The Evaluation of the Implementation of a Shared Medical Appointment for Patients with

Diabetes in a Rural Private Practice

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# Manuscript

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#### Abstract

**Objective:** This practice improvement project was designed to test the efficacy and feasibility of implementing Shared Medical Appointments (SMA) as an innovative approach to improve the care of diabetic patients while containing costs in a rural private practice associated with an Accountable Care Organization (ACO).

**Methods:** Five Medicare quality measures specific to diabetes were used as patient outcomes: hemoglobin A1C control (<8%), low density lipoprotein control (<100mg/dL), high blood pressure control (<140/90), tobacco non-use, and daily Aspirin use. Database with the five quality measures was established to compare three diabetic groups: SMA participants, group diabetic education participants and usual care patients. Patient satisfaction as well as staff input to the feasibility of the SMA was obtained.

**Results:** Fifteen patients participated in one or more monthly SMAs with groups ranging from two to five participants per appointment over 10 months. Participants indicated a high level of satisfaction with themes associated with social support. No significant difference between groups in the attainment of CMS measurements was found between groups however, the BMI was significantly improved for the SMA group.

**Conclusions:** The SMA may be a venue to activate patients to achieve health outcomes in a costeffective manner if the recommended census of eight participants is achieved. Recommendations for implementation are provided. Current statistics reveal a dramatic rise in the diagnosis of those with diabetes. Most recent data estimates 26.5 million affected by diabetes with a cost burden of approximately 245 billion dollars per year (AHRQ, 2014). Diabetes is currently the seventh leading cause of death in the United States and Ohio (CDC, 2014). Most common complications/comorbidities associated with diabetes mellitus are cardiovascular disease, kidney failure, lower limb amputations, and adult onset blindness. Effective management of diabetes will prevent or delay related complications for patients with this condition.

Not only is the occurrence of diabetes increasing but the occurrence of prediabetes. Prediabetes, a precursor to diabetes, is on the rise with an estimated 86 million affected (CDC, 2015). Without lifestyle interventions this population will add to the rising number of people suffering from diabetes in an estimated five to ten years (NDEP, 2014).

Diabetes self-management is a complex, multi-faceted task that requires an understanding of the disease process and the many extrinsic factors that can hasten or hinder the disease process such as exercise, stress, and dietary intake. A patient who is actively involved in his/her healthcare experiences better health outcomes and a decrease in health care spending of 8-21 percent when contrasted to patients with lower levels of involvement (RJJF, 2006-2013). The Shared Medical Appointment (SMA) is a potential venue in the activation of self-management for patients with diabetes at one private clinic addressing this population in the context of an Accountable Care Organization. The Shared Medical Appointment (SMA) refers to a healthcare appointment for multiple patients, sharing a common diagnosis, being seen simultaneously by a healthcare provider with the added benefit of a supportive group setting (Noffsinger, 2013).

In January 2013, Northern Ohio Medical Specialist (NOMS) Healthcare, became one of 37 Advanced Pay Accountable Care Organizations (ACO) in the United States. An ACO is a group

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of physicians or hospital that is charged with providing coordinated care for a group of Medicare beneficiaries having the Triple Aim as a framework to model care which includes:

- 1. Improving the patient experience,
- 2. Improving the health of the population and
- Containment of expenditures in caring for this population (Bard & Nugent, 2011, IHI, 2015).

NOMS has approximately 7500 beneficiaries assigned to the ACO. NOMS ACO will be rewarded for containing Medicare expenditures and meeting performance standards on quality of care by sharing the savings with Medicare. Medicare has 33 quality measures. Six are specific to the chronic disease diabetes:

- 1. ACO 22: Diabetes Mellitus: hemoglobin A1C control (<8%).
- 2. ACO 23: Diabetes Mellitus: low density lipoprotein control (<100mg/dL)
- 3. ACO 24: Diabetes Mellitus: high blood pressure control (<140/90)
- 4. ACO 25: Diabetes Mellitus: tobacco non-use
- 5. ACO 26: Diabetes Mellitus: daily Aspirin use with patients with diabetes and ischemic vascular disease.
- 6. ACO 27: Diabetes Mellitus: hemoglobin A1C poor control (>9%) (CDC, 2013).

The Shared Medical Appointment has the potential to have a positive impact on these measures. This project explored the feasibility and efficacy of the SMA as a potential costeffective approach to care of patients with diabetes before implementing this approach organizational wide.

#### **Purpose and Goals**

The purpose of this project was to determine the efficacy and the feasibility of implementing a SMA in a rural private practice that is associated with an ACO. The objectives of the project were to:

- Develop an evidence based protocol for the implementation of a SMA at a rural clinic for patients with diabetes,
- 2. Evaluate the implementation of the SMA over a 10-month period relevant to:
  - a. Participant outcomes related to diabetes,
  - b. Implementation process, and
  - c. Analysis of cost benefit.

#### **PICOT Question**

An interventional PICOT (population, intervention, comparison, outcome and time) question was developed to assist in discovering the best evidence to evaluate the efficacy and feasibility of implementing the SMA. The PICOT question was: In patients with Type II DM in a rural primary care private practice setting, how does a SMA compared to monthly diabetic group education and traditional office visits affect 6 CMS diabetic reportable measures over a tenmonth period.

In order to ensure clarity of the concepts related to the formation of the PICOT question, definitions are provided. Patients with type II diabetes were defined as people over the age of 18 who have a chronic condition where the body either resists the effects of insulin or does not produce enough insulin to maintain normal glucose levels. The second group for comparison, the Diabetic Education Group (DGE), consisted of participants of a one-hour diabetes educational class monthly. Patients attending the DGE who had type I diabetes were excluded from the

analysis. Lastly the traditional office visit participant is defined as a person over the age of 18 with type II diabetes who regularly sees a primary care provider for the management of diabetes.

#### **Guiding Framework**

Two frameworks were used to guide the development, implementation, and evaluation of this project. First, The Chronic Care Model provided insight into the factors that contribute to the management of diabetes. This model provided perspective on the essential components necessary for the SMA to successfully contribute to the patient's transformation from a passive recipient of healthcare into an informed activated patient through a development of a proactive team creating an environment conducive to productive interactions (Stellefson, Dopnarine, & Stopka, 2013). Second, The Iowa Model, an evidence based practice framework, guided the process of the project. This model provided a team based approach from the literature review to the dissemination of the results with check points along the way that questioned feasibility of the project (Titler et al., 2001).

#### **Review of the Evidence**

A literature search was conducted utilizing CINAHL, PubMed, Ovid, and the Cochrane Library databases. A total of 38 articles were reviewed for relevance to the PICOT question. Criteria for inclusion of articles for the final review were that implementation of SMA was tested and the evaluation of the intervention focused on health outcomes relevant to diabetes such as HgA1C, fasting blood glucose, blood pressure, cholesterol, weight, and body mass index. Fifteen research articles met the criteria.

The review of these articles generated mixed results in the application of the SMA on clinical outcomes. Several of the reports addressed the outcome of A1C. Sanchez (2011) and Trento et al. (2005) reported no change in the SMA participants' A1C levels. Trento et al. (2005)

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accounts for this finding as the focus of the group visits were primarily on lifestyle issues whereas the other studies, conducted by the same author, the SMA focused on self-care management. Sanchez's (2011) implementation of the SMA was from September to November 2009, which leads to questions related to adequacy of the time period in changing clinical outcomes. Trento et al. (2001, 2002, 2004, 2010) reported no decrease in participants' A1C levels but that the levels remained stable over the course of the studies. Although this is not a documented improvement, it could be argued that the SMA should be credited in hindering the natural progression of the diabetes disease process and therefore a significant finding. Clancy et al. (2003) reports a decrease in the A1C levels but not at significant levels. Cohen et al. (2011), Dontje et al. (2011), Gutierrez et al. (2011), Jesse et al. (2012), and Kirsh et al. (2007) all identified significant improvements in participants' A1C levels related to the implementation of SMAs.

Cohen et al (2011), Riley et al (2010), Sanchez (2011), Taveira et al (2010) and Trento et al (2002, 2004, 2005) found no significant improvements in weight reduction and/or lipid levels. The exception is the findings of Trento (2010) which measured outcomes over four years. The longer timeframe potentially accounts for this finding. Table one summarizes the recommendations for practice based on evidence in the implementation of the SMA.

# Table 1. Recommendations for Practice in the Implementation of a SMA

<b>Based on the Critical Review of the</b>	Literature
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	Recommendation	References	Level of Evidence*
		Trento et al.	
		(2001, 2002, 2004, 2010)	II
	Implementation of the SMA for	Jesse et al (2012)	111
	patients with diabetes	Cohen et al (2011)	111
	patients with diabetes	Kirsh et al (2007)	111
		Dontje et al (2011)	IV
		Gutierrez et al (2011)	IV
	Proactive integrated professional	Clancy et al (2003)	П
	teamwork approach to include	Kirsh et al (2007)	111
	Nurse practitioner, dietician,	Sanchez et al (2011)	
		Dontje et al (2011)	IV
Intervention Related	behaviorist, medical assistant and	Gutierrez et al (2011)	IV
	receptionist.	Noffsinger (2013)	VII
		Kirsh et al (2007)	111
		Sanchez et al (2011)	IV
	6-8 patients per SMA	Dontje et al (2011)	IV
		Gutierrez et al (2011)	IV
		Noffsinger (2013)	VII
	Utilized standardized script for	Clancy et al (2003)	П
	MAs for invitation to SMA	Noffsinger (2013)	VII
	Require patient & Support person	Clancy et al (2003)	II
	Informed/Confidentiality consent	Dontje et al (2011)	IV
	prior to each SMA	Sanchez et al (2011)	IV
		Noffsinger (2013)	VII

	Recommendation	References	Level of Evidence		
	ACO 22 (GPRO DM-15): Composite	SMA Demonstrates ability to decrease A1C:	ICSI Guideline: HgA1C <8%		
	(All or Nothing Scoring): Diabetes Mellitus: Hemogolobin A1c Control (<8%)	Trento et al. (2001, 2002, 2004, 2010) Jesse et al (2012) Cohen et al (2011) Kirsh et al (2007) Dontje et al (2011)	              V		
	ACO 23 (GPRO DM-14): Composite (All or Nothing Scoring): Diabetes	Trento et al. (2010)	11		
	Mellitus: Low Density Lipoprotein (LDL-C) Control <100mg/dL	Kirsh et al (2007)	Ш		
Outcome Related	ACO 24 (GPRO DM-13): Composite (All or Nothing Scoring): Diabetes	SMA Demonstrates ability to decrease BP	ICSI Guideline: BP < 140/90		
	Mellitus: High Blood Pressuer	Trento et al (2010)	=		
	Control < 140/90	Taveria et al (2010)	II		
		Cohen et al (2011)	III		
		Kirsh et al (2007)	III		
	ACO 25 (GPRO DM-17): Composite (All or Nothing Scoring): Diabetes Mellitus: Tobacco Non-Use	ADA Guidelines			
	ACO 26 (GPRO DM-16): Composite (All or Nothing Scoring): Diabetes Mellitus: Daily Aspirin or Antiplatelet Medicatation Use for Patients with Diabetes and Ischemic Vascular Disease	ADA Gui	idelines		
I - Systematic review/meta- Expert Opinion (MeInyk & Fi	analysis of Random Control Trials (RCTs), nehoult, 2011)	II - RCTs, III - Non-RCTs, IV - Cohort S	itudy or Case Control Study, VII -		

Methods

## **Project Design**

This practice improvement project involved the implementation of SMAs over ten-

months as a pilot for a multi-specialty physician owned group. Data were collected from June

2014 to March 2015. SMAs were evaluated for effectiveness as compared to traditional office

visits for diabetes and group diabetic education participants using the six Medicare ACO diabetic measures previously discussed.

#### **Setting/Population**

NOMS Healthcare is a multispecialty physician group that provides care for patients in six counties in Northwest Ohio. This physician group consists of 78 providers, 43 specializing in family medicine or internal medicine.

The SMA was piloted in a rural private practice with patients who have diabetes. This rural clinic is primarily managed by a family nurse practitioner with a collaborating physician onsite one day per week. Even though the practice improvement project utilized ACO diabetic care measures, the SMA was open to all patients with type II diabetes and not limited to ACO beneficiaries. The SMA was not limited to new onset or seasoned patients with diabetes as diversity within the group is recognized to add to the supportive dynamics of the group.

The comparison intervention consisted of two groups of patients. One group was patients from the clinics within the organization who voluntarily participated in a monthly diabetic group education class. The curriculum of these classes provide a wide arrange of topics related to the self-care and diabetes. The classes are facilitated by a nurse practitioner and often have guest speakers on specialized topic such as a podiatrist speaks of foot care, a dietician on food choices, or a social worker presenting the effects of stress on diabetes. The second group was comprised of those patients with diabetes who participated in usual care (office visit) at the same rural clinic implementing the SMA.

#### Intervention

#### **Enlisting Participants**

A diabetic registry for the rural private practice was used to identify participants eligible for an invitation to the SMA. The registry reported 178 patients in this clinic were affected by diabetes with 39 having an A1C greater than 8%. NOMS' diabetic protocols recommend patients with HgA1C above 6.5 percent be seen every 3 months. Thus, all patients with a diagnosis of diabetes with an HgbA1C above 6.5% were invited to the SMA. Identified patients attributed to this rural practice meeting criteria were sent an invitation to join a SMA. The medical assistant made follow-up phone calls to potential SMA patients. The phone call served to answer any questions and to encourage the patient to join the SMA. This process was repeated throughout the 10 months on a routine basis.

#### **The SMA Intervention**

As the SMA was a new approach for providing care staff education was essential. An educational session to share information about the SMA and the proposed process was presented to the staff, allowing sufficient time for discussion. The staff assisting with the SMA along with other interested staff participated in the mock SMA to ensure knowledge of the assigned duties as well as the workflow of the SMA. Individuals were provided with scripts for their role as a mock patient with diabetes. Immediately following the mock SMA, a debriefing was conducted to address any issues in the flow, roles, and responsibilities. Those who participated were asked to provide input into the revisions needed to improve the process. This mock visit enabled the staff to offer suggestions for improvement and empowered them to answer any questions future SMA patients may have on the SMA procedure.

Each SMA was planned for a 90-minute period consisting of pre-visit planning, 45minute check in and private medical exam, with the last 45 minutes addressing individual treatment plans in a group setting. Pre-visit planning included, individualizing folders for participants, reviewing the charts and current lab values, ordering healthy snacks, and preparing a white board with patient name, lab values, and concerns. The receptionist greeted the patients and provided an individualized folder and informed consent form. The medical assistant proceeded with the checking-in of patients and preparing them in for a private medical exam. After the medical exam the participants are reunited with the other participants with discussions and introductions facilitated by the behaviorist (Licensed Social Worker or Registered Dietician). After completion of all the private examinations, the provider joins the group to complete the visit by addressing the listed concerns and laboratory values of each individual patient, adjusting the treatment regimen as necessary. The visit concluded with participants asked to evaluate the visit. The participants were encouraged to continue with this type of appointment for the management of their diabetes and if the participant agreed an appointment for the next SMA was made. Prior to the next SMA a reminder call was made to the participant, as this is the practice of the organization for traditional visits. Table two provides a vision of the flow of the SMA detailing the roles of key team members.

# Table 2. SMA Workflow for Implementation

2-4 Days Prior to the SMA	Pre-visit planning on all scheduled SMA patients
	Reviews chart with DM protocols to ensure all tests are current as well as other protocol elements.
(Medical Assistant)	<ul> <li>If testing needs completed, MA will discuss with provider and notify patient of needed test before visit.</li> <li>Preparation of a large white erase board to include all</li> </ul>
	<ul><li>participant names and lab values, will highlight all abnormal results with red circle.</li><li>MA makes confirmation phone calls to all scheduled</li></ul>
	patients.
Day of Appointment	
First 45 minutes of the SMA	Last 45 minutes of the SMA
6-8 patients arrive checking in with the receptionist with a consent to participate in the SMA being signed prior to each visit.	The provider joins the group after completion of all examinations.
MAs take the first four patients back to exam rooms for a brief private exam, completes vital signs and has patient remove shoes.	♦ The provider with assistance from the facilitator use the white boards to complete the treatment plan (addressing concerns and labs listed on the white board, educating patient on individual concerns and collaborating with the patient on a treatment plan for each individual patient).
The provider performs a medical exam	While the provider is completing documentation, writing out prescriptions or referrals, the behaviorist facilitates discussion among the group.
The behaviorist greets the other 2-4 patients reinforcing HIPAA and confidentiality, explaining the benefits and SMA flow.	The MA will see that the patient gets a copy of the care plan, prescriptions and set up any referrals when applicable.
The behaviorist will also prepare a white board with patient names and one or two concerns the patient has about his/her diabetes.	
After the patient is examined they will be taken to the join the rest of the group.	
The MA will ready the remainder of the patients for their private medical examination while the behaviorist reviews confidentiality, HIPAA, benefits and flow of the SMA as well as listing patient concerns on the white board.	
✤ Group interaction facilitated by the behaviorist.	
At the end of the SMA	After the SMA
The provider formally ends the SMA and leaves the room.	Team meets for debriefing to discuss potential improvements to the SMA
The behaviorist and the MA will stay to clean up the room and answer any logistical questions the patients may have.	

#### **The Debriefing**

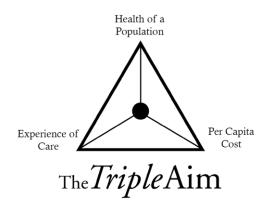
Debriefing was a critical aspect of the project and immediately followed the SMA. The team regrouped to discuss the flow of the SMA with opportunity for all team members to offer suggestions for improving the quality and flow of the visit. These recommendations were documented and integrated into the next SMA as feasible to improve the flow. For example, one debriefing offered the suggestion of changing the facilitator from a Licensed Social Worker to a Registered Dietician, as many participants' insurances do not cover nutritional counseling. This change resulted in increased number of participants in the SMAs with many requesting to return for an appointment before the protocols suggested.

#### Results

#### **Evaluation of Feasibility**

As an ACO, all new initiatives at NOMS Healthcare are evaluated with the Triple Aim Framework in mind (Figure 1). This requires a critical analysis that asks if the new initiative has an impact on improving the patient experience, improving the health of the population and does it contain cost of care. The implementation of the SMA was evaluated with these three domains in mind.





Retrieved from Retrieved http://www.ihi.org/resources/Pages/IHIWhitePapers/AGuidetoMeasuringTripleAim.aspx

#### **Evaluation on the Patient Experience**

Participants of the SMA were asked to complete a patient satisfaction form at check out. Participants rated their experience on a Likert Scale of one to five with the lower end of the scale representing dissatisfaction and a five representing high satisfaction with this type of appointment. Figure one provides a visual of the satisfaction ratings of the patients who participated in a SMA which illustrates high satisfaction of the SMA participants in this alternative type of medical appointment.



Figure 1 Summary of Responses to Patient Satisfaction Survey

#### **Evaluation of Health Measures**

The approach for data analysis considered the group size, and the availability of the outcome measures obtained and recorded on the participants' medical records, and the goal of the ACO to attain specific measurements to qualify for shared savings. A total of 15 patients participated in the monthly SMAs with the number of visits ranging from one to six visits. The recommendations for obtaining the specific outcomes of interest for this population were based on the organizational protocols. For example a patient with an A1c

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above 8% follow-up monthly and above 6.5% follow-up every three months is recommended. Patients also may not have followed up as recommended. Based on these recommendations the outcome data were not consistently available among all participants. Savings for an ACO is based on attainment of specific measurement goals. Consideration of the ACO goals, the small sample size and inconsistencies of obtaining measurements, the outcomes measures were categorized. Categorization of measures were based on meeting the established ACO criteria and if the individual had experienced a change in meeting the criteria. Categories established were: met criteria at baseline and continued to meet criteria, did not meet criteria and continued to not meet criteria, did not meet criteria and changed to have met criteria, and met criteria but changed to not meeting criteria. Nonparametric analysis was used to compare the three groups using these categories.

Significant differences were noted in participants between groups in age, number of visits and baseline HgbA1C. The DGE participants were found to be older and attended a greater number of educational sessions than persons attending a SMA or the traditional office visit. The baseline HgbA1c was found to be lower in the traditional office visit group. No significant differences between the groups were noted in LDL-C, baseline body mass index (BMI), gender or tobacco use. Although gender between groups was not significant the percentage of females to males in the SMA was 66.7% and 33.3% respectively which was a higher proportion of females compared to the other groups. Table 3 provides baseline demographics for each group for comparison.

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Characteristic	SMA	Participa	nts	DGE	Participa	ants	Of	fice Visit		F	Р
	Mean	SD	Ν	Mean	SD	Ν	Mean	SD	Ν		
Age	59.27	14.67	15	66.53	8.94	38	60.76	13.86	164	3.21	0.042
# of Visits	2.2	1.52	15	3.45	2.2	38	2.54	1.17	164	7.155	0.001
Baseline A1C	8	1.26	15	8.08	2.04	37	7.01	1.71	145	6.258	0.002
Baseline LDL-C	112.08	38.37	12	98.5	27.79	34	103.44	36.81	116	0.685	0.506
Baseline BMI	37.22	12.07	15	35.55	7.02	38	33.58	7.37	158	2.234	0.11

#### **Table 3. Demographics of Participants**

	SMA Participants %	DGE Participants %	Office Visit	Contingency	
Characteristic	Within Group	Within Group	Participants % Within	Coefficiency	Ρ
Female/Male	66.7%/33%	45% / 57%	43% / 57%	0.119	0.21
Tobacco Use	20%	16%	11%	0.368	0.472

Blood pressure, A1C, LDL-C, tobacco use and Aspirin use for patients with coexisting diagnosis of diabetes and ischemic vascular disease were analyze as defined by CMS for measure attainment to meet quality reporting. Tables 4 and 5 provides a comparison from baseline to the end of 10-months of SMA and the two comparison groups.

Although not significant, the SMA group participants improved in meeting the measure from baseline BP (16.7%, p = 0.859), A1C (10%, 0.139) and LDL-C (33%, 0.782) with the number of participants changing from not meeting the measurement criteria at baseline to meeting the criteria at end of the practice improvement pilot. An analysis of the nominal level data using Contingency Coefficient indicated there was no significant difference between groups on the change in criteria attainment except for tobacco use. The attainment of the tobacco nonuse measure illustrated a significant difference between groups (P=0.019) with the DGE having more participants not meeting the measure than the SMA and the office visit participants. An analysis of health measures, displayed in Table 5, was performed between genders in an attempt to reveal the reason the DGE would have a higher percentage of patients not meeting the tobacco use measure. The analysis did reveal a higher level of measurement attainment among women but not at a significant level.

110/10	Junuar		Juics	
	BP			Tobacco
	<	A1C	LDL	Use
	140/90	<8.0	<100mg/dl	Non-user
SMA	N =12	N = 10	N = 3	N=8
Not Met No Change	8.3%	30%	33.3%	25.0%
Met with No Change	75.0%	50%	33.3%	75.0%
Changed Not Met to Met	16.7%	10%	33.3%	0%
Changed Met to Not Met	0%	10%	0%	0%
DGE	N = 27	N = 20	N = 10	N=8
Not Met No Change	7.4%	35%	30%	75.0%
Met with No Change	70.4%	50%	50%	25.0%
Changed Not Met to Met	11.1%	15%	20%	0%
Changed Met to Not Met	11.1%	0%	0%	0%
Office Visit	N= 129	N = 88	N = 45	N=57
Not Met No Change	7.8%	11.4%	28.9%	26.3%
Met with No Change	62.0%	69.3%	33.3%	73.7%
Changed Not Met to Met	17.8%	11.4%	20.0%	0%
Changed Met to Not Met	12.4%	8.0%	17.8%	0%
<b>Contingency Coefficient</b>				
Analysis P	0.859	0.139	0.782	0.019

# Table 4. Comparison of Health Measure Changes Between GroupsPre/Post Health Measures

# Table 5. Comparison of Health Measure Changes Between Gender Pre/Post Health Measures

	BP	A1C	LDL	Tobacco Use
	< 140/90	<8.0	<100mg/dl	Non-user
Male	N = 96	N = 66	N = 29	N= 45
Not Met No Change	8.3% (n=8)	18.2% (n=12)	31% (n=9)	37.8% (n=17)
Met with Change	57.3% (n=55)	57.6% (n=38)	37.9% (n=11)	62.2% (n=28)
Changed Not Met to Met	20.8% (n=20)	16.7% (n=11)	20.7%(n=6)	0% (n=0)
Changed Met to Not Met	13.5% (n=13)	7.6% (n=5)	10.3% (n=3)	0% (n=0)
Female	N = 72	N = 51	N = 29	N= 28
Not Met No Change	6.9% (n=5)	15.7% (n=8)	27.6% (n=8)	21.4% (n=6)
Met with Change	73.6% (n=53)	74.5% (n=38)	34.5% (n=10)	78.6% (n=22)
Changed Not Met to Met	11.1% =8)(n	5.9% (n=3)	20.7% (N=6)	0% (n=0)
Changed Met to Not Met	8.3% (n=6)	3.9% (n=2)	17.2% (n=3)	0% (n=0)
Р	0.163	0.186	0.895	0.144

An analysis was also performed to determine whether or not the SMA had an effect on attaining the CMS measure on the percentage of patients with diabetes and IVD who are on Aspirin. This analysis is displayed in Table 6. No significant differences (p = 0.235) was found between groups.

# Table 6. Changes in Status for Criteria of Aspirin Use with Patients with Diabetes andIschemic Vascular Disease Between Groups

Group	Criteria	DX of DM & IVD with ASA Use
SMA - (N=4)	Not Met No Change	50%
Sink (11-4)	Met with No Change Changed Not Met to	50%
	Met Changed Met to Not	0%
	Met	0%
	New DX IVD Not Met	0%
	New DX IVD Met	0%
DGE (N = 3)	Not Met No Change	33.3%
	Met with No Change	33.3%
	Changed Not Met to Met Changed Met to Not	0%
	Met	0%
	New DX IVD Not Met	0%
	New DX IVD Met	33.3%
OV (N= 8)	Not Met No Change	0%
	Met with No Change Changed Not Met to	75%
	Met Changed Met to Not	0%
	Met	0%
	New DX IVD Not Met	0%
	New DX IVD Met	25%
Contingency Coefficient		
Analysis	Value 0.410	P = 0.617

An analysis of BMI between groups was also obtained for two reasons. Most importantly, lowering of one's BMI will improve diabetes and BMI is also a measure the ACO is graded. CMS does not establish goals centered on attaining a certain BMI but grades the ACO on whether or not interventions are documented for individuals with abnormal BMIs. Table 7 illustrates significant changes (P = 0.014) among the comparison of baseline BMI and end of study BMI within the SMA group with a change in BMI (0.27 to -9.91) compared to DGE participants (2.87 to -2.37) and office visit participant (3.25 to -4.38). The significance of these findings are limited considering the small sample size and for this reason no post-hoc analysis was performed.

Group Summary										
Group	Ν	Mean	Std. Deviation	Minimum	Maximum					
SMA	5	2.6329	4.11962	0.27	-9.91					
DGE	9	-0.2701	1.59688	2.87	-2.37					
OV	46	0.1336	1.53521	3.25	-4.38					
Total	60	0.2813	1.95602	3.25	-9.91					
		AN	OVA							
	Sum of Squares	df	Mean Square	F	Sig.					
Between Groups	31.39	2	15.695	4.603	0.014					
Within Groups	194.344	57	3.41							
Total	225.734	59								

 Table 7. BMI Change per Group with Group Comparison (ANOVA)

## **Evaluation of Cost Containment**

The SMA has the ability to increase productivity of the Nurse Practitioner (NP) by allowing eight patients to be scheduled in a 90-minute period compared to the 4.5 in the traditional setting. Table 8 compares the cost/revenue of each type of intervention compared with this practice improvement project.

# Table 8. Cost/Revenue Comparison by Visit Type

		S	MA Ecor	nomic Ev	aluation	÷	· · · ·					Goal # of Participants	Goal # of Participants
Month	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Total	8/SMA	8/SMA (TOTALS)
# of Participants	3	2	4	0	3	6	0	2	2	2	24	8	80
Expenses per visit	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$706.75	\$7,067.50	\$706.75	\$7,068
Expenses per participant	\$235.58	\$353.38	\$176.69	\$0.00	\$235.58	\$117.79	\$0.00	\$353.38	\$353.38	\$353.38	\$2,179.15	\$88.34	\$88.34
Billed per participant	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114			
Revenue Received	\$342.00	\$228.00	\$456.00	\$0.00	\$342.00	\$684.00	\$0.00	\$228.00	\$228.00	\$228.00	\$2,736.00	\$912	\$9,120
Cost of Program	(\$364.75)	(\$478.75)	(\$250.75)	\$0.00	(\$364.75)	(\$22.75)	\$0.00	(\$478.75)	(\$478.75)	(\$478.75)	(\$2,918.00)	\$205.25	\$2,052.50
Total Revenue											(\$182.00)	\$706.75	\$7,067.50
		D	GE Ecor	nomic Ev	aluation								
Month	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Total		
# of Participants	19	17	16	13	11	0	9	11	12	11	119		
Expenses per program	\$277.87	\$277.87	\$277.87	\$277.87	\$277.87	\$0.00	\$277.87	\$277.87	\$277.87	\$277.87	\$2,500.83		
Cost per participant	\$14.62	\$16.35	\$17.37	\$21.37	\$25.26	\$0.00	\$30.87	\$25.26	\$23.16	\$25.26	\$21.02		
Total Revenue											N/A		
			Traditio	nal Offic	e Visit								
Month	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Total		
# of Patients	32	21	18	28	30	26	42	30	41	32	300		
Expenses per 4.5 patients/hour	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00			
Cost per patient	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$16.67	\$5,000.00		
Billed per patient	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114	\$114			
Revenue per patient	\$97	\$97	\$97	\$97	\$97	\$97	\$97	\$97	\$97	\$97			
Revenue Received	\$3,115	\$2,044	\$1,752	\$2,725	\$2,920	\$2,531	\$4,088	\$2,920	\$3,991	\$3,115	\$29,200		
Total Revenue											\$24,200.00		

#### Discussion

The outcomes of the project were related to the Institute for Healthcare Improvement's Triple Aim framework. Patient satisfaction survey indicated that the SMA was successful in improving the patient experience. The key aspects overall visit, social support, understanding of the treatment plan, helpfulness of the nurse practitioner/staff, and ease of getting an appointment were rated as very good to excellent by all of the participants except for one good rating on one question. Responses on the open ended questions on what was liked about the visit included social support and learning from others in the SMA. Several participants attended at least two SMAs demonstrating their preference for this type of visit.

The health outcomes of the pilot implementation of the SMA were in a similar direction as findings reported in the literature. The SMA was able to improve CMS measure attainment from baseline in BP (16.7%, p = 0.859), A1C (10%, 0.139) and LDL-C (33%, 0.782) by changing the number of participants from not meeting the measurement criteria at baseline to meeting the criteria at end of the practice improvement pilot. The improvement did not reach significant levels but coincides with the findings of Cohen et al. (2011), Kirsch, Dontje et al. (2011), Gutierrez et al. (2011), Jesse et al. (2012), Kirsh et al. (2007), Taveira et al. (2010) and Trento et al. (2010). The improvement of measurement attainment for LDL is supported by the findings of Kirsh et al. (2007) and Trento et al. (2010). The significant finding of the decrease in BMI is limited by the sample size and cannot be generalized but indicated a loss in weight for the attendees. The health outcomes of this pilot are compared with outcomes reported in the literature on Table 9.

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The SMA census ranged from two to five patients per SMA with an average of three per SMA. The SMA had the potential to be a cost-effective approach to providing care for patients with diabetes if a minimal census of 8 could have been attained.

Table 9 Pilot SMA Implementation Results Compared with the Literature
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Results Compared with the Literature							
Citation	HgA1C	Weight/ BMI TC		LDL/ HDL	BP	Tobacco	
SMA at NOMS	(ns)	(p= 0.014)	NR	📕 (ns)	(ns)		
Clancy et al., (2003)		NR	NR	NR	NR	NR	
Cohen et al., (2011)		NR	NR			NR	
Dontje et al., (2011)		NR	NR	NR	NR	NR	
Gutierrez et al., (2011)	₽	NR	NR	NR	NR	NR	
Jessee et al., (2012)		NR	NR	NR	NR	NR	
Kirsh et al., (2007)		NR	NR	LDL 👢		NR	
Riley et al., (2010)		NR	NR			NR	
Sanchez, (2011)		NR		LDL 💻	NR	NR	
Taveira et al., (2010)			NR			NR	
Trento et al., (2001)	A1C stable 2 yrs	NR	NR	NR	NR	NR	
Trento et al., (2002)	A1C stable 2 yrs			HDL	NR	NR	
Trento et al., (2004)	A1C 👃 stable 2 yrs		-	HDL	NR	NR	
Trento et al., (2005)					NR	NR	
Trento et al., (2010)	Ļ	Ļ	↓	LDL/HDL	↓	NR	
Wagner et al., (2001)		NR	NR	NR	NR	NR	
NR Not Re	ported 1	Increased	decre	ased 📃	No Change		

#### **Cost/Benefit Comparison between Groups**

Although the SMA did not produce revenue as projected, it was able to improve the attainment of meeting CMS reportable measures that will allow the organization to share in savings with CMS. The cost/benefit analysis is limited in being able to illustrate a savings by the prevention of emergency department visits or the hospitalization of patients lacking skills to self-manage their diabetes. The social support the SMA and DGE participants receive is also a value that cannot be monetarily defined. The SMA also provides patients more time with their provider and the ability to learn how others are managing their diabetes. In contrast, the DGE provides educational topics with limited discussion on the application of self-management skills used by fellow participant and in the traditional office visit time is limited and is often spent managing current needs. The SMA participants are also able to see the impact recommended interventions can have on their diabetes. For example, one patient had a dramatic drop in A1c, when asked by the provider how this goal was accomplished the patient reported no changes in diet but the addition of exercise daily. These exemplary patients maybe the key in helping others achieve their goals.

#### **Limitations of the Practice Improvement**

The evaluation of the SMA implementation revealed limitations such as time, lab value attainment, and number of participants. The evaluation over 10 months limits the evaluation of the SMA when considering sustainability of improvement and dosing of the SMA. Extending the time of the SMA evaluation would provide data that would determine if the frequency of attending a SMA would have a greater impact on outcomes. The second limitation was the varied attainment of baseline to follow-up lab values to evaluate the effectiveness of the SMA. Lastly, the

implementation of the SMA at this clinic was not able to attain a census to increase the productivity of the NP resulting in a cost to provide this type of appointment.

#### Models Guiding the Implementation and Evaluation of the SMA

The integration of The Chronic Care Model and the Iowa Model of Evidence-Based Practice to Promote Quality Care (EBPPQC) effectively provided a framework for the project. The Chronic Care Model's focus is that of a prepared proactive team helping to empower patients to self-manage their diabetes by connecting them with self-management and decision support needed to transform them into an informed, activated patient (Fiandt, 2006). The SMA offered patients the social support (learning from peers) and tools (knowledge gained from dietician) to help support daily decisions that lead to improved outcomes. These concepts were themes the patient satisfaction survey detected.

The Iowa Model provided the framework for implementation encompassing the literature review for determining the evidence through the evaluation of the project. The Iowa Model of EBPPQC was chosen as it highlighted an interdisciplinary team approach with seven steps to implementing a quality improvement process. This is a linear process that is complicated by feedback loops. The feedback loops accentuate needed adjustments to the project required to produce optimal outcomes for the unique healthcare setting the intervention was being implemented (Melnyk & Fineout-Overholt, 2011). The debriefings after each SMA became the feedback loops. The staff would discuss successes and challenges encountered with each visit. For example, one debriefing resulted in a change in facilitator from a social worker to a registered dietician. The team approach advocated in the Iowa Model was essential in the implementation with recognizing the value each team member could offer to the continual improvement of the SMA.

#### **Barriers to Implementation and Evaluation of the SMA**

Barriers were identified before implementing the SMA in attempts to offset the barriers with facilitators. Potential barriers identified before the implementation were an electronic medical record (EMR) that was not capable of producing accurate registries and data sets and patient buy-in. Plans to convert to another EMR system compounded the problems with data extraction due to difficulties with migration of data from original EMR to new EMR. This resulted in the need to manually extract data from the EMR by medical home advocate (LPNs). The conversion to a new EMR occurred during the pilot which put the office in a state of chaos. This was an unanticipated barrier to the SMA pilot.

The second barrier to implementation was patient buy-in. Marketing material such as invitational letters explaining the SMA, posters advertising and scripts for the front office to assist in answering questions of potential SMA participants was prepared. Patient buy-in may have been affected by the small community of which the SMA was implemented. Fear of sharing the appointment with others they may know as well as the culture of a rural community may have played a role in the inability to obtain a census that would support the continuation of the SMA. The staff and provider attempted to correct the inadequate census by encouraging patients to attend. Selecting patients to encourage attendance of a SMA is problematic with potential of a Hawthorne effect.

Initial thoughts of piloting the SMA in a small rural practice with one provider was that it would be a facilitator to the implementation of the SMA. The size of the office proved to be an unanticipated barrier to implementation of the SMA as the recommended census of eight patients per SMA was not ever attained.

#### **Feasibility of Implementation**

Prior to implementing the SMA, staff was provided with the workflow and a mock SMA and debriefing was conducted. The mock SMA provide the staff confidence in their ability to implement the SMA in an efficient manner. The debriefing empowered the staff to take ownership of the practice improvement by allowing them the opportunity to voice concerns and offer suggestions for improving the workflow of the SMA. The debriefing continued after each SMA. Changes made as a result of the debriefing were time the appointment was offered from first appointment to last appointment before lunch and changing the credentialed facilitator from a social worker to a dietician. The changes made as a result of the debriefings did produce a spike in the census up to five patients but was unable to be sustained. Marketing material for patients provided another avenue to explain the benefits of the SMA. The EMR conversion was thought to improve the organizations ability to generate reports however this was complicated by the poor migration of data from the previous system resulting in the need to manually extract data.

#### Recommendations

The literature supports the SMA as an effective way to provide care for patients with diabetes yet identifies a gap in the process. This project provided insight into the process of implementation of a SMA. Recommendations for implementation of the SMA were developed based on the outcomes of the project that include evaluation of the setting and timing of SMA, tool kit for implementation and continuous process improvement plan.

#### **Evaluation of Setting and Timing of the SMA**

Evaluation of the setting for a potential SMA is critical to the success of this type of appointment. The evaluation should take into consideration the patient base to ensure there are adequate numbers of patients with diabetes to attain a census of eight patients per SMA as seven is the minimum for the SMA to be cost effective. It is imperative that the setting also be able to accommodate up to 16 people as family support is encouraged. Conducting the SMA in the waiting room in order to comfortably sit up to 16 people will limit scheduling possibilities at the end or beginning of workday to avoid patient traffic in order to protect the privacy of SMA patients. Consideration into the timing of the appointment should take into consideration the population's needs. Morning appointments may limit who can participate due to work commitments.

#### The Toolkit

Preparing a toolkit prior to implementing a SMA will help staff transition to this by giving them the confidence in orchestrating this type of visit. The tool kit prepared prior to implementing the SMA included marketing material, educational material for patients and educational material for staff. Marketing material prepared for the implementation included an invitation to potential participants and posters advertising the benefits of this type of appointment. Folders were also created for each patient that included educational materials on diabetes and worksheets to record personal health information to track improvements in health indicators. Educational material was prepared for staff that included workflow of the appointment with defined roles for each team member. Case studies were prepared that voluntary staff used to present themselves as mock patients attending a SMA. A mock SMA appointment was conducted with a debriefing following to allow the staff an opportunity to ask questions and to suggest improvements in workflow.

#### **Continuous Process Improvement**

Often those implementing practice improvement projects forget the importance of clinical significance and over emphasize statistical significance. Although statistical analysis is vital to the evaluation of a project, it is not a research project and the team implementing should not be discouraged at not finding statistically significant improvements in the data analysis as a result of the intervention. Instead of discounting the results, an analysis of the clinical significance of the effect of the intervention should be conducted. Kazdin (1999) defines clinical significance as the practical, applied value or importance of the effect of the intervention. The SMA demonstrated the ability to have a positive affect on participants' ability to self-manage the disease process which is consistent with what was found in the literature.

Continuous process improvement also took into consideration the patient satisfaction surveys and debriefings after each SMA. The patient satisfaction surveys did not reveal any area's in need of improvement. The debriefings exposed a need for different type of facilitator. Initially the SMA employed a licensed social worker as the facilitator. During one debriefing a staff member suggested the idea of utilizing the registered dietician as the facilitator since not all insurance cover nutritional counseling. This did result in an increase in the number of participants of the SMA. Lastly the length of time needed to note change and the effectiveness of the change should be over a minimum of one year. This would facilitate ample collection of data to determine efficacy of the program.

#### Conclusion

The rapid progression of the diabetes epidemic requires an efficient manner in which we care for those affected, ensuring those affected by the disease have the capabilities to care for themselves and become engaged patients. The Chronic Care Model guided the development of this project to seek the feasibility and effectiveness of the SMA. The literature supports this alternative to the traditional office visit as an effective way to treat those with diabetes. However as an ACO, a practice improvement project must consider the patient experience, the health of the population and the cost-effectiveness of the initiative. Implementation of this project needed to be effective in all areas of the Triple Aim. Although patient satisfaction with the SMA was high the deficiencies of the SMA to produce significant health outcomes and to be a cost effective approach to providing care to patients with diabetes does not support its continuation in a small rural clinic. Evaluation of the clinic setting for size of population and environment will ensure an adequate census can be obtained and accommodated comfortably. Further studies on the sites that have successfully implemented a SMA could prove useful to those wishing to implement a thriving SMA.

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This Addendum was developed to supplement the manuscript to address the items on the guideline for the DNP project in more depth. The addendum includes content that was part of the project proposal yet have been updated to reflect the current status of the project. Sections related to the process as presented in The Iowa Model are labelled in each section.

### **ACO Diabetic Health Measures**

ACO clinical measures were used to evaluate the effectiveness of the SMA for patients with diabetes. Table one provides a specific measurement approach that was proposed for the purpose of evaluating the SMA. This approach included an analysis based on the number of visits attended due to clinical protocols that suggest patients with an A1C over 8% return monthly and above 6.5% every three months. Unfortunately the sample size did not allow for an evaluation of SMA dosing and health outcomes.

 Table 1. ACO Diabetic Health Measures

Evaluation Component	Measurement Approach for ACO Reporting	Measurement Approach for the Purpose of this Project
ACO 22 (GPRO DM-15) (NQF #0729): Composite (All or Nothing Scoring): Diabetes Mellitus:	Chart review or sequel report to extract data with criteria as required by CMS:	Chart review or sequel reports will be used to extract data with the following criteria
HemoglobinA1cControl (<8%)	<b>DESCRIPTION:</b> Percentage of patients ages 18 to 75 years of age with diabetes mellitus who had HbA1c 8.0 percent <b>DENOMINATOR:</b> Patients 18 to 75 years of age with a diagnosis of diabetes mellitus with two or more face-to-face visits for diabetes in the last two years and at least one visit for any reason in the last 12 months	DESCRIPTION: Percentage of patients ages 18-75 years of age with diabetes who had an HbgA1C <8% before implementation/participation of the SMA and Group Education Percentage of patients ages 18-75 years of age with diabetes who had an HbgA1C <8% after

	EXCLUDED FROM PERFORMANCE DENOMINATOR POPULATION: • Diagnosis of polycystic ovaries, gestational diabetes or steroid induced diabetes NUMERATOR: Patients with most recent hemoglobin A1c < 8.0 percent (RTI International, 2013, p. 41)	<ul> <li>implementation/participation of the SMA and Group Education</li> <li>Participation levels <ul> <li>6 appointments or educational classes</li> <li>3-5 appointments or educational classes</li> <li>&lt;3 appointments or educational classes</li> </ul> </li> </ul>
ACO 23 (GPRO DM-14) (NQF #0729): Composite (All or Nothing Scoring): Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control	Chart review or sequel report to extract data with criteria as required by CMS: DESCRIPTION: Percentage of patients ages 18 to 75 years of age with diabetes mellitus who had LDL-C 100 mg/dL DENOMINATOR: Patients 18 to 75 years of age with a diagnosis of diabetes mellitus with two or more face-to-face visits for diabetes in the last two years and at least one visit for any reason in the last 12 months EXCLUDED FROM PERFORMANCE DENOMINATOR POPULATION: • Diagnosis of polycystic ovaries, gestational diabetes or steroid induced diabetes NUMERATOR:	Chart review or sequel reports will be used to extract data with the following criteria DESCRIPTION: Percentage of patients ages 18-75 years of age with diabetes who had an LDL-C < 100 mg/dL before implementation/participation of the SMA and Group Education Percentage of patients ages 18-75 years of age with diabetes who had an LDL-C <100 mg/dL after implementation/participation of the SMA and Group Education • Participation levels • 6 appointments or educational classes

	Patients with most recent low density lipoprotein < 100 mg/dL (RTI International, 2013, p. 44)	<ul> <li>3-5 appointments or educational classes</li> <li>&lt;3 appointments or educational classes</li> </ul>
ACO 24 (GPRO DM-13) (NQF #0729): Composite (All or Nothing Scoring): Diabetes Mellitus: High Blood Pressure Control	Chart review or sequel report to extract data with criteria as required by CMS: DESCRIPTION: Percentage of patients ages 18 to 75 years of age with diabetes mellitus who had a blood pressure 140/90 mmHg DENOMINATOR: Patients 18 to 75 years of age with a diagnosis of diabetes mellitus with two or more face-to-face visits for diabetes in the last two years and at least one visit for any reason in the last 12 months EXCLUDED FROM PERFORMANCE DENOMINATOR POPULATION: • Diagnosis of polycystic ovaries, gestational diabetes or steroid induced diabetes NUMERATOR: Patients with most recent	Chart review or sequel reports will be used to extract data with the following criteria DESCRIPTION: Percentage of patients ages 18-75 years of age with diabetes who had a blood pressure < 140/90 before implementation/participation of the SMA and Group Education Percentage of patients ages 18-75 years of age with diabetes who had a blood pressure < 140/90 after implementation/participation of the SMA and Group Education
	blood pressure <140/90 mmHg (RTI International, 2013, p. 47)	<ul> <li>classes</li> <li>&lt;3 appointments or educational classes</li> </ul>

ACO 25 (GPRO DM-17) (NQF #0729): Composite (All or Nothing Scoring): Diabetes Mellitus: Tobacco Non-Use •	Chart review or sequel report to extract data with criteria as required by CMS: DESCRIPTION: Percentage of patients ages 18 to 75 years of age with a diagnosis of diabetes who indicated they were tobacco non-users DENOMINATOR: Patients 18 to 75 years of age with a diagnosis of diabetes mellitus with two or more face-to-face visits for diabetes in the last two years and at least one visit for any reason in the last 12 months EXCLUDED FROM PERFORMANCE DENOMINATOR POPULATION: • Diagnosis of polycystic ovaries, gestational diabetes or steroid induced diabetes NUMERATOR: Patients who were identified as non-users of tobacco	Chart review or sequel reports will be used to extract data with the following criteria DESCRIPTION: Percentage of patients ages 18-75 years of age with diabetes who indicated they were tobacco non-users before implementation/participation of the SMA and Group Education Percentage of patients ages 18-75 years of age with diabetes who indicated they were tobacco non-users after implementation/participation of the SMA and Group Education • Participation levels • 6 appointments or educational classes • 3-5 appointments or educational classes • <3 appointments or educational classes
ACO 26 (GPRO DM-16) (NQF #0729): Composite (All or Nothing Scoring): Diabetes Mellitus: Daily Aspirin or Antiplatelet	Chart review or sequel report to extract data with criteria as required by CMS:	Chart review or sequel reports will be used to extract data with the following criteria
Medication Use for Patients with Diabetes and Ischemic Vascular Disease	<b>DESCRIPTION:</b> Percentage of patients ages 18 to 75 years of age with diabetes mellitus and ischemic vascular disease with documented daily	<b>DESCRIPTION:</b> Percentage of patients ages 18- 75 years of age with diabetes and ischemic vascular disease with documented daily aspirin or antiplatelet medication use

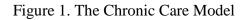
aspirin or antiplatelet medication use during the measurement year unless contraindicated <b>DENOMINATOR:</b> Patients 18 to 75 years of age with a diagnosis of diabetes mellitus with two or more face-to-face visits for diabetes in the last two years and at least one visit for any reason in the last 12 months and a diagnosis of ischemic vascular disease <b>EXCLUDED FROM</b> <b>PERFORMANCE</b> <b>DENOMINATOR</b> <b>POPULATION:</b> • Diagnosis of polycystic ovaries, gestational diabetes or steroid induced diabetes (Exclusion only applied if patient was not prescribed daily aspirin or antiplatelet medication) • Documentation of medical reason(s) for not prescribing daily aspirin or antiplatelet medication <b>NUMERATOR:</b> Patients with the diagnosis of diabetes and ischemic vascular disease with documentation of taking daily aspirin or antiplatelet medication or have a documented contraindication in the measurement year	before implementation/participation of the SMA and Group Education Percentage of patients ages 18- 75 years of age with diabetes and ischemic vascular disease with documented daily aspirin or antiplatelet medication use after implementation/participation of the SMA and Group Education • Participation levels • 6 appointments or educational classes • 3-5 appointments or educational classes • <3 appointments or
(RTI International, 2013, p. 52)	

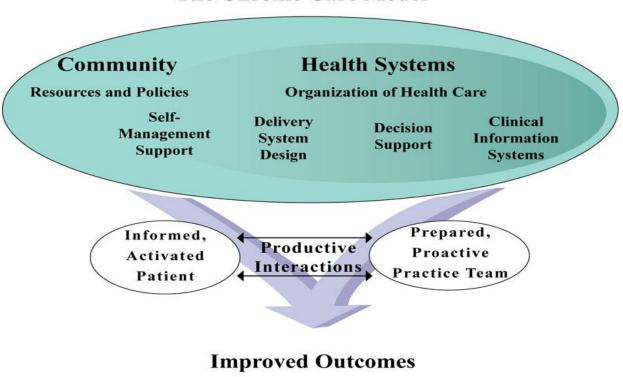
ACO 27 (GPRO DM-2)	Chart review or sequel	Chart review or sequel reports	
(NQF #0059): Diabetes	report to extract data with	will be used to extract data	
Mellitus: Hemoglobin A1c	criteria as required by CMS:	with the following criteria	
Poor Control			
	DESCRIPTION:	DESCRIPTION:	
	Percentage of patients	Percentage of patients ages	
	aged 18 through 75 years	18-75 years of age with	
	with diabetes mellitus who		
	had most recent	HbgA1C >9% before	
	hemoglobin A1c greater	implementation/participation	
	than 9.0%	of the SMA and Group	
	DENOMINATOR:	Education	
	Patients aged 18 through		
	75 years with the diagnosis	Percentage of patients ages	
	of diabetes	18-75 years of age with	
	EXCLUDED FROM	diabetes who had an	
	PERFORMANCE	HbgA1C >9% after	
	DENOMINATOR	implementation/participation	
	POPULATION:	of the SMA and Group	
	• Diagnosis of polycystic	Education	
	ovaries, gestational		
	diabetes or steroid induced	Participation levels	
	diabetes	<ul> <li>6 appointments or</li> </ul>	
	NUMERATOR:	educational classes	
	Patients with most recent	<ul> <li>3-5 appointments</li> </ul>	
	hemoglobin A1c level >	or educational	
	9.0%	classes	
		<3 appointments	
	(RTI International, 2013,	or educational	
	p. 54)	classes.	
	<b>■</b> * * /	CHUDDOD	

#### **Models Guiding the Project**

### The Chronic Care Model

The Chronic Care Model (CCM), created by Wagner, was the model chosen to illustrate needed components to successfully engage the patient in a partnership of care that will improve health outcomes. The CCM was initially designed to restructure medical care by creating partnerships between health systems and communities (Stellefeson, Dipnarine, & Stopka, 2013). This model has been adapted from use in community health to more recent application in primary care and chronic disease management. This adaptation calls for the restructuring of medical care to create a partnership between the health care team and the patient. The CCM is presented in Figure 1. Six essential interrelated elements comprise the CCM; health system, community, selfmanagement support, decision support, delivery system design, and clinical information systems. Figure 1 illustrates how these essential elements of the CCM produce interactions between the patient and the practice team that promotes patient engagement in his/her healthcare resulting in improved health outcomes.





# **The Chronic Care Model**

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The CCM highlights the importance of linking health systems and community resources to provide the tools necessary for the patient to become engaged in his/her healthcare. Health systems refers to the support from health care leaders in committing to a change in practice that utilizes all staff to the fullest potential within the scope of practices. NOMS' Healthcare administration is committed to providing care that is centered on an interdisciplinary team working to their fullest ability to provide best practices of care for all patients. Community resources and policies are concerned with connecting the patient with community tools/programs to assist in self-care (retrieved from http://improvingchroniccare.org). Self-management support focuses on the linking patients with the necessary resources and knowledge to managing their chronic disease. The SMA could be the vehicle that provides patients with diabetes the self-management support needed to effectively manage the disease. Delivery system design assures care that is proactively focused on preserving health rather than a system focused primarily on emergent care. The design of the SMA supports a proactive approach to care with previsit planning and use of a multidisciplinary team that offers a variety of proactive treatment plans. This system provides patients understandable information and promotes health literacy. Decision support promotes clinical care that is based on evidence and patient preferences. Clinical information systems utilize a comprehensive clinical information system to enhance patient care through the use of automated reminder systems, patient registries, and performance monitoring of the health system (retrieved from http://improvingchroniccare.org). NOMS electronic medical records (EMRs) have the capabilities to provide the team with a diabetes disease registry. This registry was used to reach out to patients with diabetes who could benefit from the SMA as well as

monitor the effects the SMA had on health outcomes. Unfortunately the organization converted to a new EMR system that resulted in poor data migration and the need for manual extraction of the health measures used to evaluate the SMA.

The CCM enhanced the implementation of the SMA through the incorporation of the various aspects of the model. As diabetes is a chronic condition, the use of the model illustrated the necessity of community resources and health systems to work in conjunction to provide self-management support, delivery system design, decision support, clinical information systems to produce interactions between the activated patient and the practice team to achieve optimal health outcomes. Permission to use the CCM was obtained and is presented as Figure 2.

## Figure 2. Permission to Use Chronic Care Model

AMERICAN COLLEGE OF PHYSICIANS INTERNAL MEDICINE | DOCTORS for Adults

WAECP1418376

May 26, 2015

Becky Rohrbach, CNP

Dear Ms. Rohrbach;

Thank you for your request to print the following from *Effective Clinical Practice*:

Figure 1: Wagner EH, Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? Effective Clinical Practice, 1998, Vol1

Permission is granted to print the preceding material with the understanding that you will give appropriate credit to *Effective Clinical Practice* as the original source of the material. Any translated version must carry a disclaimer stating that the American College of Physicians is not responsible for the accuracy of the translation. This permission grants non-exclusive, worldwide rights for this edition in print for not for profit only. ACP does not grant permission to reproduce entire articles or chapters on the Internet unless explicit permission is given. This letter represents the agreement between ACP and Becky Rohrbach, CNP for request WAECP1418376 and supersedes all prior terms from the requestor. The Annals of Internal Medicine wants to encourage users to go to the original article on the website for scientific integrity, in the event there are retractions and corrections.

Thank you for your interest in Annals of Internal Medicine. If you have any further questions or would like to discuss the matter further, please contact me at 856-489-8555 or fax 856-489-4449.

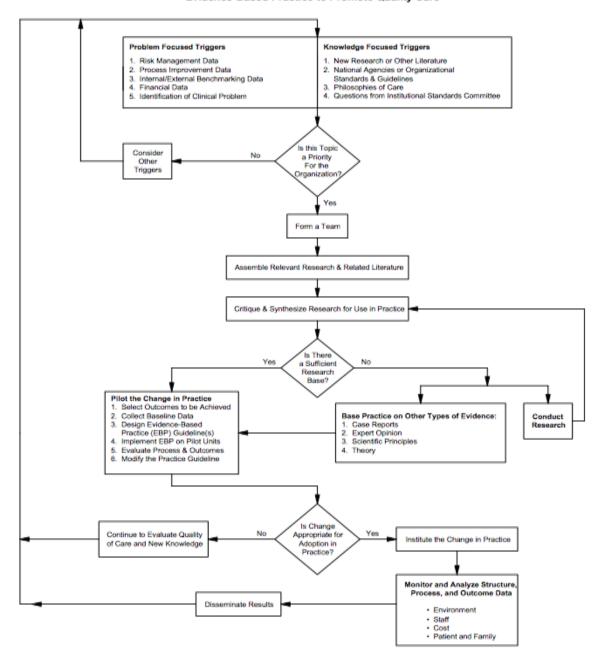
Sincerely,

Gina Brown Permissions Coordinator

### The Iowa Model

Gawlinski and Rutledge (2008) present four considerations when choosing a model: 1) ease of use, 2) model provides direction when evidence is insufficient for practice change, 3) similarity of the flow of model to practice flow, and 4) opportunity in the model for decision points for reflection and decision making (pg. 298). The Iowa Model of Evidence-Based Practice to Promote Quality Care (EBPPQC), figure 3, met these four criteria for the implementation of this project for the selected setting. The Iowa Model of EBPPQC was chosen as it highlighted an interdisciplinary team approach with seven steps to implementing a quality improvement process. This is a linear process that is complicated by feedback loops. The feedback loops accentuate needed adjustments to the project required to produce optimal outcomes for the unique healthcare setting the intervention is being implemented (Melnyk & Fineout-Overholt, 2011). The successful implementation of the SMA required the interdisciplinary team to evaluate and adjust the delivery of care for optimal outcomes throughout implementation.

### Figure 3. The Iowa Model of Research-Based Practice to Promote Quality Care



The lowa Model of Evidence-Based Practice to Promote Quality Care

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The steps of the Iowa Model are briefly reviewed with further explanation of the steps that were applied to the implementation of the practice improvement project. The first step was to identify a trigger. Diabetes is at an epidemic level with a cost burden no longer affordable. Providers have limited time to give patients all the tools necessary to manage their chronic disease. The SMA offered an alternative intervention that would give the provider more time with the patients facing the challenges of managing their diabetes. Because the goal of an ACO is to improve care while containing cost the implementation of the SMA was determined by NOMS to be an initiative of priority for the organization. Therefore the process continued with the formation of a team, the second step of the model. The team members for this project included all office staff, a nurse practitioner, and a social worker or a dietician who served as the facilitator of the SMA. The third and fourth step of the model was to assemble and critique the research and related literature. After achieving a saturation of reviewed literature another decision was to be made; did the literature support the proposed change to practice? The review of literature supported the implementation of the intervention, piloting the change in practice became the next step of the process. Step five, piloting the change required the team to select desirable outcomes, collect baseline data, design EBP guidelines, implement the project at one clinic, evaluate the process and outcomes, and to modify the practice guideline as needed (Titler et al., 2001). The results of this step lead the team to another decision point as to whether or not to institute the change in practice. Step six, a decision to institute the change into practice would require the team continue to monitor for sustainability of the process and the achieved outcomes. The last step of the process,

step 7, requires the results to be disseminated in order to ensure best practices are

achieved.

Figure 4. Permission to Use The Iowa Model

Rebecca Rohrbac	h	
From:	noreply@qemailserver.com	
Sent:	Tuesday, November 12, 2013 3:16 PM	
То:	rrohr@no-ms.com	
Subject:	Permission to Use and/or Reproduce The Iowa Model	

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The Iowa Model

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If you have questions, please contact Kimberly Jordan at 319-384-9098 or kimberly-jordan@uiowa.edu.

#### Literature Review and Establishing the Evidence

#### Steps 3 and 4 of Iowa Model: Review/Critique of Literature

Following the identification of the clinical problem and the formation of a project team the Iowa Model guides the process to complete the critical review and synthesis of the literature. The process of the literature review aspect of this project followed the following sequence: literature search, appraisal of the evidence, synthesis of guidelines, identification of the level of evidence supporting the SMA, gaps in clinical knowledge, and recommendation for practice. Each of these components will be presented as part of the literature review.

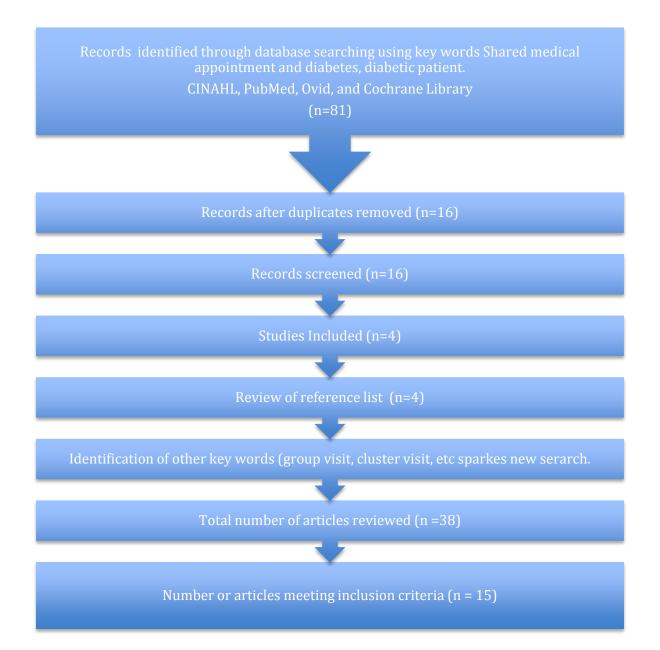
A literature search was conducted utilizing CINAHL, PubMed, Ovid, and the Cochrane Library databases. A combination of keywords from the PICOT question were employed, including diabetes, diabetic patients, shared medical appointments (SMA), and group medical appointments. Boolean connector "AND" was utilized to yield a more manageable amount of articles that contained a combination of the above key words due to the large amount of articles retrieved when searching the single term diabetes. Inclusion criteria selected were: current articles with publication date after 2002, English language, and studies limited to shared-medical appointments and diabetes. Exclusion criteria are articles published before 2002. Limits placed in the search process were: peer reviewed and research studies, all languages except English were excluded from the search and dates of publication were set. Due to the low volume of results the peer reviewed and research studies limit was retracted.

CINAHL was the initial database queried. The keywords used were shared medical appointment, group medical appointment, diabetes, and diabetic patient. A total

SMA MANUSCRIPT

of 30 results were captured. The second database searched was PubMed using the same key words. Twenty-three articles were elicited. Thirdly, the Ovid database was explored using the same keywords resulting in 16 hits. Lastly the Cochrane Library was searched and resulted in two hits. Summarization of the search strategy is provided in Figure 5 and summarization of the results is presented in Table 2. The search of these databases resulted in a total of 81 hits. Removal of duplicate entries produced 16 records for screening. Quick review of the articles' reference list and body elicited other key words such as group visits and cluster visits. CINAHL, PubMed, Ovid, and the Cochrane Library databases were searched again using these new key words extracted an additional 22 articles. A total of 38 articles were assessed for relevance to the PICOT question. Inclusion criteria for utilization of articles were the implementation of SMA (group visits) and the evaluation of the intervention on health outcomes such as HgA1C, fasting blood glucose, blood pressure, cholesterol, weight, and body mass index. Fifteen research articles met the criteria.

# **Figure 5. The Search Strategy**



Date of	Keywords	Database/Source	Listed # of	Reviewed
Search	Used	Used	Hits	
2/8/13	Diabetes	CINAHL	22	11
	"AND"			
	SMA			
2/8/13	Diabetic	CINAHL	6	2
	Patient			
	"AND SMA			
2/8/13	Diabetes	CINAHL	2	2
	"AND"			
	GMA			
2/8/13	Diabetes	PubMed	13	11
	"AND"			
<b>a</b> /0 / <b>1 a</b>	SMA	D 1) ( 1		
2/8/13	Diabetic	PubMed	10	2
	patients			
	"AND"			
	SMA "OR"			
2/8/13	GMA	OVID	12	11
2/8/13	SMA "AND"	OVID	13	11
	Diabetes			
2/8/13	GMA	OVID	3	1
2/0/13	"AND"	UVID	5	1
	Diabetes			
2/8/13	SMA	Cochrane Library	2	2
2/0/15	"AND"	Coefficience Ellorary		2
	Diabetes			
2/8/13	GMA	Cochrane Library	0	0
_, 0, 10	"AND"			-
	Diabetes			
3/8/13	Group Visits	CINAHL	35	22 (after
	"OR"	PubMed	38	duplications
	Cluster	OVID	39	removed)
	Visits	Cochrane Library	16	, í
	"AND"			
	Diabetes			

# Table 2. Databases Searched and Data Abstraction

### **Appraisal of the Evidence**

The 15 identified articles were critically appraised with a focus on effect of SMA on clinical outcomes relevant to those with a diagnosis of diabetes. The results of these articles generated mixed results in the application of the SMA on clinical outcomes. Sanchez (2011) and Trento et al. (2005) reported no change in the SMA participants' A1C levels. Trento et al. (2005) accounts for this finding as the focus of the group visits being primarily on lifestyle issues whereas the other studies, conducted by the same author, the SMA focused on self-care management. Sanchez's (2011) implementation of the SMA was from September to November 2009, which leads to questions as appropriate time frames necessary to see changes in significant clinical outcomes. Trento et al. (2001, 2002, 2004, 2010) reports no decrease in participants' A1C levels but that it remains stable over the course of the studies. Although this is not a documented improvement, it could be argued that the SMA should be credited in hindering the natural progression of the diabetes disease process and therefore a significant finding. Clancy et al. (2003) reports a decrease in the A1C levels but not at significant levels. Cohen et al. (2011), Dontje et al. (2011), Gutierrez et al. (2011), Jesse et al. (2012), and Kirsh et al. (2007) all identified significant improvements in participants' A1C levels related to the implementation of SMAs.

The majority of the articles found no significant improvements in weight reduction and lipid levels. The exception is the findings of Trento (2010) that are most likely the result with longer timeframe of measuring the outcomes of 4 years. An evidence synthesis table provided a quick view of all the clinical outcomes related to SMA. The outcomes of the pilot were added to this table to compare results with what was found in the literature (refer to Table 9. Pilot SMA Implementation Results Compared with the Literature in the manuscript).

Riley et al. (2010) performed a systematic review that appraised the effectiveness of group visits for those afflicted with diabetes. Figure 6 provides an appraisal for the review. This review examined twelve articles that included a total of 75 studies. These studies were not limited to random control trials but included all research studies and systematic reviews. This review concludes that the group visits failed to consistently demonstrate an ability to improve clinical outcomes such as A1C, blood pressure, or lipids. The review highlights several gaps in the literature such as a need for consensus or defined procedure for group visits and the need for further longitudinal studies.

Replication of the studies conducted by Trentos et al. would strengthen the evidence that SMAs positively affect health outcomes. Kirsch et al. (2007) and Sanchez (2011) demonstrate how the CCM works well to guide the implementation of the SMA as it transform the care given from a reactive (responding to acute problems) to a proactive frame of mind that creates productive interactions between the informed activated patient and the prepared proactive team. A summary and comparison of the literature is displayed in Table 3.

60

## Figure 6. Rapid Critical Appraisal of Systematic Reviews of Clinical Interventions/Treatments

Group Visits in Diabetes Care: A Systematic Review Riley & Sorensen, 2010

1. Are the results of the review valid?

a. Are the studies contained in the review randomized controlled trials? UNKNOWN

b. Does the review include a detailed description of the search strategy to find all relevant studies? YES

c. Does the review describe how validity of the individual studies was assessed (e.g., methodological quality, including the use of

random assignment to study groups and complete follow-up of the subjects)? NO NO

d. Were the results consistent across studies?

e. Were individual patient data or aggregate data used in the analysis? NO

2. What were the results?

a. How large is the intervention or treatment effect (OR, RR, effect size, level of significance)? NOT REPORTED

b. How precise is the intervention or treatment (CI)? NOT REPORTED

3. Will the results assist me in caring for my patients?	UNKNOWN
a. Are my patients similar to the ones included in the review?	UNKNOWN
b. Is it feasible to implement the findings in my practice setting?	UNKNOWN
c Were all clinically important outcomes considered including risks	and benefits of the tree

c. Were all clinically important outcomes considered, including risks and benefits of the treatment? YES

d. What is my clinical assessment of the patient and are there any contraindications or circumstances that would inhibit me from implementing the treatment? NO

e. What are my patient's and his or her family's preferences and values about the treatment that is under consideration? NO

© Fineout-Overholt & Melnyk, 2005. This form may be used for educational, practice change & research purposes without

Citation Conceptual Setting/Sample Findings Major Data **Appraisal:** Outcome Framework variables **Measurements** Analysis worth to studied) practice Design and their definitions) DV1: HgA1C Clancy et al, Framework: Setting: Adult Primary IV: Group Lacking patient Wilcoxon test DV1: decrease (2003), Group None Care Center: Medical Visits in HgA1C outcomes levels in IVG Visits in University of South DV2: Trust in Medically and Design: RCT Carolina DV1: HgA1C Physician Scale but not Small sample size Economically statistically Disadvantaged DV2: Trust in DV3: ADA Sample: significant. Patients with N=120 Physician processes of care DV2: Increase Type 2 IVG= 59 Scale Diabetes and in Trust in CG= 61 Their Physician Scale Relationship to Attrition: 1 pt. moved statistically Clinical post randomization significant in data not included the IVG. Outcomes. DV3: Significantly improved adherence to ADA Standards in the IVG Setting: VA Medical Participants invited to Cohen et al, Framework: IV: Group 6 months Chi 2 DV1: IVG participate ? Highly DV1: A1C 2011. None Center visits t-test achieved goal Pharmacist-Led VA MEDIC-McNemar A1C (40.8% in motivated DV2: LDL Shared Medical Design: RCT Sample: E difference in IVG vs. 20.4% Appointments N=103 in CG; P =Mostly male veterans proportions for Multiple IVG=50DV1: A1C DV3: OOLS .015) CG = 49Cardiovascular

Table 3. Summary and Comparison of Literature

<b>Risk Reduction</b>			DV2: LDL	DV4 Perceived		DV2: LDL	Short duration of
in Patients with		Attrition:	DV2. LDL	Confidence Scores		(82.0% in IVG	study.
Type 2		4 participants revoked	DV3: QOLS			vs. 65.3% in	study.
Diabetes.		their consent.	(VR-36)			CG; P = .059)	Limited
Diabetes.			((11 50)			no significant	generalizability
			DV4:			difference	generalizatinty
			Perceived			uniterence	
			confidence			DV3: QOLS=	
			scores			no significant	
			300103			difference	
						unicicie	
						DV4 Perceived	
						confidence	
						scores= no	
						significant	
						differences	
						unterences	
						IVG attained	
						combined goals	
						(BP, LDL, &	
						A1C) 16% IVG	
						vs. 4.1% CG, P	
						= .049	
						Significant	
						increase in # of	
						meds prescribed	
						to the IVG	
Dontje, K. &	Framework:	Setting: Faculty of the	IV: Group	DV1: PCP	Frequency	PCP satisfaction	Small sample size =
Forrest, K.	None	College of Nursing at a	Visits	satisfaction tool	Percentages	range 4.1-4.8	no statistical power
(2011),		Midwestern University				(scale $1 = poor$	to prove significance
Implementing	Design:		DV1: PCP	DV2: HgbA1C,		to 5 =	
Group Visits:	Evidence		satisfaction	Microalbumin,		excellent).	
Are They	Implementation			SBP, DBP,			

Effective to Improve Diabetes Self- Management Outcomes?		Sample: 51 participants equaling 197 patient visits	DV2:Chronic Care Measures	LDL, Eye exams, Vaccinations, tobacco use, diabetes meds.		Percent improved HgA1C 7.9% Micro 9.5% SBP -0.8% DBP 5.4% LDL -4.4% Eye exam 12.3% Foot exam - 5.6% Flu vac -5.1% Pneum vac31.9% Tobacco use 11.7%	Improved outcomes seen in those who attended $\geq$ 3 visits. Improved pt. outcomes and pt. satisfaction.
Gutierrez et al, 2011, Shared Medical Appointments in a Residency Clinic: An Exploratory Study Among Hispanics with Diabetes.	Framework: None Design: Exploratory/ descriptive study, RCT	Setting: Family Medicine Residency Clinic Sample: N= ? IVG= 50 CG= 53 Attrition: ?	IV: SMA DV1: A1C DV2: Ds management indicators	DV1: A1C DV2: Flu shot Microalbumin Lipids Annual PE Foot exam Eye exam ASA use LDL<100 Pnuemo vac.	descriptive statistics proportions	DV1: Pre-Post AIC IVG: 1.19% decrease P = <.01 Pre-post A1C CG decrease A1C 0.67 P = >.02 DV2: increase in ASA ( $P = <.01$ ) Lipid (( $P = .02$ ) Pnuemo ( $P = <.05$ ) Eye ( $P = <.01$ ) Foot ( $P = <.01$ ) Annual Pe ( $P = .045$ )	Small sample size "halo effect" providers participating in SMAs could have gained insight to better tx patients.

Jessee, B. T. & Rutledge, C. M. (2012) Effectiveness of Nurse Practitioner Coordinated Team Group Visits for Type 2 Diabetes in Medically Underserved Appalachia.	Framework: Bandura's (1977) model of self-efficacy Design: Non- randomized prospective Quasi- experimental	Setting: Family practice clinic in South West Virginia Sample: N= 26 IVG= 11 CG= 15 Attrition:	IV: GV DV1: BS/A1C DV2: Knowledge DV3: Self- efficacy	DV1: BS/ A1C DV2: Diabetes Knowledge Test DV3: Diabetes Empowerment Scale Short Form	Btw group differences group mean comparisons Within IVG differences within group mean comparisons	BS/A1C post intervention difference btw groups: +27.24/+0.8 Knowledge/ self-efficacy post intervention difference btw groups: +1.26/+0.22 BS/A1C pre- post intervention differences: +50.37/+2.0 Knowledge/self- efficacy post intervention difference within group: +1.28/+0.55	The differences are presented however the reader is unable to determine significance of the differences? Small sample size
Kirsh et al, 2007, Shared medical	Framework: Chronic Care Model	Setting: primary care clinic @tertiary care academic medical	IV: SMA DV1: A1C	A1C LDL-c	Paired t-test w/in group	A1C: 1.4 (0.8, 2.1) % p<0.001, (95% CI)	Limitations: small sample size
appointments based on the chronic care	Study design:	center Veterans Health Care Center.	DV1: AIC DV2: LDL-c	SBP	Independent t- test btw group comparison	LDL-c: 14.8 (2.3, 27.4)	Sample self-selected after invitation might be more motivated

model: A quality improvement project to address the challenges of patients with diabetes with high cardiovascular risk.	Quasi- experimental	Sample: 112 patients asked to participate by letter: 44 (39%) agreed	DV3: SBP		Fisher Exact test- baseline differences btw groups	mg/dl (p= 0.022) SBP: 16.0 (9.7, 22.3) mm Hg (p<0.001)	than general pop- Hawthorne effect? No randomization No generalizability
Riley, S. B. & Marshall, E. S. (2010), Group Visits in Diabetes Care: A Systematic Review	Framework: None Design: Systematic Review Purpose: Appraise research on the effectiveness of group visits for persons with diabetes.	Sample: 12 articles reviewed 4 articles examined total of 75 studies 8 original research articles analyzed. Searched 24 databases from 1984-2009. Included research studies, SRs, and articles that included systematic evaluation component/comparison with traditional care	IV: GV DV1: Glycemic control DV2: Patient satisfaction One study Cost of Care			IV: GV not consistently defined DV1: inconsistent statistical improvement in glycemic control, BP, or lipids. DV2: consistent improved pt. satisfaction.	Need to define specifics of GVs as an intervention and further studies. Need further studies in rural settings.
Sanchez, I. (2011), Implementation of a Diabetes Self- Management	Framework: Chronic Care Model and Plan-Do- Check-Act Cycle	Setting: Primary Care Center South Texas Sample 70 Attrition: NA	IV: DSME via SMA DV: ADAs Standards of Medical Care	DV: A1C, BP, TC, LDL, TG, Albumin, ASA use, Annual eye exam referral.	Descriptive Statistics Percentages nonparametric and parametric	A1C, TC, LDL, TG = NS change	Improvement demonstrated in HEDIS measures ?buy in of QI project from stakeholders

Education Program in Primary Care for Adults Using Shared Medical Appointments	Design: Evidence Implementation Quality Improvement Project						and timeframe of sept-nov 2009?
Taveira et al:         2010,         Pharmacist-Led         Group Medical         Appointment in         Type 2         Diabetes	Framework: none Design: RCT	Setting: VA medical Center Sample: N = 118 IVG (VA-MEDIC) = 64 CG = 54 Attrition: 118 randomized, 9 pts withdrew (6 from IVG and 3 from CG)	IV: VA- MEDIC GA DV1: A1C DV2: BP levels DV3: Lipid levels DV4: Weight	A1C SBP DBP HDL LDL BMI	t-test chi-square	A1C: $-0.9 \pm 1.6$ , 40.4 % attaining goal at P<.05 SBP: $-7.3\pm$ 20.3, 65.5 % attaining goals at P <.05 DBP: $-6.5\pm$ 10.0, 87.9% attaining goals at P<.05 HDL: NS LDL: NS BMI: Non-sig decrease in BMI in VA-MEDIC GA Slight non-sig. increase in BMI in control group	Limitations/strengths: Lacking generalizability d/t all small homogeneous pop male veterans ? length of intervention 4 week with f/u at 4mo ? efficacy over longer period. No risk identified w/ implementation
Trento et al, 2002, Lifestyle intervention by	Framework: none	Setting: Clinic not specified	IV: Group Care	DV1: A1C, BW, BMI, HDL	Student t-test Bonferroni	A1C stable in group care; worsened in CG	? length of effectiveness
group care prevents deterioration of type II	Design: RCT	Sample N=112 IVG: N=56 CG: N=56	DV1: Clinical variables DV2:	BP Diabetic retinopathy		(p< 0.001)	description of pts ? question generalizing results to my patients.

diabetes: A 4- year randomized controlled clinical trial.		Attrition: IVG: 3 died and 8 moved to another clinic CG: 2 died, 17 had moved, and 2 lost to f/u	Knowledge of DM DV3 Health behaviors DV4 quality of life	GISED CdR DQOL/mod		BW &BMI decreased (p< 0.001) HDL increased (p<0.001) BP=sig for diastolic only at p<0.001) Diabetic retinopathy: No change in IVG worsened in CG GISED, CdR, & DQOL/mod improved in IVG (p< 0.001) Worsened in CG (p<0.004) GISED, (p<0.001 for CdR & DQOL/mod)	
Trento et al, (2001), Group Visits Improve Metabolic Control in Type 2 Diabetes: A 2- year follow up.	Framework: None Design: RCT	Setting: Clinic location unknown Sample: N= 112 IVG= 56 CG= 56 Attrition: 22	IV: GV DV1: Health measures DV2: Quality of Life	DV1: HgbA1C, BMI Lipids, microalbumin/cr ratio DV2: Diabetes Quality of Life Questionnaire	Wilcoxon's Rank-sum test Spearman;s rank or Pearson's correlation coefficients Cronbach's alpha-coefficient (DQOL)	HgA1C : after 2 yrs. the IVG A1C remained stable but worsened in CG (P = < 0.002), BMI lower in IVG $(P = 0.06)$ ,	<ul> <li>? selection bias – volunteer for study</li> <li>health care providers not blinded</li> <li>Study provides good description of GV components so study could be replicated.</li> </ul>

		IVG: 13 (3 died and 10 moved) CG: 9 (1 died, 5 moved, & 3 lost to f/u)	DV3: Knowledge of Diabetes DV4: Health Behaviors	DV3: Group of the Italian Society for Diabetes GISED questionnaire DV4: CdR Questionnaire		IVG improved in DQOL, GISED, and CdR ( $P$ = <0.001, & <0.001, & <0.001 respectively) GISED & CdR scores correlated negatively differences btw initial & final A1C ( $r$ = -0.32, $P$ = <0.005 and r =-0.29, $P$ = <0.005 respectively	
Trento et al, (2004), A 5- Year Randomized Controlled Study of Learning, Problem Solving Ability, and Quality of Life Modifications in People with Type 2 Diabetes	Framework: None Design: 5 year RCT	Setting: Not described Sample: N= 112 IVG= 56 CG= 56 Attrition: IVG: 14 (3 died and 10 moved, 1 lost to f/u) CG: 14 (3 died, 9 moved, & 2 lost to f/u)	IV: GV DV1: clinical outcomes DV2: Quality of Life DV3: Knowledge of Diabetes DV4: Health Behaviors	D1: HgbA1C, TC Cr, HDL, TG DV2: Diabetes Quality of Life Questionnaire DV3: Group of the Italian Society for Diabetes GISED questionnaire DV4: CdR Questionnaire	Differences btw baseline and 5 yr.: ANCOVA Multivariate regression model for increase/decrease from yr1 and 5.	HgbA1C stable in GV but increased in CG significant difference ( $P$ =<0.001) BMI, HDL, TC, TG, Cr improved over 5 yrs. in IVG but not significantly QOL improved after 2 yrs. in IVG ( $P$ = <0.001) and	Study provides strong evidence of sustainability of results Although there was no improvement in A1C no increase is significant as normal progression of disease predicts an increase in A1C levels over time.

Managed by Group Care.						worsened in CG (P = <0.001) Knowledge increased over 5 yrs. with IVG (P = <0.001) reduced in CG (P = <0.005) Health Behaviors improved in IVG $(P = <0.001 @ 5yrs)$ And worsened in CG $(P = <0.005)$	
Trento et al, 2005, A 3-year prospective randomized controlled clinical trial of group care in type 1 diabetes.	Framework: none Design: RCT	Setting: Clinic not specified Sample: N=62 IVG= N=31 CG: N=31 Attrition: IVG: N= 30; one lost to f/u CG: N= 28 One lost to f/u 2 declined to participate in final visit/questionnaire	IV: group care DV1 Biochemical and clinical variables DV2 Knowledge of DM DV3 health behaviors DV4 Quality of life	DV1: Wt., BMI, FBS, A1C, Insulin dosage, TC, HDL, Trig, Alb/cr, foot ulcers DV2: GISED score DV3: CdR-T1DM score DV4: DQOL score	DV1: Wilcoxon signed rank test Multivariate analysis Univariate analysis Cronbach's coefficient	DV1: NS differences Knowledge, quality of life, and health behaviors improved in pts. In-group care. (p<0.001)	Group care focused more on lifestyle issues and less on specific skills i.e. carb counting and fine adjusting of insulin dosage. Generalizability to my clients who are type 2?

Trento et al, (2010), Rethink Organization to iMprove Education and Outcomes (ROMEO).	Framework: None Design: Multicenter RCT over 4 yrs.	Setting: 13 hospital based clinics in Italy Sample: N = 815 IVG: 106 CG : 128 Attrition: 2 clinics did not complete trial no other details provided as to #	IV: group care DV1 Biochemical and clinical variables DV2 Knowledge of DM DV3 health behaviors	DV1: Wt., BMI, FBS, A1C, Insulin dosage, TC, HDL, Trig, Alb/cr, foot ulcers DV2: GISED score DV3: CdR-T1DM score DV4: DQOL score	Differences McNemar test for paired samples Odds ratio	Decrease in IVG BMI, FBS A1C, TC, TG, LDL, SBP, DBP from baseline to yr. 4 w/increase in HDL ( $P =$ <0.001 for all) BMI, A1C, TG, & Cr increased in CG. Health behaviors,	Illustration of transferability
			DV4 Quality of life			knowledge, and QOL increased in IVG ( $P =$ <0.001 for all)	
Wagner et al, 2001) Chronic Care Clinics for Diabetes in Primary Care.	Framework: None Design: RCT	Setting: Seattle Region Primary Care Practices N = 35? IVG=14 CG=21 Attrition: 3 IVG practices were unable to complete study.	IV: GV DV: Clinical Outcomes DV2: Pt. medical care satisfaction DV3: Pt. diabetes care satisfaction	DV1: HgbA1c & TC DV2: Surveys Sf-36 DV3: Surveys not specified	Satisfaction surveys: Cronbach's coefficient	<0.001 for all) DV1: NS DV2: NS DV3: NS	Poor attendance in chronic care clinics HMO setting had initiated major diabetes clinical efforts prior to study, which may have had effect on both groups.

#### **Synthesis of Guidelines**

Two guidelines were critically reviewed; The American Diabetes Association's (2012) *Standards of Medical Care in Diabetes* and the Institute for Clinical Systems Improvement's (ICSI) *Diagnosis and management of type 2 diabetes mellitus in adults* (Riethof et al., 2012). The appraisal is presented in Figure 7. The focus of these standards is on the management of diabetes. They differed in the goals for some clinical outcomes and treatment guidelines. The ADA recommends an A1C goal of less than 7.0 with moderately strong evidence to support whereas the ICSI recommends a less stringent goal of 8.0 with high quality rated evidence to support. The ADA recommends a goal of less than 140/90. Both guidelines are similar in their recommendations for exercise (150 minutes per week), Diabetic Self-Management Education (DSME), weight reduction, foot care, eye care, smoking cessation and immunizations. Neither guideline addresses the SMA as an approach for management rather focuses on goals of treatment.

# Figure 7. Print & Use to Rapidly Critically Appraise Evidence-Based Clinical Practice Guidelines CREDIBILITY

Diagnosis and management of type 2 diabetes mellitus in adults.

Institute for Clinical Systems Improvement (ICSI)

1) Who were the guideline developers?	ICSI
2) Were the developers representative of key stakeholders in this specialt YES	y (interdisciplinary)?
3) Who funded the guideline development?	
ICSI member dues & 5 sponsoring health plans in Minnesota and	Wisconsin
4) Were any of the guideline developers funded researchers	
of the reviewed studies?	UNKNOWN
5) Did the team have a valid development strategy?	YES
6) Was an explicit (how decisions were made), sensible	
and impartial process used to identify, select, and combine evidence?	YES
7) Did its developers carry out a comprehensive, reproducible	UNKNOWN
literature review within the past 12 months of its publication/revision?	
8) Were all important options and outcomes considered?	YES
9) Is each recommendation in the guideline tagged by the	
level/strength of evidence upon which it is based and linked	
with the scientific evidence?	YES
10) Do the guidelines make explicit recommendations (reflecting	
value judgments about outcomes)?	YES
11) Has the guideline been subjected to peer review and testing?	YES
APPLICABILITY/GENERALIZABILITY	
12) Is the intent of use provided (e.g. national, regional, local)?	UNKNOWN
13) Are the recommendations clinically relevant?	YES
14) Will the recommendations help me in caring for my patients?	YES

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15) Are the recommendations practical/feasible	
(e. g. resources [people and equipment] available)?	YES
16) Are the recommendations a major variation from current practice?	NO
17) Can the outcomes be measured through standard care?	YES

Modified from Slutsky, J. (2005). Using Evidence-based Guidelines: Tools for Improving Practice, In B.M. Melnyk & E. Fineout-Overholt (Eds). Evidence-Based Practice in Nursing & Healthcare. A Guide to Best Practice. (pp. 221-236). Philadelphia: Lippincott, Williams & Wilkins.

## Print & Use to Rapidly Critically Appraise Evidence-based Clinical Practice Guidelines CREDIBILITY

## Standards of Medical Care in Diabetes

## American Diabetes Association

1) Who were the guideline developers?	ADA
2) Were the developers representative of key stakeholders in this special	ty (interdisciplinary)?
UNKNOWN	
3) Who funded the guideline development?	ADA
4) Were any of the guideline developers funded researchers	
of the reviewed studies?	UNKNOWN
5) Did the team have a valid development strategy?	YES
6) Was an explicit (how decisions were made), sensible	
and impartial process used to identify, select, and combine evidence?	YES
7) Did its developers carry out a comprehensive, reproducible	YES
literature review within the past 12 months of its publication/revision?	
8) Were all important options and outcomes considered?	YES

## SMA MANUSCRIPT

9) Is each recommendation in the guideline tagged by the level/strength of evidence upon which it is based and linked	
with the scientific evidence?	YES
10) Do the guidelines make explicit recommendations (reflecting	
value judgments about outcomes)?	YES
11) Has the guideline been subjected to peer review and testing?	YES
APPLICABILITY/GENERALIZABILITY	
12) Is the intent of use provided (e.g. national, regional, local)?	YES
13) Are the recommendations clinically relevant?	YES
14) Will the recommendations help me in caring for my patients?	YES
15) Are the recommendations practical/feasible	
(e. g. resources [people and equipment] available)?	YES
16) Are the recommendations a major variation from current practice?	NO
17) Can the outcomes be measured through standard care?	YES

Modified from Slutsky, J. (2005). Using Evidence-based Guidelines: Tools for Improving Practice, In B.M. Melnyk & E. Fineout-Overholt (Eds). Evidence-Based Practice in Nursing & Healthcare. A Guide to Best Practice. (pp. 221-236). Philadelphia: Lippincott, Williams & Wilkins

#### **Recommendations for Practice in the Implementation of a SMA**

Melnyk and Fineout-Overholt (2011) define the hierarchal level of evidence for the interventional PICOT question. This hierarchal level of evidence is rated from one to seven, with one being the strongest level of evidence. The hierarchal level of evidence for the purpose of the interventional PICOT question is:

- 1. Systematic review/meta-analysis of random control trials (RCTs)
- 2. RCTs
- 3. Non-randomized controlled trials
- 4. Cohort study or case control studies
- 5. Meta-synthesis of qualitative or descriptive studies
- 6. Qualitative or descriptive single studies
- 7. Expert opinion (pg. 33).

Trento et al. (2001, 2002, 2004, 2010) provide strong evidence that the SMA is a feasible innovative intervention for the diabetic population by providing level two RCTs that illustrate effectiveness of the SMA in hindering the progression of the diabetes disease process. Other studies considered to be level 2, 3, and 4, also provide significant positive clinical outcomes when the SMA is implemented including the studies conducted by Cohen et al. (2011), Dontje et al. (2011), Gutierrez et al. (2011), Jesse et al. (2012), and Kirsh et al. (2007). The specific rating of the level of evidence for each study is presented in Table 4.

Citation		Level				Level	Quality	Quality	Quality
	Ι	II	III	IV	V	VI	poor	medium	high
Clancy et		Х						Х	
al, (2003)									
Cohen et			X						Х
al, (2011)									
Dontje et				Х				X	
al, (2011)									
Gutierrez					Х			X	
et al,									
(2011)									
Jessee et			Х					X	
al, (2012)									
Kirsh et			Х					X	
al, (2007)									
Riley et				Х					Х
al, (2010)									
Sanchez,				Х					Х
(2011)									
Taveira et		Х							Х
al, (2010)									
Trento et		Х							Х
al, (2001)									
Trento et		Х							Х
al, (2002)									
Trento et		Х							Х
al, (2004)									
Trento et		Х							Х
al, (2005)									
Trento et		Х							Х
al., (2010)									
Wagner et		Х						X	
al., (2001)									

 Table 4. Comparison Across Literature on Level and Quality

#### Gaps in Clinical Knowledge

As Riley et al., (2010) mentioned, there is a gap in clarification of the process for implementation of the SMA. Many of the articles appraised do not describe the SMA procedure. This lack of description makes replication of the SMA extremely difficult if not impossible. Consensus is needed on a refined definition or procedure of the SMA.

Dosing of the SMA is another gap identified in the literature search. Four of the fifteen articles reviewed addressed the percentage of SMAs attended. Only two of these studies correlate the number of attended visits to the health outcomes. Dontje & Forrest (2011) provide descriptive statistics that noted improved outcomes with LDL and blood pressure with participants attending three or more visits. Wagner et al. (2001) identifies a significant improvement (p= 0.04) in HgA1C in those attending three-six appointments compared to those attending zero to two appointments. Further work needs to be done to determine if the number of SMAs attended will have a positive effect on health outcomes.

# Steps 5 and 6 of the Iowa Model: Implementation and Evaluation Setting/Population

NOMS Healthcare is a multispecialty physician group that provides care for patients in six counties in Northwest Ohio. This physician group consists of 78 providers, 43 specializing in family medicine or internal medicine. The physician group employs three social workers and two registered nurses that focus attention on high-risk patients in need of help coordinating their care.

The SMA was piloted in a rural private practice with type II diabetic patients with a HgA1C greater than 6.5 percent. This rural clinic is primarily managed by a family nurse practitioner with a collaborating physician onsite one day per week. Even though the practice improvement utilized ACO diabetic care measures, the SMA was open to all patients with an HgA1C greater than 6.5 percent and not limited to ACO beneficiaries. The SMA was not limited to new onset diabetic patients or seasoned diabetic patients as diversity within the group was thought to add to the supportive dynamics of the group.

The comparison intervention consisted of patients who participated voluntarily to attend a monthly diabetic education class. This class is offered once per month. The participants were from various providers in the corporate office. The curriculum of these classes provide a wide arrange of topics related to the self-care and diabetes. The courses were facilitated by a nurse practitioner and often had guest speakers on specialized topics such as a podiatrist speaks of foot care, a dietician on food choices, or a social worker presenting the effects of stress on diabetes.

The diabetic group visits were not a convenient option to the patients of the rural private practice as it is over 40 miles of traveling for the patients seeking care at this practice. The SMA provided an alternative intervention to achieve quality management of diabetes. Potential participants were identified using NOMS diabetic registry. The current NOMS diabetic registry reveals 3,578 patients are affected by diabetes with 654 patients identified as having an A1C greater than 8%. Once patients belonging to this practice were identified, an invitation, was sent to the participant as well as a follow-up phone call inviting the patient to attend.

#### **Implementation Plan: Piloting the SMA**

The Iowa Model guided the development of a detailed plan for implementation of a SMA pilot at a rural private practice. Key stakeholders as well as strategies to engage

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were addressed along with the identification of facilitators and barriers to implementing the SMA.

Key stakeholders were defined as persons who are affected by or who may influence the implementation of the SMA (Fineout-Overholt et al., 2011). Active stakeholders of the SMA were a family nurse practitioner, the patients, a behaviorist, medical assistants (MAs), and the secretary. Passive stakeholders, who could enhance or hinder the implementation but will not be directly involved with the SMA, were the office manager, administration, patient quality care committee, two champion physicians, and information technology (IT) staff. Gallagher-Ford et al. (2011) list strategies to engage stakeholders:

- 1. Spend time and effort building trust.
- 2. Understand the stakeholder's interest.
- 3. Solicit input from stakeholders.
- 4. Connect in a collaborative way.
- 5. Promote active engagement in establishing metrics and outcomes to be measured (pg. 54).

The first four strategies were the most crucial in the implementation of the SMA. The first was thought to be most challenging as the new employee to the organization trying to make a change in practice. Tactics to gain trust of key stakeholders was the introduction of the concept through a lunch and learn presenting the literature and listening to concerns. A mock SMA also helped key stakeholders understand the process and also give an opportunity for them to participate in the development of the SMA

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protocol by offering suggestions for improvement. The engaged stakeholders played key roles in the implementation plan.

Utilization of facilitators along with anticipating potential barriers was essential to the successful implementation of the project. Three major barriers were identified. The first was the presence of "group visits" in one of the NOMS offices. In this office, patients were seen by the primary care provider (PCP), a physician or nurse practitioner, for an individual appointment then sent to a conference room for a scheduled diabetic educational topic. The two champion physicians who successfully implemented this type of group visit envisioned a NOMS wide implementation. Through the review of literature and discussion it was determined acceptable to pilot the SMA in one office to determine and compare efficacy of the different groups. The second barrier was accurate data collection. There were known difficulties in pulling accurate data from the electronic medical record (EMR). Difficulties arose due to workflow inconsistencies between offices. For example, collection of HgA1Cs becomes difficult when office staff enter into different fields within the EMR. The IT department must be able to identify all possible fields the lab may have been entered and this field has to be a structured field. Free text is not extractable. In order to ensure accurate data collection a collaborative relationship with an IT specialist was established.

The last and most significant potential barrier was patient buy-in. ACO beneficiaries are Medicare recipients and mostly elderly. This generation may not be as open to an alternative type of visit. The PCP, whom the patients trust, had to sell the benefits of the SMA to the patients. Another tactic to ensure patient buy in was to use marketing materials such as personal invitations to join, brochures and fliers explaining the SMA procedure, and a personal follow-up phone call to answer residual questions. These interventions were to ensure the patient was able to make an informed decision as to whether or not a SMA is an intervention he/she might be interested in experiencing. Table five identifies potential facilitators and barriers to implementing the SMA.

 Table 5. Facilitators and Barriers

Facilitator	Barrier	Significance to Project Implementation
	Established SMA in one NOMS Practice	Two champion physicians have already implemented "Group Visits" for diabetic patients. Current practice: the physicians see the patients for a visit than send them for a group education visit.
		Group visits w/educational scheduled topics will be compared to the SMA with topics of conversation dictated by the participants and their appointment needs.
NOMS' culture		The culture encourages innovative ways to improve patient care and satisfaction based on evidence based practice. Presentation of the literature review that supports the implementation of SMAs will reinforce the potential SMAs can have on improving care to the diabetic patient.
	EMR: data collection	<ul><li>Diabetic lab measures may be difficult to extract from the EMR if the patient utilized out of network laboratory.</li><li>Consistency will need to be established as to how staff will enter out of network labs into the EMR so data can be extracted</li></ul>

	Patient buy-in	The ACO cares for the aging population. The population may not be open to a different format of receiving care. The SMA will need to be marketed and promoted to this population in a manner that assures high quality of care will continue in this format of medical appointments.
Care Navigators		Care navigators are utilized to help patients become aware of all the possible resources available. Will utilize care navigators as facilitators to the SMAs.
Provider buy-in		The provider is open to piloting a different format of the SMA in her group practice (this is a different practice from the champion physicians that have already implemented the group visits). This provider will become the "champion provider for this project.

#### **Outcome Measures**

The outcome measures for this project encompassed patient centered outcomes and cost outcomes. Quality of care and cost containment are the central concepts to an ACO as one cannot exist without the other being evaluated. Additionally, as one purpose of this project was to determine the feasibility of the SMA for a rural practice the evaluation of the process of implementation was also to be evaluated.

CMS requires the NOMS ACO to report on six quality measures that directly relate to meeting the standards of care for CMS beneficiaries who are diabetic. Because NOMS would like to provide high quality care to all NOMS patients, these health measures were utilized to evaluate the effectiveness of the SMA intervention.

The NOMS' diabetic protocols guided the team in providing routine care for the patient with diabetes based on HgA1C levels. The frequency of checking HgA1C levels are every three months for HgA1Cs greater than 6.5% and every six months for HgA1C less than 6.5%. For example if the patient's most recent HgA1C level is less than 6.5% the patient is scheduled for an appointment every six months, 6.6% -8.9% every three months, and if greater than 9.0% every month. Due to these protocols participation levels in the SMA were anticipated to vary. In contrast, the participation in the diabetic group education class was open monthly to all diabetic patients.

A cost-benefit analysis (CBA) was performed to evaluate the SMAs ability to improve care and contain the cost of care. According to the Centers for Medicare and Medicaid Services (CMS), chronic diseases account for 75% of \$2.5 trillion being spent on healthcare annually with diabetes accounting for \$245 billion in 2012 (CMS, 2013). The financial burden diabetes places on the healthcare system, requires innovative SMA MANUSCRIPT

interventions to improve care while containing the cost of care. The Accountable Care Organization has a triple aim goal of improving the patient experience, improving the health of the population, and containment of expenditures in caring for this population (Bard & Nugent, 2011). A cost-benefit analysis is performed to evaluate the SMAs ability to improve care and contain the cost of care. Finkle, Jones, & Kovner (2013) identify five key elements in performing a CBA as;

- 1. Determine project goals.
- 2. Estimate project benefits.
- 3. Estimate project costs.
- 4. Discount cost and benefit flows at an appropriate rate.
- 5. Complete the decision analysis (pg. 306).

The goals of the SMA were to provide an efficient cost effective method of providing high quality care to the diabetic patient as evidence by improved health measures. The second step is to identify and measure estimated project benefits. The SMA had the ability to increase productivity of the Nurse Practitioner by allowing the provider to see eight patients in a 90-minute period rather than the usual 4.5 per 90-minute period. The difficulty arose with being able to place a monetary value on all the benefits the SMA could offer such as with increasing the diabetic's self-management abilities. Various approaches to capture the cost analysis were conducted. A critical review of the cost analysis indicated that a cost savings/benefit could be achieved. Table 6 provides a visual of estimated benefits possible with implementation of the SMA. Table 7 and 8 provides an estimated project cost incurred by implementing the SMA. Table 9 illustrates cost associated with the diabetic group education classes. Most importantly Table 10 provides

a visual in the differences in potential revenue each intervention is capable of achieving.

Lastly is the implementation of the intervention feasible? Review of cost and benefits

reveals potential value in implementing the SMA.

**Table 6. Estimated Project Benefits** 

Project Benefit	Description of Benefit
Increased productivity of the Nurse Practitioner	Increase in the number of patients the NP can see in 90-minute period from 4.5 to 8
SMA provides a social support group for patients with diabetes attending the SMA	Separate support group for diabetes and the need for a facilitator not necessary.
Increase in participants' self-management abilities	Increase in knowledge will enable the participant to become an engaged patient and will increase self-management abilities.

## Table 7. Estimated SMA One Time Investment Expenses

Product	Description	Estimated Expense
White Erase Boards	Two white erase boards to	\$396.00
	list lab values and patient	
	concerns	
Dry Erase Marker Set	Needed to prepare erase	\$8.25
	boards	
Staff Wages to participate	MA- \$12/hour	\$148.00
in Mock SMA approx. 1 <sup>1</sup> / <sub>2</sub>	Behaviorist- \$25/hour	
hour	NP- \$50/hour	
	Secretary- \$12/hour	
Total		\$552.00

# Table 8. Economic Consideration for the SMA

Product	Description	Estimated Expense
Participant folders	Each participant will be given a folder with educational material	\$1.02/folder x 8 = \$8.16 (box of 25/\$25.55)
Sheet protectors for educational material	4 protector sheets per folder	\$0.16/folder x 8 = <b>\$1.28</b> (box of 100/ \$3.90)
Educational material	Educational pamphlets: From Head to Toe, Self- care, Overcoming Barriers, ADA Target A1C Less than 7%, Take Control Today, Ordered Through Sanofi Aventis	\$0.00
Paper/envelopes	<ul> <li>Consent Forms: One sheet documentation of informed consent with participation in the SMA</li> <li>Fliers: describing the benefits of SMA for those with Diabetes.</li> <li>Invitations to join the Diabetes SMA</li> </ul>	5,000 Sheets/ \$31.88 Envelopes 500/ \$11.24 ESTIMATED COST PER SMA: .45/envelopes (20) .64/sheets of paper (10
Postage for invites	15-20 invites will be mailed as an alternative intervention some patients may be hesitant to join the SMA.	\$0.46/participant ( <b>\$.9.20/20 invites</b> )
Healthy Snacks	Snacks will be provided to participants- fruit, trail mix yogurt etc.	\$20.00/SMA
Behavorist	The behaviorist (social worker/care navigator) will facilitate the SMA. <b>includes travel time.</b>	\$25.00/hour ( <b>\$62.50 per visit</b> )
Milage for the behaviorist	The behaviorist will travel to satellite office. (70 miles round trip)	\$0.56/mile ( <b>\$39.20</b> )

Medical Assistant	Extra time will be required above and beyond the traditional visit with the need to mail invites and place phone calls to invite patients, pre-visit planning (putting folders together, preparing white boards)	\$12.00/hour ( <b>\$24.00</b> )
Total		165.43
Total per Participant		\$20.68/per participant

# Table 9. Economic Considerations for the Diabetic Group Education Classes

Product	Description	Estimated Expense
Participant folders	Each participant will be given a folder with educational material	\$1.02/folder x 20 = \$20.40 (box of 25/\$25.55)
Sheet protectors for educational material	4 protector sheets per folder	\$0.16/folder x 20= <b>\$3.20</b> (box of 100/ \$3.90)
Educational material	Educational pamphlets: From Head to Toe, Self- care, Overcoming Barriers, ADA Target A1C Less than 7%, Take Control Today, Ordered Through Sanofi Aventis	\$0.00
Paper/envelopes	<ul> <li>Consent Forms: One sheet documentation of informed consent with participation in the SMA</li> <li>Fliers: describing the benefits of SMA for those with Diabetes.</li> <li>Invitations to join the Diabetes SMA</li> </ul>	5,000 Sheets/ \$31.88 Envelopes 500/ \$11.24 ESTIMATED COST PER Diabetic Group Education Class: .45/envelopes (20) .64/sheets of paper (100)
Postage for invites	15-20 invites will be mailed as an alternative	\$0.46/participant ( <b>\$9.20/20 invites</b> )

	intervention some patients may be hesitant to join the SMA.	
Healthy Snacks	Snacks will be provided to participants- fruit, trail mix yogurt etc.	\$20.00/SMA
Behavorist	The behaviorist (social worker/care navigator) will facilitate the SMA. <b>includes</b> <b>travel time.</b>	\$25.00/hour ( <b>\$62.50 per visit</b> )
Healthy Snacks	Snacks will be provided to participants- fruit, trail mix yogurt etc.	\$20.00/SMA
Nurse Practitioner	Facilitate and answer questions; present pathophysiology	\$50.00/hour (\$75.00)
Medical Assistant	Extra time will be required above and beyond the traditional visit with the need to mail invites and place phone calls to invite patients, pre-visit planning (putting folders together, preparing white boards)	\$12.00/hour ( <b>\$24.00</b> )
Total		\$225.39
Total Per Participant		\$15.06/per participant

Intervention	Charges Billable	Expenses	Potential Revenue			
SMA	99213	\$20.68/participant	\$114.00/participant in 90 minutes x8 = \$912.00 <b>\$ 912.00-165.44</b> (expenses)= \$747 + \$93.37 per patient			
Diabetic Group Education Class	Not a billable service	\$18.52/participant	-\$15.06 per participant			
Traditional Office Visit	99213	No additional expense incurred	\$114.00/pt. in 90 minutes x4.5 = \$513.00 + \$114.00 per patient			

# Table 10. Comparison of Interventions: Expenses/Billable Services

#### **Implementation Process**

The literature supported the use of SMAs to provide high quality care to patients with diabetes. Risk associated with the implementation of a SMA is patient information sharing and the group setting may be intimidating to some patients. Due to the risk associated with the SMA a signed consent addressing confidentiality will be completed by the patient and any support persons accompanying the patient prior to the visit. The benefits of a SMA were supportive learning environment with others experiencing the same disease process, more education and more time with the provider. A data use agreement for analysis of the differences in the outcomes between groups was established. De-identified data were provided in a database format. The implementation of the project is presented in the following sections; preparing the team, enlisting participants, the SMA, the debriefing, and the evaluation plan.

#### **Preparing the Team**

An educational session to share information about the SMA and the proposed process was presented to the staff, allowing sufficient time for discussion. A mock SMA was conducted. Mock diabetic patients attended the mock visit. The staff assisting with the SMA along with other interested staff participated in the mock SMA to ensure knowledge of the assigned duties in the SMA. Immediately following the mock SMA, a debriefing was conducted to address any issues in the flow, roles, and responsibilities. Those who participated were asked to provide input into the revisions needed to improve the process. The mock visit enabled the staff to offer suggestions for improvement and empowered them to answer any questions future SMA patients would have on the SMA procedure.

#### **Enlisting Participants**

A diabetic registry for the rural private practice was used to identify participants eligible for an invitation to the SMA. Because NOMS' diabetic protocols recommend patients with HgA1C above 6.5 percent be seen every 3 months, all patients with diabetes with a HgbA1C above 6.5% were to be invited. Identified patients attributed to this rural practice meeting criteria were sent an invitation to join a SMA The medical assistant made follow-up phone calls to potential SMA patients. The phone call served to answer any questions and to encourage the patient to join the SMA.

#### The SMA

The SMA was scheduled for 90 minutes and consisted of pre-visit planning, 45-minute check in and private medical exam and with the last 45 minutes addressing individual treatment plans in a group setting. Pre-visit planning included, individualizing folders for participants, reviewing the charts and current lab values, ordering healthy snacks, and preparing a white board with patient name, lab values, and concerns. The receptionist greeted the patients with his/her participant folder and the informed consent form. The medical assistant proceeded with the checking-in of patients and preparing them for a private medical exam. After the medical exam the participants were reunited with the other participants with discussions and introductions facilitated by the behaviorist. After completion of all the private examinations, the provider joined the group to complete the visit by addressing the listed concerns and laboratory values of each individual patient, adjusting the treatment regimen as necessary. To conclude the visit, patients were given an evaluation form to ensure the visit met their needs and checked out with the receptionist. The participants were encouraged to continue with this type of appointment for the management of their diabetes and if the participant agreed an appointment for the next SMA

was made. Prior to the next SMA a reminder call was made to the participant as this is the practice of the organization for traditional visits.

### **The Debriefing**

Following the SMA the team regrouped to discuss the flow of the SMA. This gave all team members an opportunity to offer suggestions for improving the quality and flow of the visit. These recommendations were documented and integrated into the next SMA as feasible to improve the flow. The debriefings occurred after each SMA with documentation and evaluation of all changes made to the SMA.

#### **Evaluation Plan**

The next step in the Iowa Model is to evaluate the effectiveness of the intervention through the evaluation of the process and outcomes. Data were collected by manual EMR extraction to compare the health outcomes of the participants of the SMA, the Diabetic Group Education Class and traditional office visits.

The quality improvement project was monitored using the ACO quality measures. These metrics include blood pressure, HgA1C, LDL, tobacco use, and ASA use with patients with ischemic vascular disease and diabetes. A chart review of the participants of the SMA as well as patients attending the group diabetic education sessions, and the traditional office visit will be completed to obtain pre-intervention metrics. Descriptive analysis was conducted as appropriate for the variable. The changes over time in the participants meeting the clinical quality measure as defined by CMS were tracked.

The debriefings of the SMAs also served as a form of evaluating the SMA process. Team members were asked to complete a simple worksheet. The worksheet will served as a tool to collect data on the strengths and weaknesses of the process as well as to evaluate any adjustments made to improve the SMA process. The strengths and weaknesses were captured on a word table that will include recording any changes in the conduct of the SMA. Content analysis to capture the major themes of the strengths and weaknesses will be conducted. The tools used to assist with the implementation of the SMA are presented in Appendices A-H.

#### **Dissemination Plan**

The time and effort to explore the feasibility of implementing a SMA in this rural clinic would be futile if not disseminated so others could learn from this process. The knowledge gained from this practice improvement project was disseminated at the Midwest Nursing Research Society's 39<sup>th</sup> annual research conference. The project will also be disseminated in a nursing journal.

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## Appendix A SMA Invitation Letter



Dear Mr.

You are invited to join your healthcare provider and other patients in our practice for a "Shared Medical Appointment." It's an idea that other providers around the country have found helps them care for their patients in ways that cannot be done in the usual 15 to 20 minute office visit.

Here's how it works: Your provider and one of our nurses will visit with you and 5-7 other patients for about an hour and a half in the waiting room here at our office. During the visit, there will be time for talking with other patients as well as sharing about health problems. All patients will have their lab values displayed on a white board so that you can see you are not alone in your work to manage your diabetes. Then, your provider will spend time talking with each patient in the group about his health problems and concerns while others listen. If you have other health problems that need to be talked about privately, there will also be time to meet alone with your provider after the shared visit. You will decide if you want to be in the group or not.

We set up a shared visit to provide patients a time to meet with their provider on a regular basis and to learn how to deal with health problems. Shared visits also give you a chance to learn from other patients who are dealing with the same health problems and to ask questions about their health. Dieticians or other health providers may join your provider and nurse at the visits.

The date and time of the next shared visit is listed at the bottom of this letter. If you would like to attend call the office. Feel free to bring a family member or friend with you.

When you come in for the shared visit, simply check in as usual with the front desk and pay your usual co-pay. You will be given directions to the SMA meeting or to an exam room for a private exam.

We hope you will give this type of appointment a try. If you find this type of appointment does not work out for you, we will continue to see you as before in a one on one appointment. There will also be a support person available should you have problems with this type of appointment.

**Sincerely,** Your Doctor's Office

Next group visit date and time: \_\_\_\_\_\_\_Adapted from: Copyright © 2003 Suzanne Houck. Published with permission. Physicians may photocopy or adapt for use in their practices. All other rights reserved. Houck S, Kilo C. Group visits 101. *Fam Pract Manage*. May 2003:66-68; www.aafp.org/fpm/20030500/66grou.html

### Appendix B MA Phone Script



Hello Mr Smith?

I am calling to follow-up on the Shared Medical Appointment Invitation that was sent to you recently. Your Nurse Practitioner feels this would be a great opportunity for you to get the most of your appointment to check on your diabetes.

Here's how it works: Your provider and one of our nurses will visit with you and approximately 5-7 other patients for about an hour and a half in a conference room here at our office. During the visit, there will be time for talking with other patients as well as education about specific health problems. Then, your provider will spend time talking with each patient individually about health problems, concerns, and lab results as a group so that others can learn from you and you from them. If you have additional health concerns that need to be addressed, there will also be time to meet alone with your doctor after the shared visit. Of course, the visits are completely voluntary.

Can we schedule you for a Shared Medical Appointment for your diabetes today?

# Appendix C

# **Implementation Plan**

Goal	Task to Complete Goal	Key Stakeholders' Responsibility
Week 1 Staff /PCP education of project	<ul> <li>Meet with office staff to educate on</li> <li>What is a SMA</li> <li>Different roles staff and their importance in implementing an SMA</li> <li>Time and Scheduling needs for the SMA</li> <li>Supplies needed</li> </ul>	<ul> <li>DNP student: provide education</li> <li>Medical Assistants, PCP, Facilitator, Secretary, Office manager: be open to a different way of providing care</li> </ul>
Invitations to patients meeting criteria to join the Diabetic SMA	for SMA     Mailing to     diabetic patients	<ul><li>DNP student</li><li>Secretary</li></ul>
Week 2		
Making SMAs	<ul> <li>F/U phone call to diabetic patients who did not respond to mailing.</li> <li>Education of patients who call in with questions regarding the letter</li> </ul>	<ul> <li>DNP student: assist the secretary with script for answering questions to sell the value of the SMA</li> <li>Secretary: make appointments and answer questions to participants who may be hesitant to join a SMA</li> </ul>
Mock SMA	<ul> <li>Clearing of schedule for 1½ – 2 hours needed to run through a Mock SMA</li> </ul>	<ul> <li>DNP student: Facilitate SMA</li> <li>Medical Assistants, PCP, Facilitator (Care Navigator),</li> <li>Secretary, Office manager: be open to a different way</li> </ul>

		of providing care, participate in respective roles.
Week 4		
Pre-visit planning and preparation	<ul> <li>Organize agenda folders for diabetic participants with individualized information: i.e. current lab work, list of preventative interventions completion dates etc.</li> <li>Photo copy educational materials</li> <li>Order healthy snacks for participants</li> </ul>	<ul> <li>DNP student &amp; Facilitator (Care Navigator): Organize materials</li> </ul>
Week 4-5		
First SMA	<ul> <li>Organize waiting room to accommodate the SMA process</li> <li>Prepare white boards with patient name and current lab values</li> <li>Work as a team</li> </ul>	<ul> <li>Diabetic Patient: buy into the value of the SMA</li> <li>DNP Student: Facilitate the SMA</li> <li>Care Navigator: help facilitate the SMA</li> <li>PCP: Perform assessments, answer questions and develop individualized treatment plans</li> <li>Secretary: Check patients</li> <li>Medical assistants: Obtain vital signs, weight and BMI for all patients</li> </ul>
Patient Satisfaction/Evaluations of the SMA	• Distribute evaluation forms to patients before end of the SMA	• Diabetic Patient: Complete the evaluation form prior to leaving

Week 5 Dhug		
Week 5 Plus         Evaluation of the SMA	<ul> <li>Review of completed evaluations from the participants</li> <li>Develop a SMA focus group to review workflow and brainstorm areas in need of improvement</li> <li>Ability to gather data to report on ACO measures</li> </ul>	<ul> <li>DNP student:         <ol> <li>Facilitate SMA focus group and report on the SMA patient satisfaction/evaluation forms.</li> <li>Collect data to report ACO measures and to evaluate effectiveness of the SMA</li> </ol> </li> <li>PCP, MA, Care Navigator, and Secretary: participation in focus group to improve workflow.</li> </ul>

## Appendix D

## **Consent Form**



## **Shared Medical Appointment Consent Form**

A Shared Medical Appointment is simply a medical appointment that you will share with a group of individuals who have the same diagnosis and concerns in caring for one's self. Participation is strictly voluntary.

### **Confidentiality Agreement:**

Shared Medical Appointments require the patient to be willing to discuss openly private medical and social information. All accompanying family members and patients must agree to respect other participant's privacy and agree to keep all shared information confidential. By signing this confidentiality agreement, I agree to keep all information that is shared confidential and will not discuss outside of the Shared Medical Appointment.

Name (Please print)	 	
Signature:		
Date:	 	
Name (Please print)	 	
Signature:	 	
Date:		

Appendix E

### **Case Studies: Mock Patients**



Mock SMA

Patient Name: MaryJo Smith

Vitals: BP: 148/92, Pulse: 88, RR: 22, Temp: 97.4, BMI: 32

**PMH:** Diabetes II, HTN, Hyperlipidemia, Hypothyroidism, Obesity, Nicotine Abuse Labs:

HgbA1C: 8.4% FBS: 164 TSH: 1.49 TC: 198 HDL: 38 LDL: 88 TG: 214

#### **Medications:**

Baby ASA daily MVI daily Lisinopril 10mg daily Simvastatin 20mg daily Levothyroxine 1.25 mcg daily Janumet 50/1000 BID

**Additional Information:** MaryJo is a 62 y/o female who has been diabetic for 15 years. She is frustrated because she has been watching her diet but has not been able to lose any weight. She has tried to quit smoking several times but takes to the habit due to "weight gain". Her main concern today is her weight.



Mock SMA Patient Name: John Henery Vitals: BP: 158/78, Pulse: 92, RR: 18, Temp: 98.4, BMI: 30 PMH: Diabetes II, Nicotine Abuse Labs: HgbA1C: 9.1% FBS: 205

FBS: 205 TC: 240 HDL: 32 LDL: 172 TG: 250

#### **Medications:**

Glucaphage 1000mg BID

**Additional Information:** John is a 63y/o truck driver, newly diagnosed with diabetes after the discovery of glucose in his urine at his DOT physical. He has been instructed to watch his diet and exercise but finds this extremely difficult with his job. He doesn't understand his new diagnosis and why he needs to take medicine when he feels fine.



Mock SMA Patient Name: Kim Miller Vitals: BP: 128/70, Pulse: 80, RR: 18, Temp: 98.8, BMI: 29 PMH: Diabetes II, Pre-hypertension, Obesity Labs: HgbA1C: 6.1% down for 8.0% FBS: 138 TC: 168 HDL: 48 LDL: 120 TG: 158 Medications: Baby ASA MVI

**Additional Information:** Kim is a 48 y/o who has been a diabetic for 3 months. She wanted to try diet and exercise to control her disease process. She has improved her BP and HgbA1C and has dropped her BMI from 30 to 29 in 3 months. She exercises 5 days a week for 30 minute intervals but continues to struggle with her addiction to sweets.



Mock SMA Patient Name: Ellen Altop Vitals: BP: 140/80, Pulse: 92, RR: 20, Temp: 99.9 BMI: 31 PMH: Diabetes II, HTN, Hyperlipidemia, Obesity Labs: HgbA1C: 10.2 FBS: 188 TC: 188

HDL: 42 LDL: 128 TG: 190 Medications: Baby ASA Metformin 1000mg BID Glipizide 5mg daily Pravastatin 40mg daily Benicar 20mg daily

Additional Information: Ellen is a 68 y/o who has been diabetic for 10 yrs. She has recently developed a sore on her left little toe that doesn't seem to want to heal. She has been having trouble controlling her blood sugars which is a new problem as the medicine always seemed to work before and she thinks she maybe becoming immune to the medicine.



Mock SMA Patient Name: Manny Garcia Vitals: BP: 158/90, Pulse: 78, RR: 18, Temp: 98.9, BMI: 30 PMH: Diabetes II, Hypertension, Obesity, CAD w/Stents x 2 Labs: HgbA1C: 7.8

**FBS:** 142 **TC:** 156 **HDL:** 48 **LDL:** 110 **TG:** 138 ations:

## Medications:

Baby ASA Crestor 20mg daily Coreg CR 12.5mg daily Lisinopril 10mg daily

**Additional Information:** Manny is a 59 y/o male who has been diabetic for 20 yrs. His main concern today is that he has developed a cough that he just can't shake. He feels well otherwise.



Mock SMA Patient Name: Jim Kimball Vitals: BP: 120/70, Pulse: 72, RR: 18, Temp: 98.6, BMI: 35 PMH: Diabetes II, Hypertension, Obesity Labs: HgbA1C: 9.0 FBS: 192 TC: 244 HDL: 28 LDL: 188 TG: 250

## Medications:

Baby ASA Benicar 40mg daily Zocor 40mg daily Janumet 50/1000 BID Glucotrol XL 5mg daily

**Additional Information:** Jim is a 68 y/o retired school teacher. He has trouble remembering to take his medications sometimes. He admits to cheating on his diet and say that he can't exercise because of his arthritis in his back. His biggest concern today is that his feet have been hurting a lot lately and feel like they are asleep at times. It is very annoying to him.



Mock SMA Patient Name: Tracy Tebow Vitals: BP: 122/70, Pulse: 68, RR: 18, Temp: 98.2, BMI: 31 PMH: Diabetes II Labs: HgbA1C: 7.1% FBS: 146 TC: 148 HDL: 58 LDL: 111 TG: 130 Medications: MVI Glucaphage 500mg BID Additional Information: Tracy 68y/o who has been a diabetic for 6 months. She was started on

Glucaphage at the last visit when lifestyle modification was not successful in bringing down her blood sugar levels. Her main concern today is that since starting the medication she has been experiencing some GI distress. Therefore, she doesn't always take the medicine as directed if she needs to go away for the day.



Mock SMA Patient Name: Sue Hill Vitals: BP: 156/80, Pulse: 84, RR: 20, Temp: 98.0, BMI: 33 PMH: Diabetes II, Obesity Labs: HgbA1C: 6.9 FBS: 138 TC: 159 HDL: 56 LDL: 102 TG: 140 Medications: Metformin 1000mg daily

**Additional Information:** Sue is a 43 y/o stay at home mom. She has a busy life caring for 4 y/o triplets. She says she does not have time to exercise (besides she gets enough exercise chasing the kids) and feels stressed out, not sleeping well and easily irritated. Admits to being a stress eater and finds herself cleaning up the left-over food from the kids' plates. She spends so much time caring for others she admits to neglecting caring for herself.

## Appendix F

## Patient Satisfaction Survey

	ALTHCARE			
	Patient Satisfactio Shared Medical Ap	v		
Date:	Age:	Male	or Female	<b>k</b>
•	d a Shared Medical App /?		Yes	No

## How would you rate your Shared Medical Appointment today?

<u>SMA</u>	Excellent 5	Very Good 4	Good 3	<u>Fair</u> 2	<u>Bad</u> 1
Ease of getting an appointment					
Helpfulness of staff					
Helpfulness of nurse practitioner					
Understanding your treatment plan					
The social support					
The visit overall					

How would you rate the shared medical appointment in helping you understand how to manage diabetes? (Circle one)

- SMA improved my understanding of diabetes management
- SMA did not improve understanding of diabetes management
- SMA decreased my understanding of diabetes management

Would you recommend a Shared Medical Appointment to your family and friends? (Circle one)

Definitely Yes Probably Yes Probably Not Definitely Not

What did you like about the appointment? What did you not like about the appointment?

## Appendix G. SMA Debriefing Worksheet



What went well with the implementation of the SMA?	What were problems you identified with implementation of the SMA?	What recommendations do you have to improve the SMA?

Based on the debriefing the following changes will be made to the SMA process:

# Appendix H.

									Number											IVD & DM	IVD & DM	IVD & DM
Patient					Baseline			DX IVD &	of Visits								Tobacco	Tobacco	Tobacco	DX using	DX using	DX using
Assigned			Type of	Baseline	Smoking	Baseline	Baseline	DM with	in 9	A1C @ 3	A1C @ 6	A1C @ 9	BP @ 3	BP @ 6	BP @ 9	LDL-C @	use at	use at 6	use at 9	ASA @	ASA @	ASA @
Code	Patient Age	Sex	Visit	A1C	Status	LDL-C	BP	ASA use	months	months	months	months	months	months	months	9 months	3months	months	months	3months	6months	9Months