

THE IMPACT OF POINT OF CARE HBA1C ON INTERVENTIONS AND
OUTCOMES IN TYPE 2 DIABETES

by

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DEDICATION

This is in dedication to my family for all of their tremendous sacrifice, support and encouragement and for all of the patients I have cared for who suffer from this disease.

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ABSTRACT

Diabetes mellitus, type 2 is a growing epidemic in the United States and the world. The purpose of this study was to compare (a) interventions performed by the health care provider; (b) provider compliance with standards of care and recommended guidelines; and, (c) differences in the subsequent HbA1c in persons with type 2 diabetes who receive POC HbA1c testing with those who do not receive POC testing. Reports were obtained from the electronic medical records system showing those who had POC HbA1c's and another showing non-POC HbA1c. Data collected included (1) the intervention trigger, of an HbA1c greater than 8.0%. LDL greater than or equal to 100 mg/dL, BMI greater than or equal to 27 and/or BP greater than or equal to 130/80, (2) interventions initiated, and (3) the method of intervention. The results showed that there was a statistically significant higher rate of compliance to standards of care of those in Clinic X in comparison to those in Clinic Y. ($\chi^2(1, N=45)=5.148, p=0.03$). There was no statistical significance between the POC group ($M=0.86; SD=2.16$) and the non-POC group ($M=-0.9; SD=1.02$); $t(1.92)p=0.61$ however, there was a clinically significant drop in HbA1c in Clinic X of nearly one percentage point. In conclusion, POC HbA1c testing increases provider compliance in addressing diabetes and its complications. Providers addressed elevation in HbA1c, LDL, BP and BMI at a higher rate in those who received POC testing than in those who did not. Additionally, the rate of improvement in the HbA1c in those who received the POC testing was clinically significant, showing a decrease in potential microvascular complications of 25% as well as a potential decrease in macrovascular disease. Those who did not receive POC testing showed no decrease in risk at all. POC testing has been identified as an important tool in improving diabetes outcomes and is found through this study to be superior compared to outside testing.

CHAPTER 1

INTRODUCTION

Diabetes mellitus, type 2 is a growing epidemic in the United States and the world. According to the World Health Organization (WHO), approximately 347 million people worldwide live with type 1 and 2 diabetes and that the rates of death related to uncontrolled diabetes will more than double by 2030 (WHO, 2012). According to the American Diabetes Association (ADA) there are currently 18.8 million people diagnosed with type 2 diabetes in the United States and an estimated seven million are undiagnosed. Even more alarming is the 79 million people with pre-diabetes (ADA, 2011).

Background and Significance

Type 2 diabetes is a disease marked by hyperglycemia due to insulin resistance and/or decreased insulin production (Tabers, 2001). Although often preventable if diabetes is diagnosed and controlled early in its course, type 2 diabetes can lead to long term and disabling health disparities including loss of limbs, heart or coronary artery disease, liver disease, kidney disease, blindness, and death. Hemoglobin A1c (HbA1c) is a measurement used to both diagnosis diabetes and gauge its glycemic control. HbA1c is a measure of the hemoglobin A molecule and attached glucose and provides a calculation of average blood glucose over three months' time. According to the American Academy of Clinical Endocrinologists (AACE, 2012) an HbA1c level of 5.5% to 6.5% is categorized as pre-diabetes. HbA1c levels greater than 6.5% warrant a diagnosis of

diabetes and HbA1c levels of greater than 7% are consistent with uncontrolled diabetics. Reports from the Health Resources and Services Administration (HRSA) show a startling number of individuals with type 2 diabetes whose HbA1c results greater than 9% which far exceeds the recommendation to maintain HbA1c levels below 7% (ADA, 2012). Rates of uncontrolled HbA1c are 29.6% for persons with private insurance, 27.3% for Medicare patients, and a staggering 48.7% for Medicaid participants. The reports of uncontrolled diabetes are likely low given the number of individuals with undiagnosed diabetes and pre-diabetes and the 22% of known individuals with type 2 diabetes who do not regularly have their HbA1c checked (HRSA, 2013).

Other important areas to monitor in persons with type 2 diabetes include low density lipo-protein (LDL), body mass index (BMI), blood pressure, vision, neurovascular and renal health. The goal for LDL established by the ADA is less than 100mg/dL. BMI is suggested to maintain at less than or equal to 25. If BMI is greater than 25 in persons with a diagnosis of type 2 diabetes, reduction to a BMI of 25 or 7% loss of total body weight is recommended. Blood pressure recommendation is less than 130/80 mmHg.

HRSA's quality improvement goals are 1) to assist providers in establishing systems to track and assure the HbA1c are being performed, and 2) develop programs that assure interventions for diabetic patients are being created and implemented to prevent further complications and enhance control. Commonly, HbA1c testing is handled in two ways: a) patients have their HbA1c drawn prior to their appointment with their health care provider or, b) patients have their HbA1c drawn following their

appointment. A growing approach, termed point-of-care (POC) testing, is to draw HbA1c levels at the time of the visit to the clinical setting. POC testing yields immediate results and eliminates relying solely on patient compliance to have labs drawn either before or after their provider contact and decreases lengthy amounts of times to receive results. Emphasis is being placed on POC testing to ensure more effective and efficient care for the diabetic patient population.

Statement of Purpose

The purpose of this study is to compare (a) interventions performed by the health care provider; (b) provider rates of meeting with standards of care and recommended guidelines; and, (c) differences in the subsequent HbA1c in persons with type 2 diabetes who receive POC HbA1c testing with those who do not receive POC testing.

Conceptual/Theoretical Framework

The Core Conditions theory (Rogers, 1967) guided this study. Rogers hypothesized that humans, once they begin to feel respected and understood by the facilitator, the facilitator becomes more successful in his or her teachings. In the case of this research, the health care provider is the facilitator and the patient is the student. Rogers proposed that in order for this to occur, the facilitator must meet face-to-face with the student. Personal contact combined with acceptance and empathy facilitates trust between the two, making the student more open and eager to learn (Smith, 2004).

Hypotheses

It is hypothesized that individuals who receive POC HbA1c testing will receive a greater percentage of recommended interventions from their health care provider (HCP) and their HbA1c will be decreased at subsequent visits at a higher percentage when compared to individuals who did not receive POC testing.

Definitions

HbA1c also known as glycosylated hemoglobin is defined as hemoglobin A molecule with attached glucose. This concentration of glucose attached to the cell can assist in identifying the average glucose levels in the blood over a period of approximately three months (Tabers, 2001).

Type 2 diabetes is a chronic metabolic disorder marked by hyperglycemia. Type 2 diabetes is caused by insulin resistance that can lead to inadequate insulin secretion to sustain normal metabolism (Tabers, 2001).

Point of care testing is testing that occurs at the time of the visit to the clinical setting which yields immediate results (National Institutes of Health [NIH], 2013).

LDL A lipoprotein of blood plasma that is composed of a moderate amount of protein with a little triglyceride and a large amount of cholesterol. This lipoprotein is associated with increased risk of developing atherosclerosis” (Merriam-Webster Online Dictionary, 2013)

BMI is defined as “A measurement of the relative percentages of fat and muscle mass in the human body, in which mass in kilograms is divided by height in meters squared and the result used as an index of obesity” (thefreedictionary.com, 2013).

CHAPTER TWO

LITERATURE REVIEW

In this chapter, standards of care for type 2 diabetes will be reported including HbA1c, LDL, blood pressure and BMI goals. . In addition, study results of POC will be evaluated. For this review, the Cumulative Index to Nursing and Allied Health Literature(CINAHL), PubMed, National Institute of Health and the (NIH) and Centers for Disease Control (CDC) websites were searched using the following key phrases: “POC testing of HbA1c”, “interventions in type 2 diabetes”, “standards of care of type 2 diabetes”, and “improved outcomes in type 2 diabetes”. This search was conducted from September of 2012 through December of 2012.

Standards of Care

ADA (2012) guidelines pertinent to this study include HbA1c of less than 7%. This standard was identified as decreasing the risk of stroke, myocardial infarction and microvascular disease. Other recommendations include LDL less than 100mg/dL, and blood pressure less than 130/80. In addition, for BMI greater than 25, 7% weight loss was recommended. Increased BMI, especially those over 30, increases the risk of uncontrolled type 2 diabetes, stroke and myocardial infarct and/or other forms of heart disease.

There have been few and limited studies regarding the impact of POC HbA1C testing performed to assess glycemic control in relation to interventions (Table 1). This

study was designed to provide insight to the types of interventions performed in conjunction with HbA1C POC testing and to compare those results with the interventions and HbA1C results for clients not tested at POC. In addition, health care provider compliance with standards of practice and the efficacy of these interventions on HbA1c outcomes will be compared across groups.

Intervention Delivery Methods

In a review of studies, Ellis et al., 2004, performed a meta-analysis of 21 randomized control trials (RCTs). Educational methods of those with type 1 and type 2 diabetes were evaluated and their impact on improved glycemic control was compared. Using a taxonomy system researchers evaluated each of these studies for setting, methods of teaching and how education was provided, types of assessments performed, whether the education was patient-centered and whether the participants received diabetes education prior to the study. Educational interventions were defined by the authors as those that “included physical, intellectual or psychological means to improve the patient’s condition” (Ellis et al., 2004, pg 1). Their conclusion was, “Despite terrific progress in refining education interventions, the diabetes literature continues to contain substantial inconsistencies in reporting the elements of educational interventions” (Ellis et al; 2004). There is scant evidence for fidelity in using specified interventions. This study adds to the body of that evidence. Educational interventions which included didactic teaching, dictated or negotiated goal setting, situational problem-solving and cognitive reframing, did result in improvement of diabetes management with the areas of “exercise content;

face-to-face interaction and cognitive reframing increased the likelihood of success” (Ellis et. al., 2004 pg. 2). The researchers identified the need to properly plan, design and implement diabetes education.

Although specific types of intervention were not identified, there have been studies indicating that POC intervention performed after a POC HbA1c testing can have a large impact on improved health of an individual. Piatt et al, (2012) authored the REACT (Rethinking Eating and Activity) study. The question of which lifestyle intervention was more effective in health education and promotion was evaluated. These areas of intervention were face to face, internet based, and DVD viewing. Four hundred thirty four (434) adults with abdominal obesity (waist circumference > 40 inches in males and > 35 inches in females) were selected and randomly divided into three groups. One hundred one (101) of these participants were allowed to choose for themselves which of the three intervention methods they would prefer. Sixty percent (60%) selected the face to face while 40% selected internet based. Of the 101 participants assigned to self selection, none chose the DVD intervention format. The researchers looked not only at which was best regarding satisfaction and outcome, but which had the greatest adherence to lifestyle modifications of diet and exercise at six months and which was most cost effective. Results showed that at six months, 71.4% of participants in the face to face group lost weight, while 53.1%, 42.6% and 55.5% of participants lost weight in the DVD, internet, and self-selection groups, respectively. The study concluded that although all of the interventions were effective in educating the patients appropriately and all groups showed reduction from baseline weight, it was not equal in adherence to the

intervention program (face to face, DVD or internet) or cost effectiveness. Participants in the face to face interaction had a 76% rate of adherence to lifestyle modifications at six months while adherence among the other participants was 57% (internet group) and 53% (DVD group). Face-to-face methods were also the most cost effective, although the term cost effective was not specifically defined, at \$63,377.00 per quality-adjusted life year compared with no intervention. The findings from this study provide support for point-of-care testing, which involves a face-to-face interaction between provider and patient (Piatt et al; 2012) as a means to improve patient health outcomes. (Table 1).

Point of Care Testing

Cagliero, Levita, and Nathan (1999) performed a study of 201 individuals greater than 18 years of age with type 1 and insulin dependent type 2 diabetes for at least one year to evaluate if POC testing impacted their HbA1c control. Study participants were randomly divided into two equal groups: an intervention group, which had HbA1c determined at point-of-care and the control group which had HbA1c determined per routine laboratory draw. Members in both groups had similar baseline characteristics for insulin dosing, age, average HbA1c of 8.67 +/-1.79 versus 8.49 +/-1.59. At the end of the study, 14 participants in the intervention group, and 23 in the control group were no longer in the study. Of these participants, three died, one refused further participation, six changed to other providers outside of the study physician group and seven were lost to follow up. At 6 and 12 months there was a significant decrease of HbA1c in the intervention group but not in the control group; 0.57 +/- 1.44% versus 0.19 +/- 0.79% at 6

months and 0.40 +/- 0.65% versus 0.19 +/-1.16% at 12 months. The researchers reported that no specific behavior changes were identified which may have contributed to the decrease in HbA1c (Cagliero et al., 1999). The results are believed to have occurred due to the inducement of clinically appropriate adjustments made to diabetes management plans by the providers at the time of the visit and immediate education of the patient at time of service. (Table 1).

. A larger study in Atlanta, Georgia by Miller et al (2003) was designed to evaluate the use of POC testing and standards of care education of providers in their relationship to HbA1c outcomes. Included were 597 participants with an average HbA1c of 8.5%. Prior to the study, the HCP were educated in the standards of care in diabetes. The participants received a baseline visit and a follow-up visit two to four months apart and HbA1c improvement was evaluated over a six month period. The interventions were provider decision based, not specified by study parameters. The rapid testing (POC testing) increased the intensity of the intervention by 51% versus 32% in the outpatient laboratory group when the HbA1C result was greater than 8.0%. Intensification of interventions was defined by the investigators as an “increase in the dosage of hypoglycemic agents that the patient was taking at the time of the baseline visit or the addition of a new agent” and the amount of intensification was defined as “milligrams of oral agents or units of insulin” (Miller et al., 2003, pg. 1159). Those with two follow-up visits had intervention intensity of 55% compared to only 28% in the routine test group. There were three other significant findings in this study. The first was that those with HbA1C results greater than 7.0% did not dramatically improve with intensity of

intervention. Secondly, rapid testing led to more intensity of the intervention by the provider. Finally, those with two follow-up visits with rapid testing had modest, but significant decreases in their HbA1c levels. Also of importance was that no improvement in HbA1c was seen in those who did not receive intensification however, in those instances where intensification did occur the average HbA1c result decreased from 9.7% to 9.0% in the control group and 10.1% to 9.1% in the rapid testing group (Miller et al., 2003). (See Table 1).

There has also been one study which reported POC HbA1c testing that does not improve outcomes. Khunti et al., (2006) evaluated improvement of HbA1c and the cost effectiveness of care (cost of testing, travel expenses, out of pocket expenses, and time missed from work) when POC testing was used. Six hundred thirty- eight (638) participants were included in the open randomized study which found a minimal cost savings of £20, leading investigators to question whether POC testing was cost effective. The participants however, had relatively good glycemic control prior to the study with a median HbA1c of 7.5%, making it difficult to assess improvement. The only intervention measured was the testing itself, not the interventions of the provider as a result of the POC test. Kuunti et al., acknowledged that there were funding constraints in place and the participants had to come in twice for follow-up since providers did not change their normal routine to include POC testing. With this being noted, the importance of further research and evaluation of specific interventions is needed,

As reported above, improvement in HbA1c levels has occurred when using the POC testing method. Noted improvement in HbA1c levels is significant clinically due to

the impact of the improvement on health. The UK prospective diabetes study (UKPDS) of 1999 concluded that improved glucose control decreased the progression of diabetes microvascular disease. In fact, for every 1% decrease in levels achieved, the risk of complications of microvascular disease decreased by 25% (UKPDS, 1999). Therefore, it is safe to conclude that any decrease identified, has significant benefit. Research is needed to identify which interventions may have a significant impact on overall control of diabetes. (See Table 1)

Table 1
Studies of Impact of POC

Study	Data Summary	Results
Ellis, SE., Speroff T., Dittus, RS., et al. (2004). <i>Diabetes patient education: a meta-analysis and meta-regression</i> . Patient Educ Couns. 52:97-105. Type: RCT Purpose: evaluated the effectiveness of patient education on glycaemic control in adults with diabetes	(P=0.78) heterogeneity (n=2,439) HbA1c change 12 weeks (net change - 0.29, 95% CI: -0.68, 0.09) 24 weeks (net change - 0.49, 95% CI: -0.92, - 0.05), 52 weeks (net change - 0.33, 95% CI: -0.76, 0.10) post-intervention. face-to-face delivery (P=0.009) cognitive framing teaching method (P=0.028) exercise content (P=0.038)	The change in HbA1c was greater in the education group than the control Those interventions that included face-to-face delivery, cognitive reframing teaching and had an exercise content appear to have had an increased likelihood of reducing HbA1c.

Table 1 Continued

<p>Piatt, G., Seidel, M., Powell, R., et al. (2012). <i>Comparative effectiveness of lifestyle interventions in the community</i>. Diabetes Care. July 1-9. Type: Interventional Purpose: determine the comparative effectiveness of three lifestyle intervention modalities In decreasing risk for diabetes.</p>	<p>Total loss in pounds Face-to-face 212.5 lbs, P = 0.01; DVD 212.2 lbs, P , 0.0001 INT 213.7 lbs, P , 0.0001 SS 214 lbs, Percentage of group with wt loss: Face-to-face 90.7 % DVD 90.9%, INT 92.1%, SS 100%)</p>	<p>marked decline was observed in weight after the intervention in all groups Participants in SS experienced the largest average weight loss</p>
<p>Cagliero E, Levina EV, Nathan DM. 1999. <i>Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients</i>. Diabetes Care. Nov;22(11): 1785-9. Type: RCT Purpose: POC HbA1 c testing results could improve glycemic control by changing physician or patient behavior or both</p>	<p>Assay group HbA1c decrease: (20.57 ± 1.44 and 20.40 ± 1.65%, respectively; P,0.01 Control Group HbA1c decrease: 20.11 ± 0.79 and 20.19 ± 1.16%, respectively; NS</p>	<p>H b A1 c levels decreased significantly at 6 and 12 months in the immediate assay group changes were similar for both type 1 and type 2 diabetic patients</p>

Table 1 Continued

<p>Miller CD, Barnes CS, Phillips LS, Ziemer DC, Gallina DL et al. 2003. <i>Rapid A1c availability improves clinical decision-making in an urban primary care clinic.</i> Diabetes Care;26(4): 1158-63 Type: Prospective control trial Purpose: to determine whether rapid-turnaround A1c availability would improve intensification of diabetes therapy and reduce A1c levels in patients with type 2 diabetes.</p>	<p>597 subjects Diagnosis of diabetes for 10 yrs HbA1c of at least 8.5% BMI of 33</p> <p>Decrease in HbA1c P=0.01</p> <p>Rapid HbA1c testing group Decrease 51% of participants</p> <p>Control group non rapid testing Decrease 32% of participants</p> <p>HbA1c decrease:</p> <p>Rapid test group: 10.1 to 9.1 Control group: 9.7 to 9.0</p>	<p>Rapid A1c availability resulted in more frequent intensification of therapy when A1c was $\geq 7.0\%$ at the baseline visit</p> <p>In 275 patients with two follow-up visits, A1c fell significantly in the rapid group</p> <p>Increased intensity in rapid testing group</p>
<p>Khunti K, Stone MA, Burden AC, et al. <i>Randomised controlled trial of near-patient testing for glycated haemoglobin in people with type 2 diabetes mellitus.</i> Br J Gen Pract 2006; 56:511-7. Type: Pragmatic open RCT Purpose: To evaluate whether POC testing impacts HbA1c results</p>	<p>638 patients 2 groups: Control group and POC group 12 month following Decrease in total participants in control group HbA1c of 37% Decrease in test group participants of HbA1c of 38% Confidence interval 0.69 to 1.31</p>	<p>POC testing does not result in significant cost savings or significant improvement in HbA1c 20 euros in cost savings between groups</p>

Interventions

A review of 21 RCTs by Gillies et al., (2007) evaluated the impact of specific interventions on type 2 diabetes. Participants in all of the studies were required to have at a minimum hyperglycemia and be 18 years of age or older. In the end 17 studies were included for review. Of those excluded, one included an oral medication no longer recognized as a viable intervention for the prevention and progression of type 2 diabetes and the other three were excluded due to insufficient data. The interventions reviewed were the initiation or adjustment of medications (oral and herbal) and lifestyle interventions, most significant of which was weight loss through diet and exercise. Lifestyle interventions were found to be equally as effective at prevention or progression of type 2 diabetes as pharmacological approaches. Noted increases in adverse effects were found in the intervention groups with oral medication therapy when compared to the placebo groups in these studies. This review of studies supports the importance of lifestyle modifications to enhance the health of those with or at risk of developing type 2 diabetes. Please refer to Table 2 for detailed statistical findings. It is important to note the need for lengthy follow up to assess compliance of medicinal or lifestyle interventions (Gillies et al., 2007).(Table 2).

Gibbs et al., (2012) began a RCT in 2001 known as the Look AHEAD (Action for Health in Diabetes) study and will follow participants for 13.5 years. The RCT will evaluate the impact of decreased caloric intake and increased physical activity on the incidence of cerebral vascular accident (CVA), myocardial infarction (MI) and cardiovascular related deaths, all known risk factors of uncontrolled type 2 diabetes.

Participants (N= 5,145) with type 2 diabetes, ages 45-76 years, with a BMI of over 25, were recruited from 16 centers and divided into two groups. Group one had monthly meetings with assigned caloric intake and exercise goals with individualized supervision. The second group was given three sessions per year of DSME. At one year (2007) those enrolled in the monthly intervention group showed a 6.2% average loss in total body weight with the DSME only group showing a total weight loss of 0.9% of total body weight. Overall, dietary and exercise control showed improvement in overall fitness, glucose control, blood pressure and increase in high density lipoprotein (HDL) cholesterol. The long term effects in regards to CVA, myocardial infarctions and cardiovascular related deaths will be measured at the end of the 13.5 year period.

Mitra, Dewanjee and Dey (2012) studied the mechanisms of interventions in 60 participants with type 2 diabetes over a one-year period of time. All participants were 18 years or older and had baseline HbA1c, LDL, HDL, triglycerides, and BMI measured. Participants were randomly divided into two groups of 30. The intervention group received detailed dietary information recommending a reduction of sugar containing foods, red meats and trans fats and an increase in whole grains, green vegetables and fruits. They were also given detailed information and support in development of an exercise program of brisk walking, stretching, jogging and aerobic exercises. The control group received the routine office visit and no counseling. After one year the investigators re-measured the values taken at baseline. . Results of this study showed a significant decrease in lab values and BMI at the end of the one year for the intervention group compared to the control group. The control group in this study showed less improvement

in the areas of HbA1c, LDL, HDL, and BMI than the intervention group (Table 2).

These results indicate the importance of diet control, education referrals and exercise interventions on the impact of type 2 diabetes and overall health.

Table 2
Studies showing specific intervention improving diabetic outcomes

Study	Data Summary	Results
<p>Gillies, C., Abrams, K., Lambert, P., et al. (2007). Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. BMJ. doi: 10.1136/bmj.39063.689375.55 Type: Meta-analysis Purpose: to quantify effectiveness of pharmacological and lifestyle interventions to prevent or delay type 2 diabetes.</p>	<p>21 RCT evaluated 17 included in response 4 removed. 1 due to lack of intervention still existing as recognized and 3 due to lack of adequate data. Medications included both prescribed and herbal Primary focus of intervention was on weight loss Confidence interval 0.44 to 0.60 Absolute difference in incidence of diabetes: -15.8% Absolute difference for lifestyle interventions: -93% Absolute difference for oral diabetic drugs: -18.4% Absolute difference for oral herbal medication: -22.7%</p>	<p>Lifestyle and Pharmacological interventions were equally effective. Less side effects in life style modification group. Long term follow up is needed to identify long term success and prevention.</p>

Table 2 Continued

<p>Gibbs, BB., Brancati, FL., Chen, H. et al. (2012). <i>Effect of improved fitness beyond weight loss on cardiovascular risk in individuals with type 2 diabetes in the look AHEAD study</i>. Johns Hopkins Bloomberg School of Public Health and School of Medicine. Baltimore.</p> <p>Type: RCT Intervention Purpose: to identify intensive lifestyle intervention (ILI) to a diabetes support and education (DSE) control group in adults with type 2 diabetes</p>	<p>5000 participants n = 4408 p < 0.05 improvements in glucose (+0.7%), HbA1c (+1.1%), high-density lipoprotein (HDL) cholesterol (+0.4%), and triglycerides (+0.2%) in ILI and diastolic BP (+0.3%), glucose (+0.3%), HbA1c (+0.4%), and triglycerides (+0.1%) in DSE. Variability 0.1-9.3%</p>	<p>Increased fitness explained statistically significant improvements in several cardiovascular risk factors beyond weight loss. Further research identifying other factors that explain cardiovascular risk factor change is needed.</p>
<p>Mitra, A., Dewanjee, D., Dey, B. (2012). <i>Mechanistic studies of lifestyle interventions in type 2 diabetes</i>. World Journal of Diabetes. 3(12) 201-207.</p> <p>Type: RCT Purpose: investigate the effect of lifestyle interventions in the non-pharmacological management of type 2 diabetes Via a mechanistic approach.</p>	<p>60 participants divided into 2 groups of 30. Followed for 1 year HbA1c at baseline for both groups was 8.3 +/- 0.58 HbA1c of control group was 6.3% +/- 0.32 HbA1c for the control group was 7.2% +/- 0.42. LDL at baseline was 122 +/- 7.58. Intervention group: LDL levels to 118 +/- 2.31 Control group LDL: 136 +/- 3.55. HDL levels 38.1 +/- 2.12 at baseline reading Intervention group readings improved to 58 +/- 0.62 Control group at 49 +/- 0.96. BMI readings at baseline were 27 +/- 0.92 Intervention group BMI</p>	<p>test group who had a lifestyle intervention was found to show a significant improvement in blood glucose lipid profile signifies the value of non-pharmacological management of type 2 diabetes via lifestyle intervention strategies</p>

Table 2 Continued

	<p>in 1 year: 25 +/- 0.51 in BMI control group at 1 year 26 +/- 0.65 in the control group</p> <p>Values at completion of test group: Fasting plasma glucose level (FPG): 145+/- 2.52</p> <p>postprandial plasma glucose level (PPG): 174+/-2.59</p> <p>HbA1c: 6.3+/- 0.32</p> <p>(BMI): 25+/- 0.41</p> <p>Values at completion of control group:</p> <p>FPG: 193+/- 3.36</p> <p>PPG: 249 +/- 4.24</p> <p>HbA1c: 7.2+/- 0.42</p> <p>BMI: 26+/- 0.65</p>	
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The majority of studies performed regarding POC testing have shown that it benefits HbA1c outcomes. Although there are few studies exploring the value of POC A1c measurement; those in print show a benefit for this addition to diabetes care. A decrease in HbA1c, can lead to better health outcomes, including reduction of microvascular diseases. Lifestyle interventions have also been studied and shown to have a positive effect on health outcomes, which include reductions of risk of vascular diseases, a known major complication of type 2 diabetes. More studies are needed to specifically identify the interventions that take place during POC testing to better understand the relationship to the improvement in HbA1c.

CHAPTER THREE

DESIGN AND METHODS

Design

A quasi-experimental design was used and a comparative analysis performed. Quasi experimental design is defined as “a design that entails researcher manipulation of the independent variable but lacks randomization, a control group or both. It uses other strategies (such as sampling, data collection, or statistical control) to impose control over threats to internal validity” (Norwood, 2010 pg 485). A comparative analysis is a side by side examination of two or more alternatives, processes or sets of data (Business Dictionary, 2013). In this instance, a retrospective audit of electronic medical record (EMR) was conducted to examine the relationship between the type of HbA1c testing used (POC or outside laboratory) and the interventions employed by the health care provider in response to an HbA1c of 8% or greater. Furthermore, the adherence to recommended guidelines by providers and the patients’ subsequent HbA1c from each group was compared to determine if a statistically significant difference was present.

Sample

The study sample consisted of patients from two medical clinics, 21-65 years of age with a diagnosis of type 2 diabetes for a minimum of one year, and HbA1c value greater than or equal to 8.0%. The minimum of one year diagnosis was established to allow time for the participant to adjust to the new diagnosis of type 2 diabetes. The age

limit was set higher at age 65 to allow for newly established guidelines which show less aggressive control is necessary in the aging population to avoid adverse outcomes (ADA, 2012) The value of HbA1c was selected as it clearly shows uncontrolled diabetes by established ADA standards and as previously noted in the Khunti study, levels less than 7.5% were near goal already and provided less opportunity for significantly measureable improvement. A sample of 150 patients was projected based on interviews with clinic providers.

The EMR's at each clinic were used to select eligible participants. Patients were placed into two equal groups representing clinic X and clinic Y based on type of testing and qualifying factors mentioned above. Clinic X used POC testing while Clinic Y did not. The first group, hereafter referred to as Group A, was defined as those study participants who received POC HbA1c testing from their provider through Clinic X. The second group, hereafter referred to as Group B, did not receive POC HbA1c testing but instead had blood drawn through venipuncture at clinic Y which was subsequently sent out for laboratory evaluation.

Setting

The information obtained regarding Group A and Group B was obtained through interview of the practice manager. The clinics are located in a Northwestern rural state and associated with a critical access hospital that operates several local clinics. Clinic X, during the time frame data were collected employed four family practice physicians.

Clinic Y, during this same time, employed three family practice physicians and one physician's assistant.

Both clinical sites served people with Medicare, Medicaid, private insurance, Indian Health Services (IHS) coverage, and self-pay patients of all races, with the largest demographic groups being American Indian/Alaska Natives and Caucasian. It was estimated that the clinical sites saw relatively equal numbers of patients per year.

Interventions to be Measured

Three specific methods of interventions performed by the providers were evaluated. These included face-to-face intervention, use of a letter to communicate medical advice, or use of a phone call to communicate medical advice. Those who included only an education pamphlet and no personalized and specific counseling were excluded from this study. The intervention trigger was an HbA1c of 8% or greater, indicating less than desirable glycemic control, LDL greater than or equal to 100 mg/dL, BMI greater than or equal to 27 and/or BP greater than or equal to 130/80. As per the ADA recommendations (2012), an intervention must be made in response to any elevations in these triggers in order for the provider to be deemed in compliance with standards of practice. Recommended interventions included referrals to DSME and/or medical nutritional therapy (MNT), changes to medications and/or compliance inquiry, diet education or discussion, and exercise plan. Providers of participants who did not receive interventions would be deemed as non-compliant with standards of practice.

Collection Method

Reports were obtained from the electronic medical records system showing those who had POC HbA1c's and another showing non-POC HbA1c. Those subjects identified were then audited for subject qualifications for the study as described above. Charts documenting patient visits from January 1, 2012 through January 1, 2013 were audited using the chart audit tool for Group A (see appendix A) and chart audit tool for Group B (see appendix B). Data collected included (1) the intervention trigger, of an HbA1c greater than 8.0%. LDL greater than or equal to 100 mg/dL, BMI greater than or equal to 27 and/or BP greater than or equal to 130/80, (2) interventions initiated, and (3) the method of intervention. Finally, the HCP initiated interventions were evaluated as in or out of compliance with standards of care as defined above. Initial HbA1c levels were considered the first obtained value within the established time frame and follow-up HbA1c was considered the value subsequent to the initial documented value. Demographic data (including gender, race, age, marital status, level of education time since diagnosis, and insurance type) were collected.

Data Analysis

The independent variables in this study were (1) POC testing performed or (2) POC testing not performed. Dependent variables were intervention types which included (1) referrals to DSME and/or MNT, (2) changes to medications and/or compliance inquiry, (3) diet education/discussion, (4) exercise discussion and (5) meeting with standards of practice.

Statistical Calculations

Two statistical analysis calculations were used to determine statistical significance of this study's findings. The first was the Pearson chi-squared test which was used for calculating compliance between Group A and Group B. Secondly, the two-tailed t-test was used to identify statistical significance in HbA1c outcomes at follow-up between the two groups.

Human Subjects Consideration

This study was approved by the Montana State University Institutional Review Board (IRB). Permission was also obtained from the administration of the clinic systems where this study was conducted.

CHAPTER 4

RESULTS

Demographics

For Group A, a report of POC HbA1c levels showed a total of 174 subjects. Of the 174, 44 had HbA1c results greater than or equal to 8.0%. Of those 44 subjects, 22 qualified for the study, 14 were excluded due to age greater than 65, six for a diagnosis less than one year and one subject did not qualify as they were diagnosed with type 1 diabetes.

In a report generated for the Group B a total of 97 HbA1c levels were processed through an outpatient lab affiliated with Clinic Y. The HbA1c levels included 53 with values greater than or equal to 8.0% with 23 subjects qualifying under study parameters. The number of subjects excluded, included 19 due to age greater than 65 and one for age less than 21. Two had a diagnosis of type 1 diabetes, two were HbA1cs ordered by providers outside of Clinic Y and six had a diagnosis for less than one year. At the end of the selection process, 45 subjects were selected with 22 in Group A and 23 in Group B. (See Appendix D).

Comparison of both groups showed very close similarities in demographics in regards to all categories. The majority of the subjects were male at 55% (n=25) with 45% being female (n=20). American Indian/Alaska Native was the highest reported race at 67% (n=30) with Caucasians following at 31% (n=14) and 2% listed as undefined (n=1). The smallest age group was between 21-30 years old at 2% (n=1), followed by

31-40 and 61-65 years of age at 13% (n=6), and 51-60 at 31% (n=14). Those aged between 41-50 years made up the largest portion of the groups (n=40%) with an average group length of diagnosis of 5.1 years. Most subjects were married with a rate of 56% (n=25), single at 33% (n=15), divorced at 4% (n=2) and 7% did not indicate marital status (n=3). Education level was not a demographic collected by the EMR. Several different payer types were identified and included with the majority being IHS and private coupled with IHS both at 27% (n=12). Other payor types were private insurance at 20% (n=9), self pay at 13% (n=6), Medicare with Medicaid and Medicaid with IHS at 4.5% (n=2) and both Medicare with private insurance and Medicaid alone at 2% (n=1). (See Table 3).

Table 3
Gender, Age, Race, Marital Status, Length of Diagnosis (N=45)

Responses		Number Of Cases	% of Total Sample
Gender	Male	25	55%
	Female	20	45%
Age	21-30	1	2%
	31-40	6	13%
	41-50	18	40%
	51-60	14	31%
	61-65	6	13%
Race	American Indian/Alaska Native	30	67%
	Caucasian	14	31%
	Undefined	1	2%
Marital Status	Married	25	56%
	Single	15	33%
	Divorced	2	4%
	Widowed	0	0%
	Not Indicated	3	7%
Age	1-2 years	10	22%
	3-5 years	14	31%
	>5 years	21	47%

Missing Data

Review of follow-up HbA1c values of those subjects in Clinic Y showed five had no repeat HbA1c performed. Statistical analysis using the two-tailed t-test was performed both by excluding those subjects with missing data as well as carrying the initial HbA1c values forward and no differences in results was found. For the purpose of this study, the reported testing is that of the initial HbA1c value being carried forward to the follow-up HbA1c results.

Achievement of Standards of Care

In order to be within standards of care, all areas out of suggested range had to be addressed with an intervention (HbA1c greater than or equal to 8.0%, BMI greater than 27, LDL greater than 100 and BP greater than or equal to 130/80). Achievement of the standards of care was noted to be higher in Group A than in Group B. Group A had a rate of 12 of the 22 charts reviewed had achieved standards of care at a rate of 55%. Group B chart audits showed that 5 of the 23 met with standards of care. This calculated to an achievement rate of 21%.

The Pearson Chi-Square two-sided test was performed to determine if an association was present between compliance and clinic residence. The results showed that there was a statistically significant higher rate of achievement to standards of care of Group A in comparison to those in Group B. ($\chi^2(1, N=45)=5.148, p=0.03.$) (See Table 4).

Table 4

Clinic Condition *Achievement to Standards of Care Cross Tabulation

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 8.31.

		Compliance		Total
		0	1	
Clinic	.0	10	12	22
Condition	1.0	18	5	23
Total		28	17	45
Pearson Chi-Square		Value	df	Exact Sig. (2-sided)
		5.148 ^a	1	0.03

HbA1c

The mean HbA1c in Clinic X initially was 10.2 (sd=1.9837). Participants in Group A had changes in their HbA1c at follow-up in the achievement of standards of care group ranging from a drop of 6.8 points at its greatest to an increase of 1.7 points. Those in Group A, who were determined to not meet the standards of care, had changes at follow-up to their HbA1c levels ranging from a decrease of 2.6 points to an increase of 3.0 points. The mean HbA1c at follow up was 9.3 (sd=1.7983) in Group A. HbA1c mean value in Group B was 9.3% (sd=1.3791) initially. These subjects considered to have compliant interventions had changes to their HbA1c ranging from a decrease of 1.4 to -0.1 points. Those with repeat values showed changes ranging from a decrease of 1.5 points to an increase of 1.9 points with a mean HbA1c at follow-up of 9.8 (sd=1.67). (See Table 5)

A variable was created for mean differences. Using this data, a two-tailed, paired samples t-test was performed to determine if POC HbA1c testing was relative to a larger decrease in HbA1c results at follow-up between the two groups. This test showed no

statistically significant difference between Group A (M=0.86;SD=2.16) and the Group B (M= 0.9;SD=1.02); $t(1.92)p=0.61$.(See Table 5).

Table 5
t-test (2-tailed)

Clinic Condition		Mean	Std. Deviation	N	
HbA1c Initial	.0	10.186	1.9387	22	
	1.0	9.626	1.3791	23	
	Total	9.900	1.6808	45	
HbA1c follow-up	.0	9.318	1.7983	22	
	1.0	9.722	1.6700	23	
	Total	9.524	1.7262	45	
Clinic Condition	N	Mean	Std. Deviation	Std. Error Mean	
Difference	.0	22	.8682	2.16209	.46096
R	1.0	23	-.0957	1.02668	.21408
t-test for Equality of Means					
		Sig. (2-tailed)	Mean Difference	Std. Error Difference	
DifferenceR	Equal variances assumed	.061	.96383	.50099	

CHAPTER 5

DISCUSSION

The purpose of this study was to evaluate the impact of POC HbA1c testing on the meeting with standards of care by providers and subsequently, HbA1c values at follow-up. It is important to note that the ADA, (2012) guidelines indicate multiple standards in the appropriate management of diabetes however, for this study, the goal was to identify the factors that most directly impact microvascular complications. These are HbA1c, LDL, and BP. As previously discussed, an elevated BMI is a direct contributor to elevation in HbA1c, LDL and BP. If any of these values were greater than the recommended values established to decrease the risk of microvascular and macrovascular complications, the provider needed to address them in order to be deemed in compliance with standards of practice.

A study of compliance of ADA standards in rural Montana was performed from January of 1999 through August of 2000 (Coon & Zulkowski, 2002). Chart reviews were performed at four separate rural clinical sites. The study results showed that ADA standards were not met. HbA1c was drawn at least once in 85% of the subjects with 50% having HbA1c higher than recommended standards. The HbA1c frequency was lacking with established guidelines of 3 months in uncontrolled diabetes and 6 months in well controlled diabetes, as well as recording and addressing other standards which effect micro and macrovascular complications as mentioned above (LDL and BP) (Coon & Zulkowski, 2002). In the current study, subjects in Group A showed a statistically

significant ($p=0.03$) higher rate of compliance with ADA standards of practice in regards to HbA1c, LDL, BP and BMI in relation to Group B. Therefore, it can be concluded that POC HbA1c testing increased compliance with ADA standards of practice.

Microvascular complications in diabetes are caused by hyperglycemia and the associated tissue damage that is with it and is the leading cause of blindness, nephropathies including end-stage renal failure and neuropathies. It causes thickening of the basement membrane capillaries, altering tissue perfusion and formation of thrombosis and causes microangiopathy. Macrovascular complications include coronary artery disease (CAD), cerebral vascular disease such as stroke and peripheral artery disease (PAD). These complications stem partially from hyperglycemia and elevated LDL, and hypertension (HTN). Those with type 2 diabetes are particularly at risk for macrovascular complications (McCance et al., 2010).

The Diabetes Control and Complications Trial (DCCT, 1983-1993) followed 1,441 subjects with type 1 diabetes. Those who underwent intensive management of their glucose levels and were able to maintain an HbA1c as close to goal of 6.0% as possible had dramatic decrease to their microvascular risk. The reported findings showed a 76% risk reduction of development of eye disease, 50% risk reduction in developing kidney disease and 60% decrease in neuropathic complications. Following the DCCT, the Epidemiology of Diabetes Interventions and Complication (EDIC, 1993-2005), followed the subjects further to monitor for implications of this continued control on macrovascular risk complications. This study showed significant decreases in the risk when glucose levels were tightly controlled. Risk of any cardiovascular disease event

was decreased by 42% while death from MI, heart disease and stroke decreased by 57%. This study points out that while it focused on those with type 1 diabetes, it is likely that it is reflective on type 2 diabetes as the pathophysiology of hyperglycemia's effects on the body are the same (NIDDK, 2008).

Although the study reported here showed no statistically significant reduction in HbA1c ($p=0.06$), the findings were clinically significant. Group A showed a mean decrease of nearly 1% (0.9%) while Group B remained virtually the same with a 0.1% mean increase in HbA1c. According to the UKPDS, (1998), lowering of the HbA1c of 1% decreases the risk of microvascular complications by 25%. Group A, therefore decreased their risk significantly in respect to clinical outcomes in comparison to Group B who had no decrease in their microvascular risk. A reduction in HbA1c by 1% results in a 30 mg/dL drop in average blood glucose readings. HbA1c levels in those with diabetes range an average of 6.0% to 12.0% (NIDDK, 2014). Group A had a mean HbA1c level of just over 10 points and a follow up of nearly 9%. This means that their average daily glucose levels dropped 30 mg/dL while Group B had an increase of 15 mg/dL in their average daily glucose levels. This shows a 45 mg/dL change in total between groups.

Study Limitations

Limitations to this study include sample size and potential for lack of documentation by providers. It is possible that had the sample size been larger, the HbA1c results may have been statistically significant. Additionally, by using

retrospective chart reviews, the researcher could rely only on the documentation provided. As a result, it is possible that interventions may have been provided in the form of education by nurse or provider, but not documented.

Implications

Meeting the standards of practice as well as improvement of HbA1c was greater in Group A. These findings support that POC testing is a tool which assists in the improvement of diabetes care and management. Additionally, the interventions in the POC group were all face-to-face, while in Group B, the intervention type varied from face to face to phone call. While not all subject charts were within standards of practice, it is important to note that all but one of the subjects in Group A had at least one intervention performed, while 10 in Group B had no interventions performed. Further studies are needed to determine if POC testing of HbA1c can have an even greater impact on compliance in all areas of ADA recommendations including eye exams, monofilament testing, and microalbuminuria testing. This would require a controlled study in which HCPs are appropriately educated on current ADA standards and then compared to a group who receives care by patient education, but lacks the POC testing. This may further assist in determining the impact POC testing plays in diabetes management. Increase in interventions might also increase patient satisfaction with diabetes care received from their providers.

Conclusion

In conclusion, POC HbA1c testing increases provider compliance in addressing diabetes and its complications. Providers addressed elevation in HbA1c, LDL, BP and BMI at a higher rate in those who received POC testing than in those who did not. Additionally, the rate of improvement in the HbA1c in those who received the POC testing was clinically significant, showing a decrease in potential microvascular complications of 25% as well as a potential decrease in macrovascular disease. Those who did not receive POC testing showed no decrease in risk at all. POC testing has been identified as an important tool in improving diabetes outcomes and is found through this study to be superior compared to outside testing.

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APPENDICES

APPENDIX A

CHART REVIEW TOOL FOR POC PATIENTS

CHART REVIEW TOOL
POC PARTICIPANTS

GENDER: _____
AGE: _____
LENGTH OF DIAGNOSIS: _____
RACE: _____
INSURANCE TYPE: _____

INITIAL FINDINGS:

BMI: _____

LDL: _____
BP: _____
ENDO
HBA1C: _____

INTERVENTION:

MED CHANGES: Y N TYPE:

EXERCISE COUNSELING: Y N
REFER: Y N MNT DSME

DIET COUNSELING: Y N

FOLLOW UP FINDINGS:

BMI: _____
LDL: _____
BP: _____
HBA1C: _____

INTERVENTION METHOD: FACE TO FACE LETTER PHONE CALL

APPENDIX B

CHART REVIEW TOOL FOR NON-POC PATIENTS

CHART REVIEW TOOL
NON-POC PARTICIPANTS

GENDER: _____
AGE: _____
LENGTH OF DIAGNOSIS: _____
RACE: _____
INSURANCE TYPE: _____

INITIAL FINDINGS:

BMI: _____

LDL: _____
BP: _____
ENDO
HBAIC: _____

INTERVENTION:

MED CHANGES: Y N TYPE:

EXERCISE COUNSELING: Y N
REFER: Y N MNT DSME

DIET COUNSELING: Y N

FINDINGS AT FOLLOWUP

BMI: _____
LDL: _____
BP: _____
HBAIC: _____

INTERVENTION METHOD: FACE TO FACE LETTER PHONE CALL

APPENDIX C

CONSENT/NOTICE OF PRIVACY PRACTICES

St. Luke Community Healthcare
107-6th Ave. S.W. - Ronan, Montana 59864

**CONSENT TO ADMISSION AND MEDICAL TREATMENT
FINANCIAL AGREEMENT**

Name of Patient: _____

Name of Attending Physician(s): _____

Date of Admission: _____ Time: _____ (am) (pm)

1. I, (or _____) acting on behalf of _____
(name of authorized representative) (name of patient)
suffering from a condition requiring hospital/nursing home care/clinics, hereby consent to the rendering of such care, which may include routine diagnostic procedures and such medical treatment as the named attending physician(s) or others of the facility's medical staff consider to be necessary.
2. I understand that the practice of medicine and surgery is not an exact science and the diagnosis and treatment may involve risks of injury, or even death. I acknowledge that no guarantees have been made to me as to the result of examination or treatment in this facility.
3. I understand that:
 - A) It is customary, absent emergency or extraordinary circumstances, that no substantial procedures are performed upon a patient unless and until he or she has had an opportunity to discuss them with the physician or other health professional to the patient's satisfaction:
 - B) Each patient has the right to consent, or to refuse consent, to any proposed procedure or therapeutic course.
4. All photographs taken during my hospitalization or treatment will become part of my permanent medical record which is handled pursuant to the hospital's medical record policy.
5. I understand that many of the physicians on the staff of this facility are not employees or agents of the facility but, rather are independent contractors who have been granted the privilege of using its facilities for the care and treatment of their patients.
6. I understand St. Luke Community Healthcare is a tobacco free campus and I agree to abide by the policy _____
(Initial)
7. Release of information: I hereby authorize the hospital, nursing home and physician associates to furnish to my insurance carriers and/or payers requested information from my hospital/nursing home records.
8. I understand that I am responsible for charges made for the use of all hospital/nursing home facilities, services, emergency room, x-ray, laboratory work, drugs, dressings, etc. by the facility and separate charges may be made for the physician's service. I hereby assign insurance benefits to the facility and physician associates.
9. I acknowledge receipt of the St. Luke Community Healthcare Notice of Privacy Practices (effective 4-14-03).
10. In case suit or action is instituted to collect this bill, or any portion thereof, I agree to pay such additional sum as the court may adjudge reasonable as attorney's fees in said suit or action.
11. I understand that St. Luke Community Healthcare has a Patient Financial Assistance program and I wish to be pre-certified.
12. This form has been fully explained to me, and I am satisfied that I understand its content and significance.

Date: _____ Time: _____

(Signature of parent or legal guardian)

(Signature of Witness)

If patient is unable to consent or is a minor, complete the following:

Patient (is a minor _____ years of age) (is unable to consent because _____).

Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW PROTECTED MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GAIN ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

1. St Luke Community Healthcare Network is permitted to make uses and disclosures of protected health information (PHI) for treatment, payment and health care operations, as described in the following examples:
 - a. For treatment – If you're being treated for a knee injury, we may disclose your PHI to the physical therapy department in order to coordinate your care.
 - b. For payment – We may provide portions of your PHI to the billing department and your health plan to get paid for the health services we provide to you. We may also provide your PHI to our business associates, such as billing companies, and others that process our health care claims.
 - c. For health care operations – We may use your PHI in order to evaluate the quality of health care services that you received or to evaluate the performance of the health care professionals who provided health care services to you. We may also provide your PHI to our accountants, attorneys, consultants, and other in order to make sure we're complying with the laws that affect us.

2. St Luke Community Healthcare Network is permitted or required, under specific circumstances, to use or disclose PHI without the individual's written authorization.
 - a. When a disclosure is required by federal, state, or local law, judicial or administrative proceedings, or law enforcement. For example, we make disclosures when a law requires that we report information to government agencies and law enforcement personnel about victims of abuse, neglect, or domestic violence; when dealing with gunshot and other wounds; or when ordered in a judicial or administrative hearing.
 - b. For public health activities. For example, we report information about births, deaths, and various diseases, to government officials in charge of collecting that information, and we provide coroners, medical examiners, and funeral directors necessary information relating to an individual's death.
 - c. For health oversight activities. For example, we will provide information to assist the government when it conducts an investigation or inspection of a health care provider or organization.
 - d. For purposes of organ donation. We may notify organ procurement organizations to assist them in organ, eye, or tissue donation and transplants.
 - e. For research purposes. In certain circumstances we may provide PHI in order to conduct medical research.
 - f. To avoid harm. In order to avoid a serious threat to the health and safety of a person or the public, we may provide PHI to law enforcement personnel or persons able to prevent or lessen such harm.
 - g. For specific government functions. We may disclose PHI of military personnel and veterans in certain situations. And we may disclose PHI for national security purposes, such as protecting the President of the United States or conducting intelligence operations; or
 - h. For worker's compensation purposes. We may provide PHI in order to comply with worker's compensation laws.

APPENDIX D

CONSORT FLOW CHART FOR INCLUSION/EXCLUSION

