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Examining Dose of Diabetes Group Medical Visits and Characteristics of the Uninsured

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Abstract

Type 2 diabetes is a significant problem for the uninsured. Diabetes Group Medical Visits (DGMVs) have been reported to improve outcomes. However, it is not known if the increased workload of the health care team to treat and educate patients at multiple visits has an impact on patient functioning and well-being. The aim of this study was to explore the impact of dose of DGMVs on biophysical outcomes of care in uninsured persons with diabetes. No significant correlations were found between number of DGMVs attended and biophysical outcomes of care. However, the majority of patients attended two or less DGMVs in 1 year. Dose of DGMVs did not impact outcomes and may not be enough to assure attendance. Involving patients to construct patient-centered interventions may decrease the treatment burden faced by both patients and providers. In addition, such interventions should be aimed at understanding reasons for low attendance, particularly in rural impoverished adults.

Keywords

metabolic; clinical focus; community; location of care; adults; population focus

Diabetes is a significant problem for the uninsured. Uninsured adults with diabetes predominantly have low incomes, are members of minority groups, live in medically underserved areas, and receive fewer preventive services than those with health insurance (Agency for Healthcare Research and Quality, 2008; DeNavas-Walt, Proctor, & Smith, 2011; Stark Casagrande & Cowie, 2012). Health disparities faced by uninsured individuals lead to delaying medical treatment. Hence, the uninsured wait until their illness becomes critical, leaving care of diabetes to emergency department (ED) visits. Uninsured people with diabetes visit the ED 55% more than people who have insurance (American Diabetes Association, 2013). One visit to the ED for patients under age 65 averaged US\$1,397 (Machlin & Chowdhury, 2011) in comparison with an office visit, which on average costs US\$104 (U.S. Department of Health and Human Services, 2012). Hence, there is a need for the development and testing of novel primary care interventions in underserved areas, which could improve care access and outcomes for uninsured people with diabetes.

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Overall health status is poorer among individuals in rural versus urban settings, and chronic illnesses such as type 2 diabetes are most prevalent in rural Appalachia, compared with other more urban parts of the country (Barker, Kirtland, Gregg, Geiss, & Thompson, 2011; Howard et al., 2011). Many rural areas in Appalachia rank lowest in the nation for number of citizens graduating high school, highest in numbers of underinsured, and lowest for availability of primary care providers (United Health Foundation, 2012). All these factors have been identified as determinants of health. The leading causes of death, illness, and disability in rural Appalachia are chronic diseases, including type 2 diabetes (Centers for Disease Control and Prevention [CDC], 2012). Access to high-quality and affordable prevention measures, including screening and appropriate follow-up, are essential for decreasing an individual's risk of lifelong health complications, including blindness, chronic kidney disease, lower-limb amputations, peripheral neuropathy, decreased quality of life, decreased functional status, and emotional distress (Aiello, 2014; American Diabetes Association, 2010; Lachin, Orchard, & Nathan, 2014; Mills et al., 2014; Nathan, 2014). It is well established that the risk of complications is related to glycemic control, as measured by glycosylated hemoglobin (A1C; Inzucchi et al., 2012). However, free care may not be enough to ensure access to care or attendance at office visits and, thus, improved glycemic control. Hidden costs and barriers of attending health care visits include the following: the inability to quickly access care due to distance, lack of an interstate transportation system, lack of a personal automobile, lack of well-developed public transportation systems and cost of transportation, needing family members assistance with transportation, and taking time off work (Arcury, Gesler, Preisser, Sherman, Spencer, & Perin, 2005).

In addition, due to a lack of primary care providers in underserved areas, interventions will not be successful if additional burden is placed on health care practices. Hence, achieving improved outcomes must be done while allowing primary care providers to deliver culturally acceptable interventions that optimize time-efficiency and affordability (Barker et al., 2011). Discovering which interventions are successful and how often to use such interventions may be the key to improving outcomes for uninsured diabetes patients, while not placing undue burden on health care practices in medically underserved areas.

Diabetes Group Medical Visits (DGMVs)

Due to the complexities of managing diabetes, a significant proportion of the care provided by primary health care providers is related to education and management of this chronic illness (Østbye et al., 2005). Yet, despite increasing provider time and ever advancing treatment options, adherence to treatment regimens continues to be less than optimal (Raebel et al., 2012). The treatment of diabetes is dependent not only on knowledge and awareness of the provider, but also on the knowledge, awareness, and situation of the patient (Barud, Marcy, Armor, Chonlahan, & Beach, 2006). We implemented DGMVs for patients in a rural free clinic to improve the process of providing diabetes care and education. In addition, we wanted to assist patients with significant health disparities to improve their diabetes self-management ability and biophysical outcomes of care.

DGMVs have been used in recent years to improve outcomes for patients with diabetes. To meet the increasing demand for health care delivery to patients with chronic illnesses,

primary care health care professionals meet with groups of patients who have the same disease and provide education and disease management. A group medical visit is defined as any visit that several patients meet together with a primary care provider and trans-disciplinary team, to improve health care quality, cost, and access (Burke & O'Grady, 2012). Mental health providers and behavioral therapists have long recognized the value of groups when seeking improved psychological and behavioral outcomes for people with chronic illnesses (Beck et al., 1997). We have known for a decade that group interaction appears to provide emotional support while lessening feelings of isolation and stigmatism that are associated with some chronic illnesses (Weinger, 2003). A group medical visit must include at least two patients, who are united in a health-related situation, and a medical provider (Barud et al., 2006). DGMVs differ from Group Diabetes Self-Management Education (DSME), where patients may receive group education but do not receive health care.

Research has documented that persons with diabetes who participate in group visits experience an increase in the following: satisfaction with care, interaction with providers, diabetes knowledge, education, quality of life, and preventive procedures and screenings (Cohen et al., 2011; Jackson, Edelman, Olsen, Smith, & Maciejewski, 2013; Mallow, Theeke, Whetsel, & Barnes, 2013; Raballo et al., 2012; Rygg, Rise, Grønning, & Steinsbekk, 2012; Schillinger, Handley, Wang, & Hammer, 2009; Trento et al., 2001; Wagner et al., 2001). Clinical outcomes associated with group visits have been documented to include an improvement in A1C, cardiovascular risk, body mass index (BMI), low density lipoproteins (LDL), high density lipoproteins (HDL), blood pressure, and progression of retinopathy (Clancy, Cope, Magruder, Huang, & Wolfman, 2003; Edelman et al., 2010; Jackson et al., 2013; Mallow et al., 2013; Naik et al., 2011; Rygg et al., 2012; Schillinger et al., 2009). Positive process of care outcomes have been achieved with an increase in patient-reported provider trust and providers report a decrease or more effective use of time (Clancy, Cope, Magruder, Huang, Salter, & Fields, 2003; Eisenstat, Ulman, Siegel, & Carlson, 2013; Lavoie et al., 2013).

The majority of the participants in each reviewed study were from ethnic minority groups and female. All but one study focused on participants in their fifth and sixth decades of life. Most of the participants had some type of health care insurance. A recent meta-analysis of DGMVs for diabetes revealed a positive effect on patient-reported outcomes, such as satisfaction with care, and significant reductions in A1C (Housden, Wong, & Dawes, 2013). However, it is not known how many group visits are needed to impact biophysical outcomes. There is a considerable gap in current knowledge related to the dose of DGMVs needed to impact outcomes. In addition, little is known about the relationship between health disparities and DGMVs.

Conceptual Framework

The theoretical framework guiding this study is the Quality Health Outcomes Model (QHOM). The QHOM was developed by the American Academy of Nursing's Expert Panel on Quality Health Care in 1996 as an expansion of Donabedian's structure-process-outcome framework. The QHOM is a more dynamic framework that acknowledges the feedback that

occurs between patients, the system or context in which care is provided, and interventions (Bandura, 1986). This model links outcomes to the interactions of patients and the health care system with health care interventions intended to treat the individual, family, or community (Barud et al., 2006). The four major concepts included in this model are system, interventions, patients, and outcomes. In the original model, these concepts have reciprocal connections, except for interventions and outcomes. However, in this study, we did not analyze the reciprocal connections. We studied the intervention that was delivered by practitioners in a free clinic setting for the impact on patient outcomes of care (see Figure 1).

Purpose

The purpose of this study was to explore the impact of dose of DGMVs on biophysical outcomes of care in uninsured persons with diabetes. The specific aims were to (a) analyze the differences in characteristics of uninsured persons with diabetes who are attendees of DGMVs versus those who receive usual care, and (b) explore the impact of dose of DGMVs on biophysical outcomes of care in uninsured persons with diabetes who receive care in a free clinic after 1 year.

Method

A retrospective study using a convenience sample of patients was used. Two independent groups were studied, those who attended DGMVs and those who received usual care. This study was approved by the Institutional Review Board of West Virginia University. The inclusion criteria are (a) age 18 years or more, (b) diagnosis of type 2 diabetes, and (c) uninsured and received care at a free clinic during the study period. The only specific exclusion criteria would be an accidental charting of diabetes where no diabetes exists, which was determined based on diagnostic criteria for diabetes of a non-medicated A1C above 6.5%, fasting plasma glucose above 126 mg/dl, or oral glucose tolerance test above 200 mg/dl (American Diabetes Association, 2012). Patients were referred to the DGMV by their primary care provider for additional care. Intervention group patients received DGMV services during the study time frame and met the inclusion criteria. The usual care patients were randomly selected from diabetes patients who received usual care services during the study time frame and met the inclusion criteria.

Sample and Setting

This study was conducted at a free clinic in North Central West Virginia. West Virginia is located in Appalachia. Appalachia is a 13-state region of the Eastern United States that has a long history of rurality and poverty (United Health Foundation, 2012). The majority of patients in both groups were female (73.9%), White (95.5%), severely obese (mean BMI = 37.6, $SD = 28.48$), age 50 years or younger (53.2%), not college educated (95.4%), averaging five co-morbid conditions other than diabetes ($M = 5.5$, $SD = 2.1$), and driving long distances to receive care (mean miles = 21, $SD = 20.4$).

Intervention

The intervention was derived from the Quality Outcomes model, as described above. The system in this study was a free clinic in North Central West Virginia, the intervention was

DGMVs, the patients were low income uninsured adults, and the outcomes were biophysical measures. The key players involved in the intervention were the interventionists, that is, the Nurse Practitioner at the clinic (J.A.M.) in conjunction with a Pharmacist (PharmD; T.W.) who is a diabetes educator. The recipients of the intervention were patients of the clinic with diabetes. The targets of the intervention were adults with low incomes with diabetes.

In the free clinic where this study took place, the DGMV was an additional health care visit and was meant to supplement individual health care visits to improve patient outcomes. Patients were referred to the DGMV by their primary care provider for additional care. DGMVs included group education and interaction, and elements of an individual patient visit, such as the collection of vital signs, history taking, physical exam, medication adjustments, appropriate standardized referrals, and laboratory procedures related to diabetes care as per the Standards of medical care in diabetes (American Diabetes Association, 2010). The curriculum for this clinic's DGMV education component, which was adapted from the National standards for diabetes self-management education and support (Haas et al., 2013), was developed by the Nurse Practitioner at the clinic (J.A.M.) in conjunction with a Pharmacist (PharmD; T.W.) who is a diabetes educator.

The free clinic offered up to six DGMVs, in which the patients were provided education about a different topic each session. The sessions included blood glucose monitoring, medication, nutrition, exercise, foot care, heart disease, complications including sick day care, and behavior changes. Educational information was imparted to the participants during lecture/discussion format with the aid of key points being displayed on a white board. Specific tools such as a transparent food label that could be edited on the white board were used. In addition, images such as pictures of feet were used to illustrate foot care. These sessions were guided by the same key points that were derived from the National Standards for Diabetes Self-Management Education and Support (Haas et al., 2013).

The patients were scheduled to attend the clinic up to once a month until they had received all the education offered. Because the classes were offered four times per month, the patients could schedule at their convenience. Hence, the participants in each group varied from class to class. Each group had 4 to 10 participants. The group education session usually took about 45 min and was led by the Pharmacist (T.W.). The DGMVs were held at the clinic in a conference room, with a large table and seating for each participant. Individual patient visits were held after the group education session. While one patient left to have an exam, the rest of the patients discussed goal setting, shared experiences of success, and asked questions of the Pharmacist. Exam rooms are located across the hallway from the conference room. Individual patient visits were conducted by the Nurse Practitioner (J.A.M.) with one patient at a time. While the patients were receiving education, the Nurse Practitioner was able to review the charts and finger-stick logs of the patients in attendance and prepare referrals, laboratory requests, and write refill or prescription renewals for each patient. Hence, each physical exam lasted for approximately 10 min. Attendance at the DGMVs was voluntary. Participants received no incentive to attend session. There is no charge for any care received at the free clinic.

Usual Care

Usual care for persons with diabetes in the free clinic where the study took place included collection of vital signs, history taking, physical exam, medication adjustments, appropriate referrals, laboratory procedures, and education provided by the health care provider related to general care. Usual care did not include education provided by a PharmD or diabetes educator with a group of other diabetes patients at the time of the usual care visit.

Measures

Dose—Data related to the number of DGMVs were collected from the chart and was coded 1, 2, 3, 4, 5, or 6, depending on the number of visits patients experienced. The data were recorded as categorical for each of the following DGMV categories: blood glucose monitoring, medication, nutrition, exercise, foot care, heart disease, complications including sick day care, and behavior changes.

Biophysical Outcomes of Care

An outcome is said to be a component of a patient's clinical and functional status after an intervention has been applied (Barr, Schumacher, & Myers, 2001). Biophysics refers to the process of assigning an objective measurement to a bodily process. For the purposes of this study, a biophysical outcome of care was defined as the measurable result of care collected over a specific time frame.

This study collected the common biophysical outcomes measured in diabetes, body weight, BMI, A1C, fasting blood glucose, serum creatinine, serum lipids, urine microalbumin, and blood pressure.

Body weight—Body weight was obtained routinely and recorded in the chart at the beginning of each clinic visit. Weight was measured and recorded in pounds (lb). The clinic used an upright mechanical medical scale with capacity to weigh patients up to 350 lb. This study collected the first body weight available prior to May 2007, and the most recent body weight recorded on or before August 18, 2009. The weight of patients who weigh more than 350 lb is reported in the chart as "350+." These data were recorded and analyzed as a continuous variable.

Body mass index—BMI was calculated with the following formula: weight (lb)/height (in.)² × 703. Height was collected via patient report and recorded in the chart upon initial visit. Weight was obtained routinely and recorded in the chart at the beginning of each clinic visit. This study collected the first body weight available prior to May 2007, and the most recent body weight recorded on or before August 18, 2009. BMI was calculated based on the initial patient-reported height. These data were entered as a continuous variable.

Glycosylated hemoglobin—Glycosylated hemoglobin levels were drawn as part of routine diabetes care. In this clinic, the measurement of A1C was performed by two separate outside laboratories. One laboratory used the Dade Dimension technique, applying the turbidimetric inhibition immunoassay principle, where the total hemoglobin was based on a modification of the alkaline hematin reaction (Chang, Hoke, Ettinger, & Penerian, 1998).

The percentage of total hemoglobin that was glycated was calculated and reported as %A1C. The reference range is 4.8% to 6.0%. The other laboratory performed A1C testing using the BioRad Variant II system, which used ion exchange high-performance liquid chromatography (HPLC) to determine percentage of glycated hemoglobin (Higgins, Blakney, & Dayton, 2001). The reference range is 4.4% to 6.8%. The American Diabetes Association (2010) recommends that laboratories use only glycohemoglobin assay methods that have been approved by the National Glycohemoglobin Standardization Program. Both laboratories met these requirements and reported results in percentage of A1C. While the laboratories reported different reference ranges, both laboratories reported values in percentage of A1C. Hence, the difference in laboratory testing procedures was not clinically significant and would not affect percentage values or clinical decision making. This study collected the first A1C available prior to May 2007, and the most recent A1C recorded on or before August 18, 2009. These data were recorded and analyzed as a continuous variable.

Fasting blood glucose—Fasting blood glucose measures blood glucose after a patient has fasted for at least 8 hr. Fasting blood glucose was self-reported by the patient and recorded in the clinic visit note. All patients measure fasting blood glucose with a glucometer provided for home use by the free clinic. The meter then displays the level in milligrams per deciliter. This study collected the first fasting glucose available prior to May 2007 and the most recent fasting blood glucose recorded on or before August 18, 2009. These data were recorded and analyzed as a continuous variable.

Serum creatinine—A serum creatinine test measures the amount of creatinine in the blood. The test was done to evaluate kidney function. Creatinine levels were drawn as part of routine diabetes care. In this clinic, the measurement of serum creatinine was performed by two separate outside laboratories. Both laboratories reported creatinine in milligrams per deciliter. The reference range for both laboratories is 0.5 to 1.2 mg/dl. This study collected the first serum creatinine available prior to May 2007, and the most recent serum creatinine recorded on or before August 18, 2009. These data were recorded and analyzed as a continuous variable.

Serum lipid levels—Serum lipid levels are considered to be any major lipid in the circulation. Serum lipid levels were routinely collected and reported as total cholesterol, HDL, LDL, and triglycerides (TG). Serum lipid levels were drawn as part of routine diabetes care. In this clinic the measurement of serum lipid was performed by two separate outside laboratories. Both laboratories reported serum lipids in milligrams per deciliter. The normal reference range was equivalent in both laboratories. This study collected the first serum lipids available prior to May 2007, and the most recent serum lipids recorded on or before August 18, 2009. These data were recorded and analyzed as four separate continuous variables.

Urine microalbumin—Often, urine microalbumin can be an earlier sign of potential kidney disease than serum creatinine. A urine microalbumin test measures the amount of albumin in the urine. The test was done to evaluate kidney function. Urine microalbumin was collected as part of routine diabetes care. In this clinic the measurement of urine

microalbumin was performed by two separate outside laboratories. Both laboratories reported urine microalbumin in milligrams per deciliter. The normal reference range was equivalent in both laboratories. This study collected the first urine microalbumin available prior to May 2007, and the most recent urine microalbumin recorded on or before August 18, 2009. These data were recorded and analyzed as a continuous variable.

Blood pressure—Blood pressure was obtained routinely and recorded in the chart at the beginning of each clinic visit. Blood pressure was measured and recorded as systolic over diastolic millimeters of mercury. The clinic used an automated blood pressure cuff. This study collected the first blood pressure available prior to May 2007 and the most recent blood pressure recorded on or before August 18, 2009. These data were recorded and analyzed as two separate continuous variables.

Patient Characteristics

Patient characteristics collected were as follows: age, gender, ethnicity, marital status, duration of diabetes, education level, distance in miles from residence to clinic, depression score, and co-morbidities.

Demographic characteristics—Age was collected from the chart from date of birth. Age was recorded at the age of the first visit within the time frame for the study. These data were recorded and analyzed as a continuous variable. Gender was collected from the chart, and recorded as a dichotomous variable, either male or female. Ethnicity, recorded upon establishment of care at the clinic, was collected from the chart. Ethnicity was collected by patient self-report. Ethnicity was recorded in the following categories: White, African American, Asian, Hispanic, Native American, and other. Marital status was collected from the chart. Marital status is asked on the initial visit and was reassessed every year. Marital status was collected by patient self-report. The most recently recorded marital status was collected in the following categories: single, married, divorced, separated, widowed, and significant other.

Duration of diabetes—Duration of diabetes was collected by chart review using patient self-report data. Subjects are asked to report the number of years that they have had diabetes during clinic visits. The duration of diabetes was recorded from the beginning of the study period. Duration of diabetes was recorded as a continuous variable.

Educational level—Education was collected by chart review. Education was recorded in the chart upon initial visit to the clinic. Education was recorded from the beginning of the study period in the following categories: less than high school, graduated high school, some college, college graduate, master's degree, doctorate, and general education development.

Distance in miles from residence to clinic—Home address was recorded in the chart at the initial visit and is verified after every visit. Miles from residence to the clinic was calculated with Google Maps using the clinic address and the patient address. Home address was not kept in any study data file. Miles from residence to clinic was analyzed as a continuous variable.

Depression score—Depression score was collected upon initial visit, using The Center for Epidemiologic Studies Depression Scale (CES-D; Deeb-Sossa, Perreira, Harris, & Bollen, 2003). The CES-D is a commonly used screening test for determining depression quotient. While the tool is not diagnostic of clinical depression, it has been used in the past as indicating risk for depression. The CES-D was filled out by the patient and can be completed in less than 5 min at the first visit prior to receiving care at the free clinic. While the CES-D was to be filled out yearly, it is not commonly updated at the free clinic. Hence, it was not measured as an outcome of care but rather as a patient characteristic at baseline. The CES-D measured depressive feelings and behaviors during the past week. Each question was scored using a range of 0 to 3 points. A score of less than 15 indicated no or few depressive feelings and behaviors during the past week. A score of 15 to 21 indicated mild to moderate depression. A score of over 21 indicated the possibility of major depression. Depression score was collected and recorded as a categorical variable.

Co-morbidities—An ongoing list of active and prior medical conditions was kept on the medical chart. For the purposes of this study, a co-morbidity was the diagnosis of all other chronic diseases an individual patient might have other than diabetes. The data were recorded as a continuous variable, reflecting the total number of co-morbidities the patient has, and as a dichotomous variable as yes or no for each of the following co-morbidities: hypertension, kidney disease, hyperlipidemia, heart disease, depression, obesity, kidney disease, pain, eye disease, neuropathy, and frequent infections.

Study Procedures

Data collection—A registry of all persons with diabetes who are patients was kept by the free clinic. The registry was reviewed by the research and clinic staff. All persons with diabetes who received care from May 2007, when DGMVs were started at the clinic, to August 18, 2009, were identified, and the electronic medical record was reviewed. No patient identifiers were collected or retained. The data were extracted from the electronic medical record by a medical assistant at the clinic. The medical assistant was educated by the investigator on data collection procedures. Ten percent of the charts reviewed by the medical assistant over the first week of data collection were also reviewed by the investigator. An inter-rater reliability of 95% accuracy between the data collected by the medical assistant and the data collected by the investigator was set and exceeded. Identified charts were reviewed by the investigator or medical assistant in a private setting in the clinic. Biophysical outcomes of care were collected from the chart and recorded from two separate time periods. Biophysical outcomes for patients who did not participate in DGMVs were collected as reported in the chart during or after May 2007 and then again after 1 year. Biophysical outcomes of care were collected from the chart of patients who did participate in at least one DGMV. These outcomes were assessed prior to the initial DGMV and then again in 1 year, or the measurements recorded nearest to the 1-year mark. Data were entered into Microsoft Access for ease of use for the medical assistant collecting the data and then were converted into SPSS, Version 18 for analysis of the data.

Data fidelity—Due to the retrospective nature of the study, intervention fidelity is difficult to control. However, group visits at the clinic were conducted by one diabetes educator, one

nurse practitioner, and one medical assistant. The group intervention was held in the same education room in the clinic, and the health care portion of the visit was delivered in one of six very similar exam rooms. The educational content of all the group visits were derived from one of six educational sessions developed for a standardized curriculum. The delivery format was consistent for each DGMV: instruction, questions, answers, goal setting, and then individual patient health examinations.

Analysis—Prior to analysis, the data were cleaned, looking for outliers or impossible values. This was accomplished by running frequencies and descriptive statistics and visually scanning for missing data and for patterns of missing data. Any variable item that had missing data such that it decreased power or missing data with any identifiable pattern was not analyzed.

To analyze the differences in characteristics of uninsured persons with diabetes who attend DGMVs versus those who receive usual care in a free clinic after 1 year, group means were calculated for each patient characteristic. Chi-square tests were used to look for differences in the categorical variables of gender, ethnicity, marital status, education, and type of co-morbidities in patients who attended DGMV, and patients who received usual care. Independent *t* tests were used to compare means for age, duration of diabetes mellitus (DM), miles from clinic, and number of co-morbidities. An assumption for use of the chi-square analysis is that the expected count in each category is greater than 5. If this assumption is violated, the categories of the categorical variables were collapsed until the assumption was met. A *p* value of .05 was used to determine significance of the findings.

To explore the relationship between the dosage of DGMVs and biophysical outcomes of care in uninsured persons with diabetes who receive care in a free clinic after 1 year, dose was collected as a continuous variable on a scale of 1 to 6. Correlations were performed with the outcomes of body weight, BMI, A1C, fasting blood glucose, serum creatinine, serum lipids, urine microalbumin, systolic blood pressure, and diastolic blood pressure at 1 year for those patients who attended DGMVs. Before performing a correlation analysis, a scatterplot was generated to check for violation of the assumptions of linearity. Each continuous variable was tested for normality. If assumptions of parametric testing were not violated, Pearson *r* was used for analysis. If assumptions were violated, Spearman rho was used for analysis. A *p* value less than .05 was used to determine significance of the findings.

Results

To achieve a power of .8, considering a medium effect size to detect a difference in means between two independent groups, a sample of 51 charts in each group was required (calculated with G*Power 3). There were a total of 111 patients who met the inclusion criteria. There were 53 participants who attended DGMVs and 58 participants who received usual care.

Characteristics

Our first aim was to analyze the differences in characteristics of uninsured persons with diabetes who are attendees of DGMVs versus those who receive usual care. Chi-square tests

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were used to look for differences in the categorical variables of gender, ethnicity, marital status, education, and type of co-morbidities between patients who attended DGMVs and patients who received usual care. Education level and ethnicity violated the assumptions by having an expected count of less than five observations in several categories. Education level had only one participant who had graduated from college and no participants who had graduated or attended graduate school. Hence, the categories were collapsed. The participant who graduated from college was included in the “some college” category, and the “master’s degree” and “doctoral degree” categories were removed. There were less than five participants who reported being anything other than White. Hence, the categories were collapsed into White and non-White. The expected count was still less than five observations in ethnicity. Therefore, the characteristic of race/ethnicity was not analyzed. Marital status had an expected count of less than five observations in several categories. The marital status category was compressed into the categories married and not married. Any participant who was listed as single, divorced, separated, or widowed was placed in the non-married category. Participants who were listed as married were placed in the married category.

Independent *t* tests were used to compare means for the continuous characteristics of age, miles from clinic, and number of co-morbidities between patients who attended DGMVs and patients who received usual care. The data do not meet the assumption of normality for those who attended DGMVs or patients who received usual care. However, the results of the parametric test are still valid due to the Central Limit Theorem (Polit & Beck, 2008).

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The chi-square test for independence indicated the patients who participated in DGMVs differed from the usual care group prior to the intervention by reporting significantly higher rates of depression, obesity, and pain (see Table 1). Independent *t* tests showed no difference between the means for the continuous characteristics of age, miles from clinic, and number of co-morbidities between patients who attended DGMVs and patients who received usual care (see Table 2). There were no other significant differences in characteristics at the beginning of the study between those who attended DGMVs and those who received usual care.

Dose—Our second aim was to explore the impact of dose of DGMVs on biophysical outcomes of care in uninsured persons with diabetes who receive care in a free clinic after 1 year. Dose was collected as a continuous variable on a scale from 1 to 6. Correlations were performed with the outcomes of body weight, BMI, A1C, fasting blood glucose, serum creatinine, serum lipids, urine microalbumin, systolic blood pressure, and diastolic blood pressure at 1 year for those patients who attended DGMVs. When correlations were performed, no significant correlations were found between number of DGMVs attended and biophysical outcomes of care. However, after analyzing frequencies, it is noted that only 18 individuals attended three or more DGMVs. A total of 17 participants attended one visit, and 18 participants attended two visits. The data were then collapsed into participants who attended three or more group visits and those who attended less than three visits. Because A1C is so commonly used to determine an improvement in glucose levels, A1C was also collapsed into goal met or goal not met. The American Diabetes Association (2010) sets the goal for A1C at less than 7%. The continuous biophysical outcome of A1C was

dichotomized using 7% as a threshold to create a new variable, those who were above 7% and those who were 7% and below. A chi-square test was used to analyze the differences between participants who attended three or more group visits and those who attended less than three visits, and A1C goal met or not met. There were no significant differences between the A1C met or not met outcome of patients who attended three or more DGMVs and those who attended less than three DGMVs (see Table 3).

Discussion

This study described age, gender, ethnicity, marital status, duration of DM, education, miles from clinic, co-morbidities, and depression in this population. The characteristics of patients receiving care at a free clinic may affect the effectiveness of any intervention. Prior to intervention, participants had a mean of five co-morbid conditions other than diabetes. The majority of the patients were female, White, had a high school education or less, and were age 50 years or younger. The subjects being cared for in this free clinic drove long distances to receive care.

The complexity and number of multiple chronic illnesses seen in this population could have contributed to the lack of effectiveness of DGMVs. Number of co-morbid conditions has been documented to affect outcomes of care. Patients with a greater overall number of co-morbidities place lower priority on diabetes and have worse diabetes self-management ability scores (Glasgow, Toobert, & Hampson, 1996). Attempting to perform self-management of diabetes, within the context of complex chronic illness behaviors such as checking glucose levels, taking medications, and adhering to dietary and activity recommendations is difficult to maintain (American Diabetes Association, 2010).

The gender bias in the sample could have played a part in the study findings. Gender has been documented to affect outcomes such as rates of obesity, amount of physical activity, and adherence. It has been long known that females have a greater prevalence of obesity compared with males (Ferraro et al., 1992). Obesity causes insulin resistance, which contributes to decreased effectiveness in lowering blood glucose. The resulting increase in blood glucose may raise levels outside the normal range and cause adverse health effects (McPhee, 2011). Men with diabetes have been found to be more physically active (Carpenter et al., 1998), which may significantly lower cardiovascular risks and overall mortality (Church et al., 2004). In addition, women have been found to consume more calories, make poorer food choices, and have lower levels of adherence than men (Whitlock, Vogt, Hollis, & Lichtenstein, 1997). Although there was gender bias, this sample may be representative of the population of patients with diabetes in the Appalachian region.

Nearly all participants in this study were White, which is representative of the population from which the sample was drawn. To receive care at this free clinic, subjects must have resided in West Virginia. West Virginia is the only state that is entirely in Appalachia (Appalachian Regional Commission, n.d.). Although this study did not collect data on culture, all the participants of this study lived in West Virginia. According to the 2000 U.S. Census, 74.2% of people residing in West Virginia are native to West Virginia (U.S. Census Bureau, 2000). Hence, it is the assumption of the researchers that the subjects of this study

are members of Appalachian culture, and therefore subscribe to some of the social norms of the culture. These norms and beliefs affect the patients' desire to interact with a care delivery system (Holzemer, 1994). People from Appalachian culture possess core values such as individualism, self-reliance, and fatalism (Smith & Tessaro, 2005). These core values may affect a patient's willingness to share personal information with outsiders. An outsider can be any person who is not familiar to the patient such as other patients and health care providers participating in group visits. For DGMVs to affect outcomes of care, each patient must share similar experiences and be willing to participate in a group (Barud et al., 2006).

Education level also appears to have an effect on participation in medical decision making and thus may impact outcomes of care (DeWalt, Boone, & Pignone, 2007). Over one third of subjects in this study did not graduate high school. Educational level has been shown to be significant in disease control of persons with diabetes. On the National Health and Nutrition Examination Survey from 1999 to 2006, those persons with diabetes who had a high school education or higher had consistently shown improved outcomes such as decreased A1C, decreased blood pressure, and decreased total cholesterol levels than those who were less educated (McWilliams, Meara, Zaslavsky, & Ayanian, 2009).

The age of all subjects in this study is less than 65 years, and the majority of the subjects were aged 50 years and younger. Younger adult patients, less than 60 years old, are significantly less likely to attend education programs and multiple health care visits than older adult patients (Abdulwadud et al., 1997). In addition, the largest reductions in A1C have been documented in patients who attend more health care visits (Brown et al., 2005). Consequently, lack of attendance in multiple health care visits and education programs by younger populations may contribute to decreased effectiveness of interventions.

Longer driving distances from home to the site of primary care have been associated with poorer outcomes in rural subjects (Strauss, MacLean, Troy, & Littenberg, 2006). The majority of subjects in this study live greater than 20 miles from the clinic, making both traveling time to clinic and transportation difficult. Living far away from primary health care centers, particularly in West Virginia presents multiple barriers to care. These barriers include inability to quickly access care due to distance, lack of an interstate transportation system, lack of public transportation systems, and cost of transportation (Arcury, Preisser, Gesler, & Powers, 2005). These barriers affect a person's ability and willingness to obtain needed care (Arcury, Gesler, et al., 2005).

There were differences in patient characteristics in the sample of patients who attended DGMVs versus those who received usual care. Similar to the usual care group, the DGMV group had elevated HgA1C levels, nephropathy, and dyslipidemia. However, patients who participated in DGMVs had higher depression scores, were more obese, and reported to have pain more frequently than patients who received usual care in this study. Patients with depression are more likely to experience complications of diabetes, have worse glycemic control, and be less adherent to self-care behaviors than patients who are not depressed (Prochaska, 2008). Pain has been found to limit a person's ability to perform self-management behaviors (Krein, Heisler, Piette, Makki, & Kerr, 2005). Obesity increases the

incidence of insulin resistance, hypertension, dyslipidemia, and cardiovascular disease (DeFronzo & Ferrannini, 1991). The intervention was not designed to affect depression, obesity, and pain. These differences could have contributed to diminished response to the intervention in this population. The results of the current study suggest that patient characteristics such as pre-existing multiple co-morbid conditions, education level, depression, obesity, pain, and distance to the clinic may have negatively affected biophysical outcomes of care. Future interventions for this population should be tailored to address depression, obesity, pain, and access to care first for this population. The education content would, therefore, be more patient-centered and relevant to the unique needs of these patients. Once these issues have been addressed, then the focus could be placed on the educational standard topics included in the DSME.

The biophysical outcomes reported in other literature related to DGMVs showed that participants started nearer to treatment goals prior to intervention than the sample of patients in this study (Chiu et al., 2009; Clancy, Brown, Magruder, & Huang, 2003; Clancy, Yeager, Huang, & Magruder, 2007; Culhane-Pera et al., 2005; Guzek, Guzek, Murphy, Gallacher, & Lesneski, 2009; Trento et al., 2002; Trento et al., 2001; Wagner et al., 2001). Most studies reviewed related to DGMVs reported A1C levels from 6.9% to 7.6% (Keyserling et al., 2002; Wagner, 1998; Wagner et al., 2001). Nearly 70% of the sample of patients who attended DGMVs had A1C levels above treatment goals at Time 1. In addition, greater than 62% of the sample of patients who attended DGMVs had A1C levels above what has been previously seen in the literature.

There was no significant relationship found between number of DGMVs attended and biophysical outcomes of care in this study. However, it is important to note that the majority of patients attended two or less DGMVs in 1 year. Previous studies reviewed related to DGMVs suggest that improved interventions are seen in those patients who attend DGMVs more frequently (Beck et al., 1997; Trento et al., 2002; Trento et al., 2001). Other studies that reported improvement in measured biophysical outcomes related to participation in DGMVs measured outcomes after at least 2 years of care (Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Trento et al., 2002). Hence, the lack of improvement in biophysical outcomes of care in this sample of patients who attended DGMVs may be due to low attendance rates or less time between intervention and outcome measurement than in previous studies.

Clinical outcomes associated with group visits have been documented to include decreased or stable A1C, decreased cardiovascular risk, decreased or stable BMI, decreased LDL, increased HDL, decreased or stable blood pressure, and slowed progression of retinopathy (Clancy, Cope, Magruder, Huang, Salter, & Fields, 2003). However, DGMVs were not effective in improving biophysical outcomes of care in the population of persons with diabetes cared for in this free clinic. The implementation of DGMVs may be a viable option for improving biophysical outcomes of care in some patient populations. Prior to implementation of DGMVs as an intervention, assessment of both the characteristics of the patients to be cared for and the system in which DGMVs will take place is advised.

The patient characteristics found in previous studies to contribute to the success of DGMVs as an intervention include ethnic minority groups, female gender, older age, and some type of health care insurance. Future interventions for this population should be tailored to treat people who have diabetes and multiple co-morbid conditions, depression, pain, and live long distances from the clinic. For example, instead of offering group visits as an additional health care visit, consider offering a group visit structured toward multiple common complex chronic illnesses as a replacement for a patient's primary care visit, clustering care with a primary care visit, offering online education and treatment, or moving DGMVs closer to patients in community/religious centers. Also, the addition of services from other disciplines such as social work or behavioral health for this population may contribute to improved outcomes.

In addition to tailoring interventions based on patient characteristics, an assessment of the health care delivery system is necessary. This study tested an intervention that was originally designed to operate within a traditional health care delivery system. The system of interest, the free clinic, cannot operate in the same ways as fee-for-service practices. Future interventions that investigate changes in the health care delivery system are warranted. In addition to the Nurse Practitioner and PharmD, other health care professionals are needed to address the severe obesity, poor physical condition, and macro-vascular complications seen in this population. Instead of an additional health care visit that is meant to supplement individual health care, clustered care visits where a multidisciplinary health care team work together to assess, diagnose, treat, and educate are needed (Funnell, 2004). Another idea might be the use of innovative technologies or the use of home care services to provide distance care and individualized education for this population. Based on these study results, implementation of DGMVs is only suggested if the clinic is easily accessible and can provide care from multiple health care team members. New interventions will require a change not only in practice for primary health care providers but also in the health care delivery system.

Future research with this population should focus on the unique needs of persons with diabetes who receive care in free clinics. It is clear that this population is different than those previously studied using DGMVs as an intervention. In 2008, the National Center for Health Statistics reported that 46 million individuals under the age of 65 were uninsured, which translates to 16.8 % of the population of adults under the age of 65 without insurance (CDC, 2006). Differing characteristics of uninsured patients such as obesity, multiple co-morbid conditions, less education, younger age, longer driving distances, Appalachian culture, and low incomes provide target areas for future tailored intervention research.

Future research could include multisite randomized clinical trials with consistent measures of biophysical outcomes related to DGMVs. Randomization to treatment group would correct self-selection to the intervention and non-equal groups as seen in this study. While A1C values are reported in most of the DGMV literature, other biophysical outcomes of care are inconsistently reported. Prospective longitudinal studies are needed to evaluate not only biophysical outcomes of care but also process of care indicators. Measuring and reporting consistent outcomes, as suggested by the American Diabetes Association (2010) and

multiple articles related to group visits, will assist researchers and clinicians in comparing the impact of DGMVs on biophysical outcomes and processes of care.

The persons with diabetes who were cared for in this clinic were severely obese, with elevated A1C levels, nephropathy, and dyslipidemia. DGMVs have been shown in the literature to improve biophysical outcomes. However, the dose of group visits offered in this study was not enough to improve biophysical outcomes in this population due to lack of attendance. Interventions targeted to the unique characteristics of this population are needed to prevent devastating complications. Clustering care may be one way to improve access and diminish the burden identified as distance to clinic. Improving other characteristics such as depression, obesity, and pain may require, access to an interprofessional team, which could include professionals from other disciplines such as social work or behavioral health. Future interventions could use innovative technologies or home care services for this population, and this may contribute to improved outcomes. Seeking patient input for intervention design could lead to more effective patient-centered interventions, enhanced patient acceptability, and decreased perceived treatment burden.

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Figure 1. Conceptualization of the quality health outcomes model for this study. *Source.* Mitchell, Ferketich, and Jennings (1998).

Table 1

Differences in Dichotomous Characteristics of DGMVs Versus Usual Care (DGMV, $n = 53$; Usual Care, $n = 51$).

Characteristic	<i>N</i>	%	χ^2	Significance
Gender			0.004	.947
DGMV				
Male	14	26.4		
Female	39	73.6		
Usual care				
Male	15	25.9		
Female	43	74.1		
Marital status			1.083	.298
DGMV				
Not married	29	54.7		
Married	24	45.3		
Usual care				
Not married	26	44.8		
Married	32	55.2		
Education			0.122	.989
DGMV				
Less than high school	13	24.5		
Graduated high school	22	41.5		
Some college	10	18.9		
GED	8	15.1		
Usual care				
Less than high school	15	25.9		
Graduated high school	23	39.7		
Some college	12	20.7		
GED	8	13.8		
Hypertention			0.002	.962
DGMV				
Has HTN	40	75.5		
No HTN	13	24.5		
Usual care				
Has HTN	44	75.9		
No HTN	14	24.1		
Kidney disease			1.122	.289
DGMV				
Has kidney disease	8	15.1		
No kidney disease	45	84.9		
Usual care				
Has kidney disease	5	8.6		

Characteristic	N	%	χ^2	Significance
No kidney disease	53	91.4		
Hyperlipidemia			0.968	.325
DGMV				
Has hyperlipidemia	28	52.8		
No hyperlipidemia	25	47.2		
Usual care				
Has hyperlipidemia	36	62.1		
No hyperlipidemia	22	37.9		
Heart disease			0.044	.834
DGMV				
Has heart disease	9	17		
No heart disease	44	83		
Usual care				
Has heart disease	9	15.5		
No heart disease	49	84.5		
Depression			4.583	.032
DGMV				
Has depression	24	45.3		
No depression	29	54.7		
Usual care				
Has depression	15	25.9		
No depression	43	74.1		
Obesity			6.055	.014
DGMV				
Has obesity	41	77.4		
No obesity	12	22.6		
Usual Care				
Has obesity	32	55.2		
No obesity	26	44.8		
Pain			5.565	.018
DGMV				
Has pain	12	22.6		
No pain	41	77.4		
Usual care				
Has pain	4	6.9		
No pain	54	93.1		
Neuropathy			1.405	.236
DGMV				
Has neuropathy	6	11.3		
No neuropathy	47	88.7		
Usual care				
Has neuropathy	3	5.2		

Characteristic	N	%	χ^2	Significance
No neuropathy	55	94.8	0.315	.575
Frequent infections				
DGMV				
Has frequent infections	3	5.7		
No frequent infections	50	94.3		
Usual care				
Has frequent infections	2	3.4		
No frequent infections	56	96.6		

Note. DGMV = diabetes group medical visits; GED = general education development.

Table 2

Differences in Continuous Characteristics of DGMVs Versus Usual Care (DGMV, $n = 53$; Usual Care, $n = 51$).

Characteristic	<i>M</i>	<i>SD</i>	<i>t</i>	<i>p</i>
Age			1.13	.261
DGMV	47	10.82		
Usual care	49	10.84		
Number of co-morbidities			-1.31	.193
DGMV	4.7	2.16		
Usual care	4.2	2.11		
Distance from clinic			0.25	.803
DGMV	20.7	19.72		
Usual care	21.7	21.08		

Note. DGMV = diabetes group medical visits.

Table 3Dose of DGMVs and A1C Goal ($n = 53$).

	<i>N</i>	%	χ^2	Significance
Two or less DGMVs			0.518	.323
A1C at goal	10	28.6		
A1C above goal	25	71.4		
Three or more DGMVs				
A1C at goal	7	38.9		
A1C above goal	11	61.1		

Note. DGMV = diabetes group medical visits.