen, 2012). This project was extended for five years to evaluate patient outcomes over an extended time span and the same parameters were evaluated at the end of 5 years. These parameters showed almost as good response as earlier (Cranor, Bunting, & Christensen, 2003). Another model with pharmacist intervention in diabetes education was developed by Polk County, Florida similar to Asheville project. This project showed a significant decrease in hemoglobin A1C levels, blood pressure levels as well a decrease in the total number of hospital admissions due to diabetes after patients were educated about chronic disease management by the pharmacists (Iyer et al., 2010).

Awareness amongst pharmacists about their role in diabetes management education

Pharmacists are aware of their responsibility to society as educators for chronic disease management and express involvement in diabetes management programs. Schapansky et al. reported positive attitudes of pharmacists towards participating in diabetes training. Factors responsible for this attitude were demonstrated on Diabetes Attitude Scale (DAS) in this study and include training in Control/Complications, Team Care, and the Pharmacist’s Role. The responses were recorded through surveys.
(Schapansky & Johnson, 2000). A similar study using DAS was conducted in Arizona by Younis et al. and yielded similar results (Younis, Campbell, & Slack, 2001).

There is literature that discusses various methods implemented for diabetes management and patient care by pharmacists which lead to better clinical outcomes in patients. In this study, all intervention groups received diabetes drug counseling by a pharmacist. One group received a diabetes education booklet, the second received a special medication container and the third group received both. Varied results for each of these interventions were revealed. The most favorable glycemic outcome was the group that received all of the interventions. Drug counseling by a pharmacist has little beneficial effect on diabetes management outcome compared to the diabetes booklet and special drug container (Suppapitiporn, Chindavijak, & Onsanit, 2005).

According to Cohen, diabetes educators are the new diabetes managers today and play an important role in managing the disease through educating patients about self-care (Cohen, 2012). The American Pharmaceutical Association conducted a demo project where a pharmacist was the diabetes manager. Primary Care Providers (PCPs) were kept informed about patient progress. This study showed considerable improvement in patient outcomes. It was expected that other workplaces would be encouraged by this setting and follow this model (American Pharmaceutical Association Foundation, 2003).

**Recent studies**

A national survey was conducted on pharmacist CDEs where 400 pharmacists were anonymously sent surveys about clinical activities, reimbursement, impact of certification, and intent to pursue CDE recertification. This was an important step to
identify problems and barriers faced by the pharmacists in CDE accreditation and
certification. Eighty four percent of pharmacists said they would apply for recertification
as CDEs (Shane-McWhorter, Fermo, Bultemeier, & Oderda, 2002). Another article with
a narrative qualitative study, discusses pharmacist’s perspective about being a diabetes
educator. This piece puts forward thoughts and views of pharmacists in their own words
(Ponte, 2002).

It is the position of ADA that all diabetes patients in need of education receive
DSME/T at diagnosis and thereafter. A joint statement was released by ADA, AADE and
Academy of Nutrition and Dietetics, the objective for which was to improve patient
experience, health outcomes and study health care costs (Powers et al., 2015).

One study pointed out the gap in the existing literature which is also the reason
for this study. This study mentioned the fact that the existing literature about diabetes
self- management education, pharmacy practice researchers do not appear to consider the
influence of pharmacist’s communication skills on health outcomes. Pharmacist
participation as educators and care providers in certified DSME/T programs and its effect
remains to be one of the least explored areas in the literature (Babinec, Rock, Lorenzetti,
& Johnson, 2010).

It is thus evident that hardly any literature is available on pharmacist participation
as educators and care givers in diabetes management programs. A gap thus exists in our
understanding about participation of pharmacists in the DSME/T programs recognized by
the ADA or accredited by the AADE in USA.
Need to Understand Pharmacists Involvement in DSME/T

DSME/T incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards. The objectives of DSME/T are to support the following in order to improve clinical outcomes, health status, and overall quality of life:

- Informed decision-making
- Self-care behaviors
- Problem-solving and active collaboration with the health care team

The Centers for Medicare and Medicaid Services (CMS) provide expanded coverage for DSME/T. Three organizations were originally authorized by CMS to determine whether diabetes education programs meet required standards. These three organizations were deemed "certifying bodies" and include:

- American Diabetes Association (ADA) which was authorized in 2001
- Indian Health Service (IHS) authorized in 2002
- American Association of Diabetes Educators (AADE) authorized in 2009

Health care providers such as nurses, pharmacist, physicians, physician assistants, dieticians, exercise specialists work as educators in DSME/T programs. It is observed that nurses and physicians are more involved in DSME/T as educators and care providers than pharmacists. This leads to more work pressure on a group of health care providers and does not promote interdisciplinary participation. Pharmacists are well qualified to educate the patients about medications and other aspects of self-care.
Pharmacists can contribute to DSME/T in the following ways:

- Diet and exercise for chronic control
- Monitoring drug dosage and regimen
- Medications and effects
- Reducing risks and healthy coping through behavioral changes
- Providing information about insurance policies and coverage

**Purpose of this study**

This was an exploratory study that examined the participation of pharmacists as instructors and care providers in the DSME/T programs under the AADE and ADA in the United States.

**Research questions**

The primary research question is: What was the participation of the pharmacist as educators and care providers in the DSME/T programs? The sub-question which was addressed by the qualitative component was: What are the views of DSME/T coordinators regarding the participation of the pharmacists in DSME/T programs? The research question addressed by the quantitative component was: what is the extent and what are the characteristics of pharmacists’ involvement and participation in nationwide DSME/T programs?
CHAPTER 3
RESEARCH METHODOLOGY

Introduction to this chapter

In this chapter there is a discussion of the research design selected for this study, the various steps used in an orderly manner, procedures used, protocols designed, and sampling techniques used. This study is a sequential exploratory mixed methods study. A detailed discussion initially describes the qualitative phase. This is followed by the discussion about quantitative phase, and concludes with the mixed phase.

Rationale for Study Design

This is a sequential exploratory mixed methods research study. The initial qualitative phase was conducted through in-depth interviews of DSME/T coordinators. Themes generated from these interviews were used to inform the preparation of a survey instrument. The quantitative phase involved generating a primary database from survey responses that were obtained by a nationwide survey study of CMS recognized DSME/T programs. The findings from the survey were determined through statistical analysis. In this study, themes generated from the interviews were compared for consistency to the findings from the survey as a form of validation.

Philosophical Foundations – Approach to Inquiry

The philosophical approach used here is pragmatism. This is an approach generally common to mixed methods research. This is a problem centered approach which involves addressing real world practice. The principal investigators bias and non-
bias are both considered in this approach. The most practical approach that works for the problem is adopted in this case.

**Description of mixed methods approach**

Mixed methods research is a methodology for conducting research that involves collecting, analyzing, and integrating (or mixing) quantitative and qualitative research (and data) in a single study or a longitudinal program of inquiry (Creswell, 2003).

Methodologist John Creswell suggested a systematic framework for approaching mixed methods research. His framework involves four decisions to consider (Creswell, 2003, p. 211).

1. What is the implementation sequence of data collection?
2. What method takes priority during data collection and analysis?
3. What does the integration stage of finding involve?
4. Will a theoretical perspective be used?

Mixed methods provide a perspective from both the qualitative and quantitative approaches.

Creswell also suggested six types of mixed methods designs that are likely to address most research inquiry situations:

1. Sequential exploratory: Qualitative phase informing a quantitative phase
2. Sequential explanatory: Quantitative phase informing a qualitative phase
3. Sequential transformative: Either phases conducted one after the other, with results integrated in the final analysis
4. Concurrent triangulation: Two methods used to cross validate, confirm within a study

5. Embedded design: It gives priority to one approach which guides the study, while another is embedded

6. Concurrent transformative: The use of a theoretical perspective reflected in the purpose or research questions of the study to guide all methodological choices.

**Rationale for Use of a Mixed Methods Design in This Study**

Pharmacist involvement with DSME/T programs is of national interest with little information available in the literature. Consequently a sequential exploratory mixed methods design was selected where a qualitative phase informed a quantitative phase. This mixed methods study design was optimal for developing a national survey that required being informed through access to key participants in the field who ultimately represented the national audience of interest. In-depth interviews were conducted to clarify and bound the concepts and issues to explore. This initial qualitative study helped us gain an understanding of the situation related to pharmacists and DSME/T programs; particularly issues that emerged from the point of view of DSME/T program coordinators not readily identifiable through the published literature. The findings from the interviews and an intensive literature search were used to inform the instrument (a survey questionnaire) sent to DSME/T program coordinators.
Overview of How Study Was Conducted

This study was conducted in three phases. The first phase was a qualitative phase where both in-depth interviews of program coordinators and on-site visit to observe a DSME/T program were conducted (Strauss, 1998). This was followed by a quantitative phase where a survey was sent to a nationwide sample of DSME/T coordinators (Dillman, Jolene, & Leah, 2014). In the final mixed methods phase, the results obtained from the qualitative and quantitative phase were compared and contrasted to come to a conclusion. Figure 1 provides a visual diagram of the research design (See Appendix).

Qualitative Phase

In-depth interviews of program coordinators were conducted with six DSME/T programs in various parts of Nebraska.

Sampling strategy

A purposive sampling strategy was employed for selecting the program coordinators to be interviewed based on (a) geographic location of the program in both urban and rural communities in Nebraska, (b) accreditation by ADA or AADE, and (c) variation of pharmacists involvement in the programs (both programs with and without a pharmacist involved).

Participant selection

Six DSME/T program directors were invited to participate in an in-depth interview. Of these six participants, one was a pharmacist program coordinator who was the sole instructor for the program, two were coordinators whose programs involved
pharmacists in DSME/T education, and three were coordinators whose programs did not involve pharmacists. Four of these programs were recognized by ADA and two were accredited by AADE.

Confidentiality of Participants

Participants were promised that the results and their comments would remain strictly confidential and would not be made public.

Institutional Review Board

This phase of the study was approved by the Institutional Review Board for Creighton University (IRB No- 885777-1)

Data Collection Procedures

Interview data was collected by telephone and observation data was collected by a field visit with a face to face interview.

Entry into the Field. There was an on-site visit to one of the CHI Alegent Creighton clinics in Omaha, Nebraska to conduct an on-site observation and interview. Access to this site was gained through a relationship with the pharmacist educator. Access to conduct the remaining five interviews was through relationships with the state of Nebraska Department of Health and Human Services Disease Prevention and Health Promotion unit. These interviews were conducted on the telephone.

In-depth Interviews. Each interview was conducted at a time fixed according to the program coordinator’s convenience. The interviews were conducted based on a semi-structured protocol; each interview generally requiring 30 – 45 minutes to complete.
Interviews were conducted until saturation was obtained. Theoretical saturation of data means that researchers reach a point in their analysis of data that sampling more data will not lead to more information related to their research questions (Seale C., 1999)

**Interview Protocol Development.** A protocol was developed to guide the data collection process during the interviews. Questions were drafted and three experts in DSME/T programs were asked to critique and improve the questions. The final interview protocol is shown in Figure 2 (See Appendix)

**Recording Information, Collecting and Organizing Data.** Each interview was recorded on a voice-recorder with the consent of the interviewee. After the interview was completed, the interview was transcribed word by word and a brief report of findings was generated.

**Validating interview findings.** The transcript and the report was sent to the interviewees to verify the accuracy of the transcripts and representation of the participants’ views. Each participant was asked to provide any corrections to these documents, and then asked consent to use the findings.

**Qualitative analysis procedures**

Coding was performed by developing codes for the transcribed interviews. The technique of open, axial and selective coding was followed to arrange the ideas generated into themes representing the interviewees’ responses and viewpoints. The explanation of each type of coding shown here:—

**Open Coding.** Defining and developing categories and idea based on properties and dimensions.
Axial Coding. Process of relating codes to each other through inductive and deductive thinking.

Selective Coding. This is the final step of coding before developing themes. Here one idea is developed and rest of the codes are related to that central idea.

Themes. Codes were further analyzed to give themes. Numerous codes generated were put together to form themes. Each theme represented a meaningful broad idea representing the point of view of the participants; conceived from coding analysis.

Propositions. Propositions were developed as the final results for the qualitative phase. They are the assertions formed from the analysis, supported by reasoning and background. Propositions and themes will be discussed further in the Results chapter.

Quantitative phase

In this phase of the study we collected descriptive information about the involvement of pharmacists in DSME/T programs across the country from DSME/T coordinators. Our goal is to collect adequate data through a representative sample of the overall DSME/T coordinator population across the nation.

Sampling

Representativeness. The goal was to achieve a representative sample of all 3,719 (programs under either AADE or ADA) DSME/T programs in the country. This would allow extrapolation of the proportions of the survey responses to all DSME/T programs in the country. Out of the total 3,719 DSME/T centers under either of these organizations, the ADA has 2,552 clinics under its umbrella and the AADE has 1,167. AADE has pharmacist as a program coordinator in one out of five programs; whereas in ADA, one out of fifteen program coordinators is a pharmacist. According to Leslie Kolb,
Vice President of Science and Practice, AADE, this organization is service oriented and patient focused, and involves pharmacists in its programs as it increases the overall program quality and ensures the involvement of different health professionals and their expertise. Approximately 155 of the 1,167 program coordinators recognized by AADE are pharmacists. The remainder of the DSME/T programs may have a pharmacist working or volunteering as instructors. We decided to use the AADE program listing as the database for the survey mailings, as AADE willingly provided contact information and basic demographic data and had more pharmacist involved in their DSME/T programs as compared to ADA. Therefore, in order for the survey sample to be representative for nationwide DSME/T programs, it was necessary to determine if using AADE programs as the sample would be a fair representation of all DSME/T programs, i.e., both ADA and AADE programs included. The following criteria were used to determine it:

(1) Criterion 1 - The program requirements for AADE and ADA should not be substantially different. Organizationally, ADA and AADE have significant similarities. There are a few aspects where one of the organizational features over the other. Table 1 (see appendix) compares organizational aspects of the programs.

(2) Criterion 2 – Guidelines for providing care to patients must be standardized and independent of professional background of the educators. On the level of health care providers, DSME/T programs are standard and outcome driven and are not discipline / profession specific. There are common guidelines for all the health care providers for educating the patients. These guidelines are similar to both the ADA and AADE.
(3) Criterion 3 – Patient populations cannot differ between the ADA and AADE.

Patients are referred to the DSME/T programs by the primary care providers. Patients are not aware of the organizational affiliation of the program when they are referred to a certain program and therefore the patient population would not differ between the ADA an AADE programs.

All of the above mentioned criteria support having AADE accredited programs as representative of nationwide DSME/T programs under both ADA and AADE.

**Sample Size Determination.** There were two sampling goals, (1) obtain an adequate sample for the primary study involving programs with or without pharmacists as program coordinators (primary study group) and (2) invite all the programs with pharmacists as program coordinators (sub group) to participate in the survey.

*Primary study group.* The ratio of DSME/T programs with pharmacists as program coordinators compared to DSME/T programs without pharmacist as program coordinators is 1:10 (1 in 5 in AADE and 1in 15 in AADE). The distribution of pharmacists’ coordinators to non-pharmacists coordinators in AADE is in the ratio of 1:5. Therefore, the representative sample can be expressed as:

\[0.1(x) + 0.9 (x) = x,\]

where ‘x’ is the total number of respondents needed, 0.1 is the proportion of pharmacist coordinators, and 0.9 is the proportion of non-pharmacists coordinators for nationwide sampling.

For an ideal sample size for survey distribution, we accounted for margin of error (i.e., precision/confidence level) which is an estimate of the proportion of DSME/T
programs that utilize pharmacist. A margin of error (ME) of 5% with a confidence interval of 95% was considered. Since there is sparse information on pharmacist participation in CMS recognized DSME/T programs, the proportion (P) of participation was estimated at 50%. This is the most conservative assumption when P is an unknown. Thus using the formula for determining the sample size (Cohen, J, 1988),

\[ n = \frac{z^2 \cdot p \cdot (1-p)}{e^2} \]

Where \( n \) is the sample size, \( z \) is corresponding z-value for confidence interval, \( P \) is the probability, and \( e \) is the margin of error. Calculating the sample size using the above mentioned values, an \( n = 384 \) is obtained. This implies that a minimum of 384 responded surveys are necessary to statistically compute the results for this study. With an expected return rate to be 55%, 698 surveys should be sent in order to achieve an adequate number of responses. The 55% response rate was estimated considering the responses prior studies involving the same data collection procedures yielded and considering the fact that a better response rate can be expected as Leslie Kolb, Vice-President, Science and Technology, AADE had sent an email to all the coordinators informing them about the survey they may receive.

**Subgroup sampling.** Since this project is meant to study the participation of pharmacists in DSME/T programs, it would be valuable to have input from all the pharmacist program coordinators. Thus, we would conduct this as a sub group study and surveys were sent to all 155 program coordinators. Of the 745 program coordinators, 155 were identified as pharmacists.
Sample selection. With adequate resources available, we then decided to survey all 748 program coordinators which included all pharmacist and non-pharmacist program coordinators in the dataset provided by AADE. This ensured that we would receive back the minimum number of surveys required to conduct the analysis.

Data Collection Procedures

Survey design. The survey was developed based on extensive literature review and the themes generated as a result of analyzing the interview transcripts. A structured survey with both closed ended and open ended questions was designed. Three open ended questions were included to provide a more in-depth understanding of the closed ended questions. Each survey had a code on the top right hand corner. This code had a number assigned to each member on the sample and the alphabet character in the code represented mail outs A, B and C. Each survey had a name of the DSME/T coordinator it was addressed to. This was achieved by mail merging. The survey had a note in the beginning informing the respondent about the confidentiality of their response and the latest date to return the survey.

Survey pilot test. Surveys were pilot tested to check for content and face validity. The survey was first sent to the six program coordinators who had been interviewed earlier. Four of them responded back with the survey completed. They were asked to:

1. Respond to the survey
2. Report the amount of time required to fill out the survey
3. Point out ambiguous and confusing questions
4. Provide edits and suggestions to improve the survey

The final draft of the survey was prepared and sent out after all the improvisations were incorporated in the survey. The survey instrument is shown in Figure 3 (see Appendix).

**Survey Distribution.** The survey was distributed nationwide to all AADE programs by US mail was used as a mode of distribution. The reasons for using US mail were as follows:

1. High response rates have been observed with survey responses invited by US mail rather than by emails and telephones. (Dilman et al., 2014)
2. Most of our respondent population of DSME/T program coordinators fell between the age group of 35-55 (based on AADE data provided), who found responding via paper based surveys easier

   A prepaid return envelope was sent out with each survey. The survey took approximately 5 minutes to complete and was a two page document printed front and back.

   The Dillman technique was used to send out surveys and reminder mailings (Dilman et al., 2014). We modified the Dillman technique by altering and using a timeline which has given us good response rates in earlier studies. Figure 4 describes the timeline that was followed (see Appendix).

**Data Collection and Management.** The following steps were followed to collect and manage data generated from the survey responses:

1. Database interface. A Microsoft Access interface was set up for entering the data.
2. Mail tracking. Surveys returned by responders were stamped with the return date and were tracked as received into the database.

3. Data entry. Responses were entered to a Microsoft Access interface set up by a data-entry technician trained on the database.

4. Quality assurance check. The surveys were rechecked for quality assurance by the investigator.

5. Maintaining records. Each survey was saved as a pdf file. The original paper responses were stored for retrieval in case verification was needed once analysis procedures were started.

6. Preparation of database for analysis. The access database was then cleaned for multiple and ambiguous responses. It was then converted to a SPSS database. This was the final primary database used for analysis of findings.

**Quantitative analysis procedures.** The final database was analyzed using the following approaches:

1. Descriptive statistics- Frequencies, mean, median, modes and standard deviation were calculated.

2. Comparative analysis- The results obtained for various questions were compared and analyzed to develop relations.

3. Text analysis (for open ended questions) - the answers for the open ended questions were segregated into common codes and grouped into categories. This is a procedure applied to qualitative data in order to transform the data into quantitative finding. The frequency of codes within the categories and the number of useful categories was described.
Non-response bias

Sometimes, in survey sampling, individuals chosen for the sample are unwilling or unable to participate in the survey. Non-response bias is the bias that results when respondents differ in meaningful ways from non-respondents. The following method was followed to address the non-response bias in this case. All the non-respondents were sent reminder emails twice after the third US mail attempt to send the surveys to non-respondents. Two weeks after the second email reminder, 30 random non-responding program coordinators were called via telephone. Most of these calls went on voice mails or were not received at all. The purpose for the call and contact information to call back were left as a voice note on the voice mails, but none of them called back. We were able to reach only three coordinators. When they were asked the reason for not responding to the survey in the five attempts (three by US mail and two by emails), they said that they were busy and would not be able to reply even if the survey was sent again. Through this it was determined that all of the non-respondents were likely too busy to respond to the survey or answer the call. No other reasons for non-response were offered by these persons.

Mixed Methods Phase

This was the final phase of analysis. The qualitative and quantitative findings were compared and contrasted to determine the overarching findings.

Mixed methods analysis procedures

This analysis compared the findings for the qualitative phase and quantitative phase. An effort was made to find out the similarities and contrasts between results for qualitative phase and quantitative phase. Themes generated as a result of transcribing the
interviews were broad ideas which were compared to findings obtained from analyzing survey responses which were more specific findings.

**Validation**

As described above, steps were taken both for qualitative and quantitative phase to establish validity of each phase. According to Creswell, validity in mixed methods research can be defined as employing strategies that address potential issues in data collection, data analysis, and the interpretations that might compromise the merging or connecting of quantitative or qualitative strands of the study and the conclusions drawn from the combination (Creswell & Plano Clark, 2011).

The following addressed threats in various sections of the study to ensure validity: (a) data collection threats, (b) data analysis steps, and (c) data interpretation steps. In data collection steps, inappropriate individual selection was addressed by drawing samples for both qualitative and quantitative data from the same population. Potential bias was avoided through one phase of data collection over other by using separate data collection procedures at different times and collecting data at end of the experiment. In the data analysis steps, qualitative and quantitative phases were compared by matching quotes and themes developed through interviews to the survey results. Also an appropriate statistical software SPSS (IBM SPSS Statistics Version 24) was used to analyze the survey responses and a well validated procedure was followed to verify the codes and interview transcripts prepared.

In data interpretation steps for mixed methods phase, utmost effort was made to establish validity. To resolve divergent findings for either or both the phases, strategies
such as reanalyzing the current data, developing logical reasoning for divergence were used. The mixed methods research question was clearly addressed. Theories and rational were developed to explain the overarching ideas and different stages of this study were connected.

Lastly, all the results were evaluated and checked by four researchers on the thesis committee to negotiate and address any philosophical and methodological differences.
CHAPTER 4
RESULTS

Introduction to the chapter

This chapter discusses results for qualitative, quantitative and mixed methods phases of the study. Qualitative phase results include themes and propositions. Quantitative phase results cover the descriptive statistics, comparative analysis and text analysis for the primary database generated from the surveys received. Mixed methods results are an integration and comparison of the qualitative and quantitative phase results

Qualitative phase

Themes

The interviews conducted were transcribed, coded and the following themes were developed from the perspective of a DSME/T coordinator:

1. Desired to have pharmacists as instructors for DSME/T programs
2. Report pharmacists as unique professionals with knowledge about medication
3. Pharmacists face challenges that preclude them from being licensed as CDE
4. Need for communication with local community pharmacists is not mutually recognized.

These themes were used to inform the survey questionnaire.
Propositions

Propositions were developed as final results for the qualitative phase. The following propositions were formed:

1. Due to their expert knowledge, pharmacists are desired by patients and DSME/T coordinators as educators in DSME/T programs.

It was specified by most of the coordinators who we interviewed that pharmacists are the only professionals with extensive knowledge about medications, adverse effects and interactions as compared to other health care providers. With new medications emerging rapidly in the market, other health care providers find it difficult to stay up to date with recent medications introduced into the market and believe that pharmacist is the best resource for medication related updates or doubts. The coordinators also revealed that patients consider pharmacists to be an important resource regarding medication and related issues.

2. Pharmacists are unable to complete the 1,000 direct patient hours which is a prerequisite for CDE accreditation due to their professional workload.

Completing 1,000 direct patient care hours is a requirement for attaining CDE accreditation. Pharmacists find it difficult to meet this requirement as they are engaged in their dispensing duties. Clinical pharmacists have responsibilities to take care in the hospitals, while community pharmacists are responsible for both over the counter recommendations and dispensing prescriptions. These designated responsibilities of the pharmacists make it difficult for them to dedicate time to one to one patient counseling or education.
3. DSME/T clinics and community pharmacists do not recognize each other’s importance.

We tried to find out through interviews if the community pharmacists referred the patients buying medicines to clinic based DSME/T programs and vice-a-versa. Most coordinators said that they never thought that it was important to include community pharmacist in their marketing or advertising about their DSME/T program. They said this was a decision of the program advisory board and the impetus of a mutual relation between them was never duly recognized.

**Quantitative phase**

**General statistics**: Seven hundred forty eight program coordinators were invited to answer the survey. On further exploration, we realized that six of the sites to which the survey was sent, were no more active sites for DSME/T programs. Thus, out of the 742 surveys, 532 surveys were returned back for an overall response of 71.7%. Nurse professionals were the largest proportion of respondents, followed by dieticians, pharmacists, physicians or nurse practitioners, and professionals in the miscellaneous category. The professionals in the miscellaneous category included professionals with a masters’ degree in science, public health professionals, pharmacy technicians, physician assistants, exercise specialists, and various doctoral degree professionals. The relative proportion of responses by professional category is shown in figure 5 (See Appendix).

**Profession wise participation**. Participation was greatest among nurses, followed by dieticians, pharmacists, physicians and nurse practitioners, finally followed by professionals from miscellaneous groups.
Specialized credentials for diabetes care. Out of the 532 respondents, 66.2% are Certified Diabetes Educator (CDE). Only 20 (3.8%) of the responding coordinators were Board certified in Advanced Diabetes Management.

Involvement in individual patient assessment. Four hundred eighty four (91%) of the 532 respondents were involved in individual patient assessment. Comparison of proportion of respondents who provide individual patient assessment within each professional category is provided in figure 6 (see Appendix).

Program coordinator duration. Forty four percent of the program coordinators were with the program as a program coordinator for two to five years, while 28% of them had an experience of less than two years. Sixteen per cent had an experience of six to ten years and 11% had an experience of more than 10 years.

Pharmacists on advisory board for DSME/T. Forty six percent of the responding programs had a pharmacist on their advisory board. One hundred ninety (35.7%) of the 532 DSME/T program coordinators who responded had a pharmacist participating in their DSME/T program.

DSME/T programs involving a pharmacist

Program-wise frequency distribution of pharmacists. Of the 190 programs involving a pharmacist, 107 of them include just one pharmacist, 50 programs include two pharmacists, five programs include four pharmacists and five programs involve five pharmacists. One of the programs involved 15 pharmacists.

CDE and BC-ADM accreditation. 11 of the 190 pharmacists DSME/T program coordinators were Board Certified Diabetes Educators (BC- ADM). Fifty five (29%) of
the pharmacists involved were CDEs. Of these, 37 programs had one pharmacist who was also a CDE, four programs had two pharmacists certified as a CDE, one program had four pharmacists who were CDEs and another one had six pharmacists involved in the program who were CDEs.

Considerations for completing 1000 direct patient hour pre-requisite for CDE status. For a health professional to be recognized as a CDE, he or she has to complete 1000 direct patient care hours as a pre-requisite in addition to passing an examination. So as to recognize the factors involved in helping pharmacists complete 1,000 direct patient care hours, an open-ended question was posed in the survey questionnaire. The responses were categorized as follows:

1. Program coordinators help pharmacist complete 1,000 direct patient hours.
   
   It was seen that program coordinators took special efforts to facilitate conditions where pharmacists can interact with patients on individual basis so as to complete the 1000 direct patient hour pre-requisite for CDE accreditation. On further text analysis, we obtained sub-themes. These are displayed in table 2 (see appendix). Three coordinators reported that the pharmacists complete this requirement in their residency.

2. In a few cases it was seen that pharmacists take efforts on their part to complete this requirement of 1,000 direct patient hours. These following sub themes shown in table 3 (see appendix).

Pharmacist involvement as educators. Eighty-three percent of the programs involving pharmacists (158/190) had pharmacists teach in their DSME/T
program. When asked about the number of pharmacists involved in the programs which participate in patient education- 29 programs reporting having one pharmacist involved in patient education classes, 24 programs reported two pharmacists involved, nine programs reported three pharmacists involved, 39 programs reported four pharmacists involved and 61 programs reported five pharmacists involved in patient education and four did not respond to this question in the survey.

The content areas in which the pharmacists teach in the DSME/T programs are displayed in table 4 (see appendix). The first five areas shown in the table were as listed in the survey; the respondents had to check all those apply, last two were generated from comments.

**Scale ratings for benefits due to pharmacist.** Respondents used a semantic differential scale to report the perceived benefits of pharmacist involvement (100 = highly beneficial, 0 = no benefit). Coordinators clearly believed pharmacist care is beneficial to patients (Median: 95) and also believed that patients report benefitting from having a pharmacist instructor in DSME/T programs (Median: 85). A similar pattern in response was also observed in the qualitative results derived from the interviews.

The coordinators were asked about specific benefits they were told by patients that pharmacist involvement provided by being part of DSME/T programs. Ninety of the 190 coordinators involving pharmacists in their programs answered this question and reported patient perspectives about pharmacist involvement. Text-analysis was performed on the written responses resulting in these major findings:
1. Forty-five coordinators said patients reported better understanding of medications, medication management, and medication adherence when a pharmacist was involved in the program.

2. Thirty-nine coordinators said patients feel more comfortable asking questions one on one with a pharmacist, and think that they have the easiest access to a pharmacist compared to other DSME/T staff or their medical provider when they have doubts related to medications.

3. Nine coordinators said that having patients telling them that pharmacists explain adverse drug effects in easy terms that patients can understand.

4. Seven coordinators reported patients reported pharmacists talk about insurance and inform patients about discount coupons as beneficial.

5. Four reported that patients appreciate the expertise of a pharmacist in medication related knowledge.

6. Two commented that patients report an improvement in clinical parameters such as hemoglobin A1C after pharmacist intervention.

One of the coordinators observed that patients rated being educated by a pharmacist as the most beneficial aspect in the DSME/T program in a post DSME/T class survey. Three coordinators who are also pharmacists reported that they understood medications better than any of the other providers involved in the DSME/T programs.

**DSME/T programs not involving a pharmacist**

Three hundred forty two (64%) of the 532 survey respondents did not have pharmacists involved in their program. Of these, only 25% of the program coordinators
reported on planning to incorporate a pharmacist into their program delivery in the future. Seventy percent did not feel the need to involve a pharmacist in their program while 5% of the respondents did not respond to this question. Similarly, 56% of these coordinators not involving a pharmacist in their program think that a pharmacist is necessary to bring additional benefit to their patients. From this it is evident that almost 31% of the program coordinators who do not plan on incorporating a pharmacist in their program believe that pharmacists bring additional benefits to patient care. This led us to explore the challenges that the coordinators faced when attempting to include pharmacists in their program.

The following themes emerged from the codes and categories developed through text analysis of the open ended inquiry about challenges:

1. Seventy six coordinators reported the pharmacists being unavailable due to shortage of staff, being busy in their primary dispensing services, and being inaccessible due to the program situated in rural areas. A staffing problem occurs when one or more of the staff pharmacists is involved in or with a DSME/T program.

2. Fifty-one coordinators reported having pharmacists on program as unaffordable due to higher compensation for pharmacists when compared to RDs and RNs

3. Eight program coordinators said that they had just started the program and that they would consider including a pharmacist after getting the idea from this survey

4. Three coordinators felt that pharmacist are not capable and well trained to educate the patients, and thus they preferred not including a pharmacist as an educator.

5. A few coordinators commented that they are thinking of involving pharmacists in their program after this survey and thanked us for the suggestion. This survey was therefore thought provoking for a few respondents.
Community pharmacist and clinic-based DSME/T programs

Questions in this section were answered by all the program coordinators irrespective of the fact if they had or did not have a pharmacist involved in their program. Through this section, relationships between clinic based DSME/T programs and community pharmacies in their vicinity are explored. The goal was to understand if community pharmacists were aware of the clinic based DSME/T programs and if they were involved in patient care activities at the community pharmacy.

**Referrals and awareness of the program.** Fifty six percent (296) of the 532 DSME/T program coordinators reported that community pharmacists in their vicinity were aware of their DSME/T program. In 36% cases, community pharmacists were unaware of the diabetes management resources available in their area for patient care.

When coordinators were asked if community pharmacists refer patients to their DSME/T programs, 33.2% replied positively. Similarly when the coordinators were asked if they refer their patients to community pharmacists for questions regarding medications, counselling or involve them in any other way in patient care, 33.8% of the 532 respondents replied positively. Referrals from clinic based programs to community pharmacists and vice-versa happened about 33.5% of the time.

**Benefits of community pharmacists.** Sixty four percent of the program coordinators were of the opinion that patients need community pharmacists’ care in addition to their DSME/T program. It was shown that the response for community pharmacists benefiting the care of patients is double that of community pharmacists or clinic based DSME/T programs referring patients to each other.
Program coordinators advocated having a community pharmacist on board for various reasons. Out of the all respondents:

1. One hundred one coordinators believed a community pharmacist is necessary to answer additional questions about medications, medication management and to check medication adherence.

2. Ninety two believed that having a relationship with community pharmacists was a good idea and recommend their patients approach community pharmacists with questions.

3. Forty one of them thought a community pharmacist was necessary for educating the patients about adverse drug reactions.

4. Forty one coordinators believe that community pharmacists are the most accessible providers for the patients.

5. Sixteen of them were of the opinion that community pharmacists informed patients in depth about saving cards and insurance when patients purchase their medications

6. Eight coordinators thought pharmacists provide glucometer training in depth which is beneficial to the patients newly introduced to glucometers.

7. Six coordinators commented that community pharmacists were an additional asset and added benefit to the program.

8. Four stated that they doubted the pharmacists’ knowledge about diabetes and would only refer patients to them if they were sure about their knowledge.

9. Three coordinators stated that community pharmacists were not affable and most of the times too busy to help patients. Therefore, developing relations with them is not possible.
10. Twelve coordinators commented that they had limited access to community pharmacies as their programs were situated in rural areas with no single community pharmacy within a 75 mile radius.

11. Three coordinators expressed their wish to develop relationship with a community pharmacist, but expressed that the program management did not allow that to occur.

12. Twenty of these programs were community pharmacy based DSME/T programs

13. Eight of the coordinators stated that this survey has inspired them to incorporate community pharmacist care in addition to their program for patients.

**Sub-Analysis of Pharmacist coordinators’ perspective about pharmacist participation in DSME/T programs.**

Out of the 748 surveys sent out, 155 coordinators were pharmacist by profession. Out of the 532 surveys returned, 102 respondents were pharmacists. Nearly 66% of the pharmacist coordinators responded back to the survey. It was essential to understand the pharmacist coordinator’s perspective about the involvement of clinic based or community pharmacists in the program. An in-depth analysis of this is described as below.

**CDE and BC- ADM accreditation frequency.** Of the 102 pharmacist coordinators who responded back, 43 (42.2%) were CDE. Also only seven out of 102 respondents are trained BC- ADM. The percentage of pharmacist coordinators who are CDE is less than those compared other professional coordinators who are CDEs. This is depicted in figure 7 (see Appendix).

**Involvement in individual patient assessment.** Ninety percent of the pharmacist program coordinators are involved in individual patient assessment.
**Duration.** The duration of pharmacist coordinators being in this position are depicted in figure 8 (see Appendix). It is seen here that most of the pharmacist coordinators were working as a coordinator for 0-5 years.

**Pharmacists on advisory board.** Seventy eight percent of the programs with pharmacist program coordinators have a pharmacist on their advisory board. Eighty-nine percent (91 out of 102) of these programs have one or more pharmacist participating in the conduct of their DSME/T program.

Of the programs with a pharmacist, the distribution of the programs according to the pharmacists is shown in figure 9 (see Appendix).

**Considerations for CDE pre-requisite 1,000 direct patient hours.** Most pharmacist coordinators made sure that they reserved time for the pharmacists to see patients on one- to –one basis so that they could complete 1,000 direct patient hours. Pharmacists intending to complete 1,000 direct patient-care hours were given substitute pharmacists to work in their shifts, giving them time to interact with patients. In these clinics, pharmacist coordinators were more supportive of pharmacists involved in their program completing this requirement than coordinators with other credentials.

**Pharmacists involved in patient education.** Ninety-six percent of programs with a pharmacist program coordinator involved pharmacists in teaching in their DSME/T program. Thirty-one of these programs involved four pharmacists while fifty of these programs involved five pharmacists.
**Topics taught.** The topics pharmacists teach are shown in table 5 (see appendix).

When asked to rate how beneficial of pharmacist involvement is to the patient care on a semantic differential scale 1 to 100, most of the coordinators responded with a high number rating. Figure 10 (see appendix) shows the frequency distribution of scores.

**Interactions with community pharmacists.** Sixty two percent of pharmacist coordinators reported that the community pharmacists in the vicinity of these DSME/T programs were aware of the DSME/T program and the services provided there. Only forty-two percent of the coordinators reported that these community pharmacists referred patients to these programs. Only 44% of these DSME/T programs ask patients to contact community pharmacists for extra knowledge or involve community pharmacists in the program in any way.

Seventy-two percent of pharmacist coordinators think that community pharmacist care is required by the patients for better clinical outcomes in addition to the care provided in the DSME/T programs. Almost 30% of program coordinators who think that having community pharmacist care in addition to their program do not have well established connections with the community pharmacists in their areas.

Of 11 programs which do not have a pharmacist as educator or care provider, seven of them plan on including a pharmacist as educator in their program in the future. Two of the coordinators do not plan on including one and two of the coordinators chose not to respond to this question. Five of 11 coordinators without a pharmacist educator in their program feel that pharmacists bring additional benefit to the program. Two of these 5 coordinators said that they had faced challenges when including pharmacists in their
program. When asked to elaborate about the challenges they said that one of the obstacles related to provision of services by pharmacists is the reimbursement process and the time consuming nature of this process.

Mixed methods phase

In the mixed methods phase, the results obtained from the qualitative phase and quantitative phase were compared. It was found that themes generated as findings for the qualitative phase were similar to the findings obtained from the primary database analysis. It was observed that themes were broad concepts for which specifics and supporting concepts were derived from analyzing survey responses.

Non-response bias testing

Three of 30 non responding program coordinators were reached on a telephone. When they were asked the reason for not responding to the survey in the five attempts (three by US mail and two by email), they said that they were busy and would not be able to reply even if the survey was sent again. No other reasons were cited by these persons.
CHAPTER 5

CONCLUSION

Introduction to this chapter

This chapter includes the conclusions drawn from the results of this study. The qualitative and quantitative phase are compared and contrasted to come to final conclusions. This chapter includes four parts: Conclusions from qualitative analysis, conclusions drawn from quantitative analysis, conclusions drawn from mixed methods analysis and a summary.

Conclusions drawn from qualitative analysis

Pharmacists are a valuable addition to the DSME/T program as their expertise in medications and related knowledge is valued by the program coordinators as well as the patients. In spite of this pharmacists have problems attaining CDE status because their responsibilities as a dispensing or clinical pharmacist do not spare them enough time to counsel patients on one to one basis, so that they could complete 1,000 direct patient hours, which is a prerequisite for attaining the CDE status. Also, coordinators admitted that having a pharmacist in the program is beneficial, but they did not seem to have taken much effort to establish collaborative relations either formally or informally with community pharmacists in their vicinity. The management of programs did not include the community pharmacies in their advertising and marketing efforts. Most of them thought that it would be advantageous and a prospect worthy of further consideration.
Conclusions drawn from quantitative analysis

High interest was displayed by the great participation rate of DSME/T coordinators across the United States. The 72% response rate indicates that these coordinators are engaged and interested in how pharmacists participate and fit in DSME/T programs. This same enthusiasm was displayed during the individual coordinator interviews early on in this project.

A majority of the professionals who replied back were nurse professionals followed by dieticians, pharmacists, nurse practitioners and physicians and then a miscellaneous group of professionals. It was evident from the database received from the AADE and the primary database we developed from the responses, that nurses and dieticians were a dominant population group in coordinators.

It is also observed that the proportion of nurse and dietician coordinators being a CDE is much higher than that of a pharmacist coordinator being a CDE. Seventy-six per cent of nurse coordinators were CDEs and so were 73% of physicians and nurse practitioners as compared to 42% of pharmacist coordinators. This pattern suggests that pharmacist coordinators do not get time out of their schedule to complete the requirements for CDE accreditation.

Ninety percent of the pharmacist coordinators were involved in individual patient assessment. This number is pretty close to that of coordinators with other professional credentials. Even if relatively fewer pharmacist coordinators are CDE, most of them are given an equal privilege of getting involved in individual patient care in comparison to other professionals.
Most of the coordinators have been with their respective programs for 1-5 years. With a time period of more than a year with the program, the coordinators are in a position to make changes and implement policies and have their opinions about the functioning and the requirements of the program. This suggests the responses we received from these program coordinators are reliable as they have adequate experience to reflect upon.

We gathered from the interviews that the advisory board members played a major role in making decisions about hiring staff, making changes to the teaching curriculum or styles, marketing strategy, and excluding or including particular health care providers in the DSME/T program delivery. We observed that less than half (42%) of the responding programs had a pharmacist on their advisory board. This suggests that there is more opportunity for pharmacists to contribute to making important decisions about DSME/T programs at the local level. As we knew before we received the database from AADE, only one out of five programs under the AADE umbrella had a pharmacist involved in the program. That is what we gauged from the survey respondents as well. Only one third of the responding programs had a pharmacist participating in the conduct of their DSME/T program. Even though coordinators expressed through the interviews and surveys that they thought pharmacist were essential in patient care because of their extraordinary knowledge about medications, it was seen that not even half of the programs had a pharmacist involved.

A very small number of coordinators as well as pharmacists involved in the program are BC- ADM. This implies that the health professionals involved in the DSME/T programs either did not feel the need to be BC- ADM or did not know about the
BC-ADM status which was introduced as a qualification in 2001 (Leslie Kolb, 2012). This finding is worth further study.

Only 29% of pharmacists involved in programs were CDEs. Even though a small percentage of pharmacists were CDEs, it was seen that the program coordinators provided help to pharmacists so as to facilitate them to complete 1,000 direct patient hours which is a pre-requisite for CDE accreditation. They allowed pharmacists to see patients in their office hours by adjusting their shifts or substituting other pharmacist to cover for their shift. They also allotted special clinic hours to the pharmacists to see patients one to one. All these measures taken by the coordinators with programs involving pharmacists, show that coordinators irrespective of their professional credentials encourage and support pharmacists from their end when it comes to getting CDE accredited.

Of the programs involving pharmacists, 85% actively involved pharmacists as patient educators. Pharmacists educated patients about various topics which included diet and exercise, monitoring drug dosage and regimen, medication effects, healthy coping through behavioral changes, providing information about insurance policies and coverage. Around one-third of the programs had five pharmacists involved in educating the patients in their DSME/T program which is fairly a large number to be involved in a program. It was seen that pharmacists were allowed to teach multiple topics, but the topics those pharmacists were specially preferred to teach were medications and effects followed by monitoring drug effects and drug regimens. It is thus seen that, as observed in the interviews as well, pharmacists are considered health professionals with extensive knowledge about medications. They are the preferred
professionals when it comes to teaching patients and explaining about medication and adverse drug effects or medication regimens. Most of the coordinators explicitly agree to this fact and express the need to have pharmacists on board in the DSME/T programs.

Program coordinators with programs involving pharmacists thought of pharmacists as being highly beneficial to the program as determined by rating the extent of benefit using a semantic differential scale in the survey. This shows that pharmacist involvement is believed to greatly benefit the programs and patient care provided and that this has been recognized by the coordinators. Similarly, the coordinators rated pharmacists as being highly beneficial to their patients when asked about the benefits as told to them by the patients. Patients revealed to these DSME/T coordinators that they felt more comfortable interacting with the pharmacists about medication related issues than with other health professionals. It is evident here that not only program coordinators but also patients consider pharmacists an important resource of information in DSME/T programs.

With pharmacist coordinators realizing the importance of having pharmacists on programs, almost two third of the responding programs did not have a pharmacist involved in the program. One fourth of the program coordinators who do not have pharmacists involved in their program actually plan on incorporating a pharmacist in their program delivery in the future, even though more than twice the coordinators think that having a pharmacist in the program would benefit the program. It is clearly evident that even though the program coordinators thought it was important having pharmacists on board in their programs, that they faced challenges when it came to actually including a pharmacist in their program. Most programs found it financially
unviable to afford a pharmacist while the rest that can afford pharmacists did not find pharmacists who were available to participate in the program.

Interactions between community pharmacists and clinics based DSME/T programs were an important area of interest for this study. Fifty six per cent of the coordinators reported that the community pharmacists in their vicinity were aware of their DSME/T programs but only 33% of the community pharmacists refer programs to these DSME/T clinics and vice-a-versa. This suggests that there is a lack of collaborative practice between the community pharmacies and clinic based practices. Most coordinators believe that having a community pharmacist involved would be a good idea. Thus if an initiative for collaboration is taken by one of the entities, community pharmacists can be involved in patient care through referrals.

**Conclusions drawn from mixed methods analysis**

Program coordinators and patients appreciated the knowledge of pharmacists about medications, medication adherence and regimen and believed that pharmacists make a valuable addition to the program. This was revealed extensively through the ratings provided on the semantic differential scales in the survey by the program coordinators and through the comments provided both in survey and the interviews by the program coordinators. Pharmacists were given the responsibility of educating patients in a number of classes. A minority of pharmacists hold the CDE status, but program coordinators in most programs provided encouragement with additional opportunities for the pharmacists to complete the 1,000 direct patient hour requirement
for being recognized as a CDE. Only one third of the responding programs referred patients to a community pharmacist or vice-versa. An overall pattern of finding the idea of having a community pharmacist involved in patient care was advocated by most of the program coordinators. A few expressed that this was a good idea and that they would think about developing collaborative relations with community pharmacists.

Summary

With a response rate of 72% from the survey of DSME/T coordinators, and after assuring that non-response bias is not an issue, pharmacists’ involvement in DSME/T programs is common, but there is room to grow. This study provides a comprehensive description of the current state of pharmacist participation in DSME/T programs as educators and care givers. We are enabled to understand challenges associated with involving a pharmacist in the programs as well as benefits as perceived by the program coordinators. We further have insights into DSME/T coordinator views about community pharmacists’ roles and thoughts on informal or formal collaborations with them.
CHAPTER 6

DISCUSSION

Introduction to this chapter

This chapter discusses in detail, the implications from this work. Key implications discussed relate to practice and policies about the profession of pharmacy. This study has a few limitations and an effort was made to address these in the design and conduct of the study. The implications of these limitations are discussed here in this chapter. Future areas of need where research should be conducted from the results and conclusions obtained from this study are identified. A section on global implications of this study is also covered in this chapter.

Implications

This study opens a discussion about various facets of pharmacists as educators, and their benefits or short comings as care providers in diabetes chronic disease management programs as perceived by DSME/T program coordinators. Areas for future engagement of pharmacists in two major areas are informed by this study:

1. Growth potential of pharmacists engaged in DSME/T programs in participation as educators, participation on advisory boards, and obtaining credentials important for supporting billable services in DSME/T provision.
2. Growth potential of community pharmacists’ in emerging roles in chronic disease management of diabetes.
We can classify the more specific implications of this study as practice, policy and future research:

1. Practice

This study informs both in magnitude and depth about pharmacist participation, expertise and challenges encountered when engaging pharmacists in DSME/T programs. It is evident from this study program coordinators consider pharmacist care beneficial to patients engaged in DSME/T programs. Pharmacists can be included in educating patients about medications and related topics in group classes. Also pharmacists who have expertise in diabetes disease management should be allowed to talk to patients on individual basis about their medication related questions. Community pharmacists can be better involved in the clinic based DSME/T programs by developing informal or formal collaborative practices with them. They can assist patients with daily glucose check-up, revising medication regimens or using glucose meters and answering their questions when they purchase medications. This can reduce the responsibility of health care providers in DSME/T programs based in clinics.

National view-points of DSME/T coordinators were revealed through this study and inform the pharmacy profession about their respected position in the health care profession. This gives them a sense of satisfaction that their profession, advice and expertise is appreciated amongst other professions and by patients as well and thus encourages them to participate in such chronic disease management programs with a positive attitude and dispense their services more efficiently thus increasing interdisciplinary participation in health care systems which is ideally desired.
2. Policy

Educational policies

We have learned from this study that various policies are implemented by the program coordinators to help pharmacists complete their direct patient care hours. There is an opportunity for coordinators to implement more regulated policies which can be formal in nature such as having all pharmacist complete CDE accreditation and having a special set of policies to ensure that they get their accreditation easily. Also, professional pharmacy schools can include chronic disease management in electives which can give students a chance to gain more knowledge in this field if interested. This can give them the required expertise when they get involved in DSME/T programs.

Financial policies

Often it was observed in the interview and survey responses that pharmacists could not be easily reimbursed for their services. The process for compensating for pharmacists was tedious and time consuming and this was one of the factors for coordinators to not include pharmacists in their programs. However, 90% of the program coordinators reported that they are involved in direct patient education activities; a requirement for billable services. Therefore, the potential for financial support of DSME/T programs by pharmacists is large. Policies which would enable pharmacist services to be as easily reimbursed as other health care professionals should be implemented. Thus financial policies need to align with provision of pharmacist services.
Policies for collaborative practices with community pharmacists

Collaborative practices either formally or informally should be implemented between the clinic based DSME/T programs and community pharmacists. Since clinic based DSME/T programs are the majority, this can be initiated by them by including community pharmacists in their advertising and marketing campaigns. Policies concerning the various ways community pharmacists can be included in patient care should be discussed and formulated. Policies about referrals from clinic based DSME/T programs to community pharmacists and vice-a-versa should be devised.

3. Future research agenda

Various future potential studies emerge based on the findings and conclusions from this study:

- Study to determine effective ways pharmacists can complete the direct patient hour pre-requisite for CDE status attainment.
- Pharmacist’s view on their engagement in the DSME/T programs and areas of development and opportunities they perceive where they can contribute efficiently to the program.
- Financial policy analysis for reimbursement policies which do not easily reimburse pharmacist services and changes which can be made to these policies to reduce these issues.
- A study to understand how community pharmacists feel about being involved in the clinic-based DSME/T programs.
• An in-depth qualitative study from community pharmacists’ perspective to understand the difficulties and benefits of setting up a community pharmacy based DSME/T program

**Limitations**

This was a nationwide study conducted so as to address a gap in literature, but this study has a few limitations. An effort to minimize these limitations was made when the study was conducted. The limitations for this study are:

1. Programs only under AADE were surveyed.

AADE is used to represent all the certified DSME/T programs in the USA. The various criteria for AADE and ADA were compared and were found to have much more similarities than differences. Thus through logical reasoning AADE coordinator viewpoints are a fair representative of nationwide certified DSME/T programs with coordinators from either AADE or ADA.

2. Non-response bias (For 28% non-response)

The larger the response rate, the less we have concern about the extent of non-response bias impacting our interpretation of findings. A 72% response rate is excellent, alleviating some concerns about bias from non-responders. We also examined the distribution of respondents and non-respondents, and overall, there was a similar number of non-responding pharmacists DSME/T coordinators as all other professions representing DSME/T coordinators. Thus there does not seem to be a difference based upon professional background. Finally, the likely reasons for non-response were studied and found to be the work overload that some DSME/T coordinators experienced in their
daily work. From this we determined that the non-responders were too busy to either respond to the survey or respond to a telephone message. No other reasons were provided to suggest that a response bias affected the finding or interpretation of this study.

3. Perspective limited to DSME/T coordinators

This study is the DSME/T program coordinators’ perception of pharmacist participation in DSME/T programs. But coordinators for programs are health care professionals like nurses, pharmacists, physicians, dieticians for 93% of the responding programs. Thus, opinions of various health care professionals were captured through this study simultaneously as an attempt to capture program coordinators’ perspective was made.

Global Implications

Globally, an estimated 422 million adults were living with diabetes in 2014. Diabetes caused 1.5 million deaths in 2012. Higher-than-optimal blood glucose caused an additional 2.2 million deaths, by increasing the risks of cardiovascular and other diseases. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980. In the last ten years, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries. The percentage of deaths attributable to high blood glucose or diabetes that occurs prior to age 70 is higher in low- and middle-income countries than in high- income countries (World Health Organization 2016, 2016)

Studies are reported in literature about diabetes management initiatives and programs in other countries as Chile (Soto et al., 2015), Australia (Mitchell et al.,
These studies have used pharmacist’s interventions to prove better clinical parameters attained by patients in diabetes management programs and easier and more effective attainment of behavioral goals for patients with pharmacists as educators. Two pilot studies conducted in Australia (Hendrie, Miller, Woodman, Hoti, & Hughes, 2014), India (Gangwar et al., 2014) demonstrate benefits to patient care by involving community pharmacists in the process of diabetes management for patients.

Pharmacy as a profession is not well developed in many countries and such studies can help uplift and upgrade this profession where the health systems specific to those places can realize the importance and benefits of having pharmacists participate in chronic disease management. These countries can start chronic disease management programs and contribute to patient care through interdisciplinary participation of health care professionals or through programs set up in community pharmacies.

This study is a nationwide study contributing to a number of studies evaluating the contribution and opportunities for pharmacists in chronic disease management. Since it covers the perspective of various health care professionals as DSME/T coordinators, it provides us a rich and inclusive representation, of the knowledge and opinions about the common area of diabetes management in DSME/T programs required for our further understanding and development of the pharmacist in relationship to this important work.
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Figure 1. Visual diagram of sequential exploratory mixed methods design.
1) Please describe how you are engaging pharmacist participation in your DSME/T program.
   a) Do you employ a pharmacist in your program?
      i) If yes, is the pharmacist a certified diabetes educator?
      ii) Does the pharmacist have other specialized credentials in diabetes management?
   b) Do you include a pharmacist in the care sessions/curriculum?
      i) Do you offer payment to pharmacist for instruction?
      ii) Who is primary employer of the pharmacist?
   c) Do you have a pharmacist as an advisor to you about your program?
   d) Do pharmacists in the community refer patients to your DSME/T program?
      i) How does this referral process work? (formal or informal)
   e) Do you refer patients to a pharmacist? If yes, why do you refer patients?

Figure 2. Interview protocol
Dear Program Coordinator,

You should have received an email from Leslie Kolb, Vice President of Science and Practice, ACADE regarding this survey about pharmacist participation in your DSME/T program. This survey will take around 5 minutes to complete. Your response is CONFIDENTIAL. Please return the survey back preferably before October 15, 2016 in the included prepaid return envelope provided.

For questions, contact Tanvee Thakur—TanveeThakur@creighton.edu.

1. What are your professional credentials?
   - ☐ Physician ☐ Nurse ☐ Pharmacist ☐ Dietician ☐ Other [please describe]: ______________

2. Are you a Certified Diabetes Educator (CDE)?  ☐ Yes ☐ No

3. Are you Board Certified in Advanced Diabetes Management (BC-ADM)?  ☐ Yes ☐ No

4. Are you involved in individual patient assessment?  ☐ Yes ☐ No

5. How long have you been the program coordinator? [estimate number of years] __________

6. Does your advisory board have any pharmacists as board members?  ☐ Yes ☐ No

7. Do you have one or more pharmacists participating in the conduct of your DSME/T program?
   - ☐ No: IF NO, SKIP to SECTION II and III
   - ☐ Yes: IF YES, continue on to SECTION I and II, and SKIP SECTION III

SECTION I – YOUR PROGRAM HAS PHARMACISTS INVOLVED

8. How many pharmacists do you have involved in your DSME/T program (include yourself if you are a pharmacist)? ______

9. Are any of the pharmacists Board Certified in Advanced Diabetes Management (BC-ADM)?  ☐ Yes ☐ No, if yes, how many? ______

10. Are any of the pharmacists Certified Diabetes Educators (CDE)?  ☐ Yes ☐ No, if yes, how many? ______
    If yes, were there any considerations provided to the pharmacist (e.g., scheduled time to see patients while on duty) in order to complete the direct patient care requirement? Please describe.

11. Do pharmacists teach in any of your DSME/T sessions?  ☐ Yes ☐ No
    If yes, what topics? [Check all that apply]
    - ☐ a. Diet and exercise for chronic control
    - ☐ b. Monitoring drug dosage and regimen
    - ☐ c. Medications and effects
    - ☐ d. Reducing risks and healthy coping through behavioral changes
    - ☐ e. Providing information about insurance policies and coverage
    - ☐ Other: __________________________
12. As a program coordinator, how would you rate pharmacist participation as a factor beneficial to patient health? (Mark where you believe the level of benefit is on the line below)

No benefit — — — — — — — — — — — — — — — — — — — — — — — — — High benefit

13. What do you believe your patients' perceptions of benefit are as a result of the pharmacist's participation? (Mark where you believe the level of benefit is on the line below)

No benefit — — — — — — — — — — — — — — — — — — — — — — — — — High benefit

14. Are community pharmacists in your area aware about your DSME/T services available? □1 Yes □2 No
15. Do community pharmacists suggest patients contact you about your program? □1 Yes □2 No
16. Does your DSME/T center refer patients to community pharmacists for diabetes-related medication management services? □1 Yes □2 No
17. Do you think your patients need a community pharmacist's care in addition to your DSME program? □1 Yes □2 No. Please elaborate

18. Do you have a plan to incorporate a pharmacist into your program delivery in the future? □1 Yes □2 No
19. Do you think a pharmacist is necessary to bring additional benefits to your patients? □1 Yes □2 No
20. Have you faced challenges attempting to include pharmacists in your program? □1 Yes □2 No

If yes, - What are the challenges (describe below):

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THANK YOU FOR COMPLETING THE SURVEY!

Please return the survey back in the included prepaid return envelope provided.

Figure 3. Survey instrument.
Figure 4. Timeline followed for survey distribution
Figure 5. Distribution of survey responses by professional category
Figure 6. Profession wise comparison of coordinators who provide individual patient assessment
Figure 7. Profession wise comparison of coordinators as CDEs.
Figure 8. Distribution of number of pharmacists in DSME/T programs
Figure 9. Proportion of number of pharmacist coordinators to rating on scale for benefits of pharmacists involved in the program

\[a\] Semantic differential scale (0 = least benefit to 100 = most benefit)
# APPENDIX- TABLES

Table 1. Comparison of Organizational Aspects of AADE and ADA

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Comparison</th>
<th>AADE</th>
<th>ADA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online tools</td>
<td>AADE Tools are an advantage</td>
<td>Online tracking tools available</td>
<td>Online tracking tools not available</td>
</tr>
<tr>
<td>Recognition time</td>
<td>ADA slightly longer waiting period initially.</td>
<td>30-45 days after registration for accreditation</td>
<td>90 days after registration for accreditation</td>
</tr>
<tr>
<td>Registration fees</td>
<td>Not substantively different</td>
<td>$800 for up to 10 sites</td>
<td>$1100 for primary site+ $100 per extra site</td>
</tr>
<tr>
<td>Instructor’s requirement</td>
<td>Essentially equal</td>
<td>15 hours of education compulsory annually</td>
<td>15 hours of education or CDE</td>
</tr>
<tr>
<td>Curriculum requirements</td>
<td>Equivalent</td>
<td>Written curriculum</td>
<td>Reference curriculum required</td>
</tr>
<tr>
<td>Guidelines</td>
<td>Equal in guidance</td>
<td>7 AADE Self Care behaviors</td>
<td>10 ADA guidelines</td>
</tr>
<tr>
<td>Quality reporting</td>
<td>Equal effort, reported different format</td>
<td>Continuous Quality Improvement report is collective for all sites</td>
<td>Separate continuous quality improvement reports for all sites</td>
</tr>
<tr>
<td>Patient outcomes reporting</td>
<td>Greater rigor with ADA</td>
<td>Statistics analysis for patient outcomes required</td>
<td>Rigorous statistical analysis for patient outcomes required</td>
</tr>
</tbody>
</table>
Table 2. Sub-themes for efforts coordinators take to facilitate 1000 direct patient hours for CDE

<table>
<thead>
<tr>
<th>Sub-theme</th>
<th>Number of respondents who volunteered idea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allot hours to teach in a DSME/T program</td>
<td>23</td>
</tr>
<tr>
<td>Clinical hours allotted to the pharmacists to complete this requirement</td>
<td>5</td>
</tr>
<tr>
<td>Pharmacists take a weekly rotation in educating the patients in a DSME/T program</td>
<td>4</td>
</tr>
<tr>
<td>Patients are scheduled such that there is another pharmacist who can take responsibility for medication dispensing while the pharmacist wanting to get a CDE accreditation can complete the direct patient education hours</td>
<td>3</td>
</tr>
</tbody>
</table>
Table 3. Sub-themes for efforts taken by the pharmacists themselves to complete 1000 direct patient hours requirement for CDE accreditation

<table>
<thead>
<tr>
<th>Sub-theme</th>
<th>Number of respondents who volunteered idea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work during lunch time and after office hours to complete this requirement</td>
<td>2</td>
</tr>
<tr>
<td>Attend patient programs outside the pharmacy</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 4. Number of programs pharmacists teach specific content areas in DSME/T programs (N=190)

<table>
<thead>
<tr>
<th>Content areas the pharmacists teach in DSME/T classes</th>
<th>Number (per cent) of programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications and effects</td>
<td>166 (87)</td>
</tr>
<tr>
<td>Monitoring drug dosage and regimen</td>
<td>137 (72)</td>
</tr>
<tr>
<td>Reducing risks and health coping through behavioral changes</td>
<td>116 (61)</td>
</tr>
<tr>
<td>Diet and exercise</td>
<td>98 (52)</td>
</tr>
<tr>
<td>Providing information about insurance policies and coverage</td>
<td>72 (38)</td>
</tr>
<tr>
<td>Explaining 7 AADE self-care behaviors</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Pathology related to diabetes</td>
<td>3 (1)</td>
</tr>
</tbody>
</table>
Table 5. Frequency distribution for topics taught by pharmacists

<table>
<thead>
<tr>
<th>Topic</th>
<th>Number of pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications and effects</td>
<td>88</td>
</tr>
<tr>
<td>Monitoring drug dosage</td>
<td>86</td>
</tr>
<tr>
<td>Reducing risks and healthy coping</td>
<td>83</td>
</tr>
<tr>
<td>Diet and exercise</td>
<td>76</td>
</tr>
<tr>
<td>Providing information about insurance policies</td>
<td>57</td>
</tr>
</tbody>
</table>