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Measuring Quality of Health Care in Type II Diabetes Mellitus Patients Using Certified Electronic Health Records

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Abstract

Great strides have been made in health care over the past six years after the implementation of the policy known as meaningful use by the Center of Medicare and Medicaid Services. Health care subsidies and monetary incentive programs were created for eligible professionals and critical area hospitals to encourage the use of certified electronic health records in an effort to improve quality care of all acute and chronically ill patients, as well as provide routine examinations for healthy individuals.

Patients diagnosed with type II diabetes mellitus were studied using a certified electronic health record system for compliance in physician ordered lab testing and follow-up visits with their primary care physician so as to confirm a positive effect on in the quality of patient health care. Diabetes mellitus is a disease which requires constant monitoring, thus creating an ideal patient study group. Research has confirmed that patient compliance significantly improves quality of health care outcomes; now it is time to determine that if the implementation of a certified electronic health record in the family practice setting improves patient compliance, thus improving quality of health care.

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Definitions of Key Terms

- ACA: Affordable Care Act. Enacted in 2010, the ACA has provided Americans with a higher quality of health care coverage as well as lowering costs, raising inclusiveness in health care plans, and gave people choices in their health care plans to better suit their needs.
- CDS: Clinical Decision Support. The CDS increases the quality of health care to Americans by creating more efficient, cost effective and improved accuracy when treating patients. It provides clinical alerts, guidelines, and condition order sets to health care providers in an effort to improve quality of health care.
- CMS: Center of Medicare and Medicaid Services. The CMS is a branch of the Department of Health and Human Services; it is the backbone organization behind most of the laws, acts, and initiatives geared towards protecting patient rights, improving quality of health care and reporting designs in an effort to make positive changes regarding American health care (Centers for Medicare & Medicaid Services [CMS], 2010).
- DM: Type II Diabetes Mellitus. DM is a disease or condition where a patient is unable to produce enough insulin to break down and dispose of the glucose in the blood. This disease is also known as diabetes mellitus.
- EHR vs. EMR: Electronic Health Record vs. Electronic Medical Record. An electronic medical record (EMR) is a computerized method of maintaining patient records in a health care setting (Seidman, 2011). EMRs are also capable of tracking patient data, for example patients utilizing state funded health care options with insurance benefits. However, EMRs are limited in their capabilities of sharing patient information with

other health care providers and reporting quality control measures to the respective organizations. With an EMR, the responsibility fell to the eligible professional's (EPs below) responsibility to hire outside organizations to manage patient data and assure patient safety when sharing patient health information. Electronic health records (EHRs) are capable of all the measures needed to meet quality control measures directed by the CMS while protecting patient health information. A certified EHR assures quality performance, efficiency in documentation and sharing, as well as costs associated with eliminating repeat tests and office practices (Sideman, 2011).

- EP: Eligible Professional. Professionals in health care who are eligible to apply for CMS incentive programs as long as they meet the requirements of either Medicaid or Medicare Services. Examples of EPs are doctors, therapists, dentists, or mid-level providers.
- Glycosylated. Glycosylation occurs when glucose in the blood binds to hemoglobin. Patient with untreated or undertreated type II diabetes mellitus (DM), have a higher affinity for glycosylated hemoglobin than those individuals who do not have the disease.
- HbA1c: Hemoglobin A1c. HbA1c is a measurement of glycosylated hemoglobin in the blood to evaluate patients for their control of their type II diabetes mellitus.
- HITECH: Health Information Technology for Economic and Clinical Health Act was enacted as part of the American Recovery and Reinvestment Act of 2009 in an effort to encourage the adoption of meaningful use in health care organizations with EPs.
- LDL: Low-Density Lipoprotein. LDL is a potentially, lethal cholesterol with a low enough density capable of collecting on the walls of arteries and causing blockage.

- MU: Meaningful Use. MU is a practice of using a certified EHR technology capable of improving the quality and safety to patients by their providers while increasing efficiency and reducing health related accidents in all the health care organizations the patient participates ("EHR Incentives," 2015).
- ONC: Office of the National Coordinator for Health Information Technology. This is an organization is a branch within the Department of Health and Human Services; it responsible for facilitating interoperability standards for health care professionals ("About ONC," 2015).
- PHI: Personal Health Information. Information usually collected in a health care provider's office, containing patient demographics, insurance information, lab test results and patient encounters created after visits with the health care provider (United States Department of Health and Human Services [HHS], n.d).
- PQRS: Physician Quality Reporting System. PQRS is a quality reporting system which encourages EPs to assess and report the quality of care offered and accepted by Medicare patients (CMS, 2015).

Measuring Quality of Health Care in Type II Diabetes Mellitus Patients using Certified Electronic Health Records

Chapter 1

Introduction

The Centers of Medicare and Medicaid Services (CMS) implemented the meaningful use (MU) incentive policy in 2009 to mandate how health care providers submit statistical reports on their patients. Until then, there was no consistent method to evaluate follow-through visits and compliance with physician orders, lab work and prescription medication therapy. In 2004, the Bush Administration determined that Information Technology would provide a secure connection to improve communication between health care professionals (Crossom, 2012). By 2009, the Health Information Technology for Economic Act addressed the adoption of meaningful use (MU) in electronic health records (EHRs) so that eligible professionals (EPs) such as health care providers, professionals and critical area hospitals had a means of meeting the criteria to receive incentives by way of reimbursements from the CMS. "The percentage of office based practices with EHRs increased from 48.3% in 2009 to 55% in 2011, and in the later year, 75% of physicians with EHRs stated that their system meets meaningful use criteria" (Ahmad & Tsang, 2013). One of the goals of MU is to improve patient quality of care by promoting patient compliance with orders initiated by their health care provider. There are three stages of MU and the first deadline has already come to pass in 2014. The requirements to meet MU in health care organizations require that these facilities utilize and report statistics using certified EHR's.

Eligible professionals are comprised of individuals or groups meeting the eligibility requirements to utilize benefits from meaningful use initiatives. EPs include, but are not limited to, physicians, therapists, mid-level providers and dentists who meet the quality reporting

requirements of either Medicaid or Medicare Services. Other federal programs such as the Physician Quality Reporting Systems (PQRS) were established to regulate how quality reporting is performed by all EPs and are evaluated by the CMS (American Medical Association [AMA], n.d.). "Valid and reliable electronic quality measures, coupled with decision support, could be used by providers for quality improvement and by payers to drive toward interventions targeting diabetes prevention" (Ahmad & Tsang, 2013). Both MU and PQRS are designed to evolve each year as new data is received. This purpose being to allow for changes geared towards the improvement of quality of health care services rendered, as well as narrow down methods to accurately measure quality of care in the treatment of patients.

Certified Electronic Health Records

It is believed by various health care organizations that current strategies for the certified EHR improve the way healthcare is received and delivered today. "Certified EHR technology gives assurance to purchasers and other users that an EHR system or module offers the necessary technological capability, functionality, and security to help them meet the meaningful use criteria" ("Certified EHR," 2015). EPs utilizing a certified EHR should be capable of capturing and sharing patient data accurately and efficiently. "Structured data allows patient information to be easily retrieved and transferred, and it allows the provider to use the EHR in ways that can aid patient care" ("Certified EHR," 2015). A certified EHR facilitates the communication between two collaborating health care systems while sharing the same vocabulary.

The certified EHR, regardless of the vendor an EP uses, is designed to address and capture disease symptoms in order to aid the health care provider in accurately diagnosing the patient. There are specific reviews of quality measures involved with each patient encounter which are tailored around the patient's specific health care needs; these measures act as

reminders to establish the continuity of quality health care for the patient diagnosed with a chronic disease. For instance, the EHR used by a provider for patients being evaluated for type II diabetes mellitus (DM), will present the health care professional with a reminder to either check the patient's feet for ulcers or sores, or address that it is time to recheck essential lab work.

DM patients have the potential to benefit from a certified EHR as it is capable of providing automatic reminder phone calls or texts about upcoming follow-up appointments, lab orders, current medication lists, as well as providing patient a summary for every visit, either in print or in a cloud-based, patient portal service. Patient portals are essentially a secure website where patients review their personal health information (PHI), literature about the patient's diagnoses, medications, and even bills. One quality of care measure reinforced by MU calculates the percentage of patients who were offered their summary of care after their visit. EPs utilizing certified EHRs are capable of creating this summary (customarily while in the exam room with the patient), based on the patient's individual diagnoses and problems. This is just one example of how MU and the certified EHR collaborate to keep the patient informed of their condition, appointments and the purpose of the medications and lab work the provider orders.

Certified EHR vendors have introduced technology allowing health care providers to perform their own statistical analysis of certain aspects of their practice; coincidentally most of them are capable of reporting MU data to CMS on a quarterly basis. Currently, MU involves implementing five clinical decision support rules including diagnostic test ordering as well as having the capability to track patient compliance (Centers for Medicare and Medicaid Services [CMS], 2014). Where it is not necessary for EP's to utilize an EHR which is certified to meet MU initiatives, the certification provides an assurance to the health care professional that their efforts

will be rewarded with both monetary incentives as well as patients offered the highest quality health care the provider an offer.

Defining Quality Health Care

Patients have a right to quality health care; but what defines "quality"? According to the United States Department of Health and Human Services [HHS] (2013), there are three basic dimensions to defining quality care. The first dimension is structure. Structure in health care is described as the facilities and ancillary departments where patients and providers meet and the records those services use to create and maintain patient information.

The process of medical care is the second dimension discussed by the HHS (2013). As the patient workflow is conducted in a more efficient manner, by allowing the health care provider to compose patient charts while they are in the room with the patient, they are in turn allowing themselves enough time in the room to discuss patient needs, orders for ancillary tests and refill medications. By providing health care professionals tools within a system capable of follow-up reminders (or otherwise called "appointment ticklers"), they are capable of monitoring those patients who are less than compliant and can offer a phone call to remind the patient of their outstanding order. How the patient perceives the health care professionals is important in whether or not they will comply with the provider's orders. When patients feel like someone is watching (or caring) about their status, they will more likely feel more compelled to follow through with provider orders.

The third dimension is evaluating the end result of care (HHS, 2013). After the patient completes their ancillary orders or fill their mediations, professionals require a method to establish compliancy and positively reinforce the behavior. Patients should be provided a summary of care after every office visit, as well as expect a phone call or mailed confirmation with the results of

their outstanding ancillary tests. "Increasingly evidence-based management guidelines are providing a strong clinical base for care, care systems are becoming more integrated and we are well into the "next generation" of health IT tools designed to support diabetes care" (Patel, Reed & Grant, 2015).

Background of the Problem

Type II diabetes mellitus (DM), or hyperglycemia is a chronic, metabolic disease where patients are unable to control their blood glucose over a long period of time. In most cases, hyperglycemia is genetically imprinted on the individual patient (Diabetes Care, 2009). According to this article in Diabetes Care (2009) a patient may also experience acute hyperglycemia when their body is under extreme stress, including those with high blood pressure or obesity. Those individuals who are unable to produce enough insulin to break down and dispose of the glucose in the blood are required to make changes in their lifestyle so they can continue a life without major complications of this disease. Patients diagnosed with DM often have circulatory problems and are prone to resistant infections. They also tend to experience neuropathy, or loss of feeling in their limbs, as well as ulcers or sores on their lower limbs. It is important to have a professional evaluate areas of their body that the patient cannot visibly see, or may overlook. If an infection is left unattended for too long, then risk of amputation is possible.

Patients with DM also tend to experience a reduction of quality in their vision. Health care providers should educate the DM patient about the need to visit with a vision specialist once a year to ensure the patient does not lose their eyesight. When the disease is not managed properly, it can cause irreversible damage to the patient. For these reasons, it is imperative that once diagnosed, patients with DM follow up with regularly scheduled visits with their health care provider, complete lab work orders and maintain compliance with a prescribed medication regime.

DM is rapidly becoming a major epidemic in the United States. Health care professionals with a certified EHR have the opportunity to examine factors that can improve the quality of health in these patients. There is a limited amount of literature available, discussing the comparison between certified EHR use and patients with diabetes. Healthcare providers managing patients with chronic conditions such as DM should consider using a certified EHR system capable of meeting quality measures such as MU and PQRS. These measures are routinely evaluated and updated to incorporate the specific needs of the DM patient (Berryman, Sick, Wang, Swan, & Weber-Main, 2013). Both patients and health care providers would benefit from a study using a certified EHR to compile patient data and study the trends of patient follow-up visits, lab work values, and medication compliance.

Purpose of Study

The purpose of this study is to define patient quality of care and determine whether the MU is a positive influence on patients with type II diabetes mellitus. Certified EHRs provide health care professionals with the tools to follow up on patient care and provide information which is pertinent to their diseases and conditions. This study is intended to discover a correlation between the benefits of using a certified EHR for the patient reminders, data collected and compliance during the treatment for DM.

Significance of Study

The CMS has provided EPs incentives to improve health care professional methods of charting and setting reminders for patient follow-up appointments as well as compliancy with ancillary testing. Technology has provided methods for testing indicators for DM control. Health care professionals are able to evaluate blood glucose levels in the DM patient and to test for specific factors such as for glycosylated hemoglobin (HbA1c) levels over a period of time.

Certified EHRs monitor patient progress and compliance of patient follow-up appointments, ancillary blood work, and medicine compliance. Certified EHRs are capable of running detailed reports to measure changes in data and compliance where this was once impossible with paper charting or the older, uncertified EMR systems. It is one thing to possess the tools to improve health care, but it is important that health care professionals understand how to use these tools to analyze the results of their testing methods.

With busy schedules, time restraints and more responsibility, individuals tend to lean on more fast-food options for quick meals rather than selecting more wholesome food to eat. There is less time for exercise and patients have become more sedentary. There is also the genetic factor of DM in the patient who cannot control their disease with diet and exercise alone. MU initiatives have educated health care professionals on how to provide the tools and the methods in order to help patients improve their quality of health and it is time to measure those changes. Those tools include patient summary of care sheets as well as education materials about the patient's condition, "appointment ticklers" or "pop-up" reminders for health care professionals to call the patient and direct them to the lab for further testing and appointments. These reminders can be performed by automated phone calls, texts or in some cases through the patient portal, confidential e-mail reminders. These three factors will be studied against patient compliance to establish whether there is a positive effect from these MU initiative driven reminder sets.

Conceptual Frame of Reference

What establishes quality of health care? Every certified EHR should provide the health care professional with a pay for performance dashboard where updates on MU and PQRS compliance can be monitored. For each specialty practice, the MU goals may differ. These are the

thirteen core measures on the EP Attestation Worksheet, which are required to be met by the family practice provider ("Eligible professional," n.d.).

1. Active Medication List
2. Active Allergy List
3. Clinical Decision Support Rule
4. Computerized Provider Order Entry
5. Implement Drug/Drug and Drug/Allergy Lists
6. Protect Electronic Health Information
7. Up-To-Date Problem List
8. Transmit Prescriptions Electronically
9. Record Vital Signs
10. Record Smoking Status
11. Record Demographics
12. Provide Patients Electronic Access (Patient Portal Access)
13. Provide Clinical Summaries for Office Visits (Athenanet EHR System, reviewed October 3, 2015).

PQRS provides the health care professional with three DM-related measures.

1. Hemoglobin A1c Poor Control (HbA1c measure)
2. Low Density Lipoprotein (LDL-C) Control
3. Medical Attention for Neuropathy (Athenanet EHR System, reviewed October 3, 2015).

Between MU and PQRS, health care professionals have been provided through their certified EHR a means to input, store, and tabulate data important in establishing the DM patient who is in control of their disease, or in need of further assistance.

The following five variables to be evaluated for improvement in the quality of health care offered to patients diagnosed with type II diabetes by a single provider (Gregory Hines, MD, FAAFP, family medical practice in Lawrenceburg, Tennessee.

1. **Patient Compliance with Follow-Up Visits.** The numbers of structured follow-up visits for patients with DM are not regulated by the CMS by way of MU. However, in order to maintain a consistent relationship between the provider and patient, patients are required by the physician at Family Medical Center to comply with follow up visits once every 3-4 months. This requirement is to fulfill PQRS measures of performing regular foot exams, BMI control (calculated by height and weight/vital signs), and reviewing medication and lab work compliance. Compliance for this study is measured as patient follow-up visits at a total of three or four per year.
2. The certified EHR has been instrumental in ordering and following up on patient compliance in completing physician-ordered lab work. Currently, when the health care provider orders lab work, an "appointment tickler" (automated reminder in the EHR system) is created on the desired date of the blood work to be performed. If the patient is non-compliant by a set period of time (one week is standard), then the health care provider is flagged that the patient requires a phone, text or secure e-mail/patient portal reminder to visit the lab. Most certified EHR vendors provide automated phone calls to those patients reminding them of their scheduled visit to the lab. If an automated system is not utilized, then a personal phone call from one of the nurses will clear the

automated reminder until the patient is again non-compliant, or completes the lab work order. Patients with HbA1c levels over 7% are recommended by Family Medical Center to repeat lab work every six months; especially when evaluating whether a new medication is working effectively. Stable patients are generally put on a six month schedule for repeat blood work and are considered compliant by the practice. The routine lab work ordered usually consists of a Complete Metabolic Panel, Lipid Profile and a HbA1c.

3. Patients recently diagnosed with type II diabetes mellitus often undergo a radical diet change in the first few months of their diagnosis. Education materials are provided to the patient through the certified EHR and are either delivered at the checkout window of the practice, or can be looked up on the individual's patient portal. A diabetic diet consists of lower carbohydrate and higher protein foods where the patient is responsible for counting his/her carbohydrate intake throughout the day. Professional diabetes educators are hesitant to tell patients that they cannot eat any of their favorite foods; they will ask them to document the carbohydrate value and restrict these numbers to a particular value. Over time, a patient who adheres to this nutritional structure generally loses weight as a result of the healthier diet. The best way to measure this standard is to evaluate a patient's body mass index (BMI) over a period of time. Certified EHRs are capable of charting BMI changes during each office visit when vital statistics are recorded. BMI values are calculated through the vital signs taken at the beginning of each patient visit. Acquiring vital signs and calculating BMI is a MU requirement.
4. Hemoglobin A1c (HbA1c) is a glycosylated hemoglobin blood test which measures how well patients are controlling their type II diabetes. It is a percentage value which

represents how well blood glucose levels are managed over 100 days/three to four month period. When a patient's blood glucose remains at an elevated level for a period of time, the excess glucose binds to the hemoglobin in the blood. As the glycosylated hemoglobin increases, the HbA1c level in the blood reads higher than normal. According to Gregory Hines, MD, FAAFP, family physician at Family Medical Center, PLC, a normal HbA1c value ranges up to 6.0% and anything between 6.0 and 6.5% is indicative of a patient who may be pre-diabetic. Patients with HbA1c levels over 7.0% are those who are unable to control their blood sugar with diet alone and require more constant blood work monitoring. These patients are prescribed medication designed to rapidly reduce blood glucose levels and lower HbA1c levels over time. A small percentage of diabetics still use insulin today, however medication treatments have revolutionized diabetes management over the last ten years.

5. Medication compliance with patients is heavily determined by the amount of money the medication costs to the patient and side-effects. Patients have become better informed about the side-effects that their medications can cause and will often times decline the treatment with the fear that they may react to it unfavorably. There will always be "those" patients who refuse medicinal treatment regardless of how much they are in need of it, either by claiming side-effects from the medication or cost. Current, certified EHR systems offer health care providers a way to track medicine refills so they may document whether a patient is compliant with purchasing the medication, however, blood work is the only way to truly assess whether a patient is compliant with actually taking their medication. In order for an EP to meet MU, they must be capable

of transmitting prescriptions electronically. The certified EHR also offers the ability to view when prescriptions are filled by the pharmacy and picked up by the patient.

Research Questions

There are five questions this research study seeks to answer to determine whether a patient is experiencing an improvement in the quality health care, given the requirements of MU in implementing certified EHR systems in health care provider offices.

1. Is there a direct correlation between the benefits of a certified EHR and patient compliancy in following up for their appointments as scheduled? The certified EHR of a family medical practice will be used to isolate all patients diagnosed with type II diabetes mellitus (ICD-9 250.00) and deliver data obtained from those patients. Patients will be subject to informed consent before this report is created and only those consenting patients will be evaluated for this question and those following.
2. Is there a correlation between the benefits of a certified EHR and patient compliance with physician ordered lab work?
3. Is there a correlation between the benefits of a certified EHR and changes in Low Density Lipoprotein Levels (LDL mg/dL)?
4. Is there a correlation between the benefits of a certified EHR and changes in patient Body Mass Index (BMI kg/m^2) values?
5. Is there a correlation between the benefits of a certified EHR and changes in patient Glycosylated Hemoglobin (HbA1c %) values?
6. Is there a correlation between the benefits of a certified EHR and patient compliance with purchasing and taking medication refills as prescribed?

Research Limitations

This project is limited by both scope and scale. Research is focused on a small population of patients in a single provider family practice for evaluation. In order to have full access to an EHR and the established patients within the practice, it is ideal to be able to research statistical data reflecting patient compliance with lab work and drug therapy. It is appropriate to study a single provider to achieve consistency in the results. This limited population can be questioned as it is not necessarily a direct representation of every family practice in the United States; however, research materials will be used to guide this project and compare results with larger studies with the one supplied here. Without consistent polling and studying a random sampling of family practices within the United States, then a true sampling of that population group will most likely not be achieved.

This study is performed over a two year period; the first year is where the health care provider is utilizing an EMR which is not certified, or endorsed by the CMS to meet MU initiatives in its current form. This EMR vendor was late to produce a MU compliant system and the family medical practice was forced to convert to a certified EHR system to keep them in line with current health care needs. Time may be a factor in studying this demographic as one year study of change may not be enough to see lab values change as dramatically as they would over a longer period of time.

Dr. Ahmad and Dr. Tsang (2013) discuss and valid question in their research, about the variation between EMR and EHR systems while comparing data. When there is a variation between EHR's in the same study, then the inconsistency of the data between practices seems to increase the variables. In essence, some EHR systems tend to work better for this type of study than others; not necessarily making them worse at the task they are supposed to perform, but

unable to perform the statistical evaluation required for the comparison of results. "In addition to improving the design and capabilities of EHRs, more work understanding how to integrate EHRs seamlessly into clinical workflow and to better train and support providers during implementation is needed to realize potential quality improvements from EHR adoption" (Ahmad & Tsang, 2013). There are limitations to this research project, although assurances and careful planning have been taken to collect data from both the EMR and certified EHR in an identical manner. If it was proved to be impossible to compare the two systems in each question, then exceptions were documented.

Chapter 2

Review of Literature

Search for peer-reviewed, internet-based journal articles was performed through the University of Tennessee Health Science Center (UTHSC) library database. A search was designed for the purpose of discovering peer reviewed journal articles where background information on previous diabetic studies would offer methods to measure positive progress in healthcare using EHRs in the effort to each EP to meet MU in their practices. The importance of being able to reproduce data and create a statistical analysis of the improvement of patient quality of care demanded additional studies working towards the same goal.

Methods

An extensive search using databases such as PubMed, MedLine OVID, Scopus, ClinicalKey, and CINAHL@EBSCO was performed and appropriate articles meeting the criteria of the search were collected. A personal subscription to the Journal of American Medical Association (JAMA), the American Medical Association (AMA) and the American Health Information Management Association (AHIMA) were also valuable resources utilized in this study.

Inclusions and Exclusions

With each database search, keywords were entered into the search engines to further refine the output of data. *Diabetes or Type II Diabetes* was the first and only term used in every study search. Additional keywords included: *Meaningful use* (*MU*), *Electronic Health Record* or (*EHR*), *Electronic Medical Record* or (*EMR*) and *Patient Quality of Care*. Inclusion parameters were set to include journal articles ranging from dates 2005-2015; the older references were scrutinized heavily for content which would reflect more recent changes in in healthcare today. All applicable

peer-reviewed journal articles were written in English. Although did not necessarily have to represent research performed in the United States, it had to reflect upon the consistency with the health care system currently practiced locally. Initially an American based search was included in the research because it was important to remain as close to the original methods when it came to evaluating a single family medical practice in rural Tennessee. However, a few articles representing research performed outside of the United States proved to be just as valuable as the rest of papers found during the discovery process. The search was not limited to full-text articles only as the interlibrary loan allowed for a larger scale of resources not readily available at the UTHSC library. Articles addressing diabetic care in outpatient, non-ambulatory or emergent facilities were reviewed and abstract-only references, editorials and blogs were omitted. With the search objective designed to identify the importance of health care professionals utilizing EHR usage with patients who were diagnosed with DM the CMS website was used to provide definition to the requirements of MU for eligible provider compliance.

Findings

Centers for Medicare and Medicaid Services (CMS) and Data Quality Measures. The CMS is at the center of governing, creating and enforcing the laws by which healthcare professionals are bound to follow. This organization offers information about Medicare, Medicaid, Children's Health Insurance Program, and insurance benefits offered through the Health Insurance Marketplace. In an effort to maintain a high standard of quality for these programs, the CMS is responsible for upholding the laws created in an effort to make healthcare accessible to all. The American Recovery and Reinvestment Act of 2009 was a package of incentives created in an effort to provide new programs and offer relieve from the economic recession. The information about the American Recovery and Reinvestment Act of 2009 was found on the CMS website (2010). The

CMS addressed three major goals, thus setting up the foundation for MU. The first goal would be for EP's to establish an EHR to be used in a "meaningful manner," such as electronic prescribing or facilitation of transition of care for a patient from one provider to another. The second goal was to establish an electronic healthcare exchange to promote quality care. And the final, third MU goal to be set was using EHR technology to submit clinical quality measures (CQM's) to the secretary (CMS, 2010). These measures were established in the effort to improve quality of care to patients, patient safety, improve upon the efficiency while reducing redundancy, all while managing loss from health disparities (CMS, 2010).

The American Health Information Management Association (AHIMA) provided a resource for articles related to EHR's and how they are used in conjunction for the EP to meet MU. The quality of health care is directly dependent on the quality of data collected. EHR's are necessary for health care providers to organize patient data in a manner where errors in submission and translation are reduced. According to AHIMA (2013), EHR program initiatives such as MU have brought awareness to the health care organizations and encouraged them to participate in a world-wide effort to correct the deficiencies in health care. "A meaningful electronic health record (EHR), improves the ability of health care professionals to enact evidence-based knowledge management and aids decision making for care" (AHIMA, 2013). The study in 2013 by Faraz Ahmed, MD and Thomas Tsang, MD, represents how EHR adoption has led to the improved care of patients with type II diabetes. "It examines IT (Information Technology) strategies for diabetes in the context of current evidence and identifies areas of needed research and innovation" (Ahmed &Tsang, 2013). The authors of this study used the blood test, HbA1c as a measure of improvement over a three year period. This article was the most influential to conduct this current research described in this paper.

MU is not the only quality measure reported to the CMS. There was an earlier program, equally important for EP reporting. "Under the Tax-Relief Healthcare Act (TRHCA) of 2006, CMS implemented the Physician Quality Reporting Initiative (now called Physician Quality Reporting System (PQRS)) with a bonus payment of 1.5% for successful participation based on the estimated total allowed charges for covered services during the reporting period" (AMA, n.d.). The information about the PQRS retrieved from the American Medical Association addresses the success and need for quality health care initiatives to all organizations including hospitals, nursing homes, home health agencies, and even supportive health care centers such as dialysis centers (AMA, n.d).

While studying the effects of provider variability in EHR use, Ancker, Kern, Edwards, Nosal, Stein, Hauser & Kaushal (2015), set out to test their common hypothesis that those providers who used the functions provided by recent EHR standards would "perform better on related healthcare quality measures than providers who used them less frequently." The functions discussed include best-practice alerts, order sets, and panel reports, which are all functions available from reputable, certified EHR vendors. Healthcare quality was assessed in this research project with their main focus on MU and PQRS measures with focus on both the processes involved and their outcomes (Ancker et al., 2015).

Clinical Decision Support Systems and Disease Management. The Clinical Decision Support (CDS) as part of the EHR is an important determining factor in that it provides physician with the tools to examine whether or not their methods are really improving the quality of health care in a patient. The CDS is directly responsible to increasing the quality of care while improving patient efficiency, reducing healthcare costs and improves the quality of care by reducing healthcare errors. By utilizing statistical examination, the efficacy of the patient

handouts, discussions with the physician, and lab work orders is studied, introduces the benefits of using CDS in research techniques designed to study the benefits of the quality of healthcare in patients with chronic conditions (Litvin, Davis, Moran, Iverson, Yumin, & Zapka, 2012). This paper is more focused on the geriatric population of patients but offers proven methods in research using CDS tools in the family practice. In Schnipper, Cornell, Linder, Palchuk, Einbinder, Postlinitk and Middleton's (2011) 'Smart Forms' in an Electronic Medical Record: Documentation-based Clinical Decision Support to Improve Disease Management," offers older research from 2008 on the benefits to both healthcare providers and patients when CDS is implemented in EHR use. This study establishes that CDS did show a significant improvement in diagnostic systems, practitioner performance, patient reminder systems, and disease management systems (Schnipper et al., 2008). With improvements in MU and the adoption of a certified EHR by more physicians over time, it was believed that there would later be proof of effective management of diabetic disease.

Diabetes Management with EHR Use. Dr. M. Varroud-Vial from the department of Endocrinology at South Francillian Hospital in France wrote a research paper on "Improving Diabetes Management with Electronic Medical Records" (2011). This research reports a beneficial effect on diabetes care when patients have access to their health care provider through portals, EHR, and e-mail communication. The sharing of information provides a standardized, secure platform to provide a patient with chronic conditions such as type II diabetes with the much needed information to improve their quality of care.

Health care providers who plan to manage patients with chronic conditions such as DM could possibly benefit by the use of an EHR which is capable of meeting quality measures such as MU and PQRS. These measures are regulated by the CMS and are constantly growing to

incorporate more specific needs of the patient. There is very little room for non-compliance when it comes to DM patient management. Automated reminder letters have been a success in bringing patients back into the healthcare professional offices using EHR's to generate an automated reminder letter to non-compliant patients diagnosed with type II DM patients, improved the quality measures in those patients (Berryman et al., 2013). The quality measures studies included studying patient Low-Density Lipoprotein Levels (LDL), and Hemoglobin A1c (HbA1c) Levels both pre and post intervention. They established that there was an improvement in the patients studied and therefore deduced that sending out patient reminders for treatment was an effective tool for improving the quality of care in DM patients (Berryman et al., 2013). This study utilizes a statistical calculation appropriate for this type of research and will be referenced throughout this project.

Dr. Kamal's (2014) research article on the "Use of electronic medical records for clinical research in the management of type II diabetes" was crucial as it identified with DM patient clinical characteristics and how statistical analyses could be created to study progress with these patients. "This study provides insight into the potential risk factors for diabetes such as the presence of obesity, dyslipidemia, and depression, specifically in patients with HbA1c levels above 9%" (Kamal et.al., 2014). As the potential of the EHR grows each year and MU standards increase, patients diagnosed with DM have the opportunity to increase the efficiency of treatment and patient quality of healthcare.

The previous research was predicated by the research article, "Outpatient electronic health records and the clinical care and outcomes of patients with diabetes mellitus," the authors discovered in 2012 that a "commercially available certified EHR" in conjunction with current drug therapy was a benefit to those patients diagnosed with DM (Reed, Huang, Graetz, Brand,

Hsu, & Fireman, 2012). The association with EHRs and clinical care management showed improvement among those patients and was able to lend experience with a much larger scale organization than the one studied here. The experimental study dates spanned from 2005 through 2009, showing how improvements in certified EHR vendors over the years and treatment options correlated with the "timeliness of clinical information available at the point of care with embedded decision support and order entry" (Reed et al., 2012).

A 2015 journal article, "Adherence to national diabetes guidelines through monitoring quality indicators- A comparison of three types of care for the elderly with special emphasis on HbA1c" represents a study performed in Sweden, and yet follows the same guidelines and quality measures as does the United States in regard to patents diagnosed with type II DM. Focus was on the monitoring of HbA1c percentages, low density lipoprotein levels, blood pressure values and results from regular foot exams (Neumark, Brudin, & Neumark, 2015). After nursing homes were directed to focus on quality control measures designed to improve the quality of healthcare to DM patients, those patients exhibited a considerable improvement in their overall health after a period of neglect. This information correlates with the 2011 paper by P. Benhamou as he focused on the engagement of therapeutic care plans and CDS necessary to effectively perform clinical encounters with DM patients. Using EHR, CDS systems allowed the healthcare provider to keep up with the patient's progress, thus allowing for medication changes to be made in a timely manner. The author addresses web-based systems which allow for a more rapid turn-around between provider and patient.

> The main features of these Web-based programmes include patients' access to EMRs, uploading of glucose monitoring results, a glucose diary, secure e-mail with providers, manual or automated feedback on blood glucose readings and other risk factors, an educational website and an online diary for entering information exercise, diet and medication (Benhamou, 2011).

This article is able to identify the necessity of every health care organization that treats patients with type II DM need for a certified EMR, capable of meeting quality control measures.

Conclusions and Results

Correlational research studies were able to identify and address the need for certified electronic medical records, capable of using clinical decision support systems management. Without these tools, healthcare providers are unable to provide a consistently clear health plan using quality measures which are overseen by the CMS, such as meaningful use. Compliance with these measures will improve the quality of care to patients diagnosed with type II diabetes mellitus by offering a means for provider/patient feedback, efficiency in treatment and diagnosing, as well as computerized order entry which will allow for the provider to keep up with lab and pharmacy orders more accurately. Using the keywords and the available databases through the UTHSC library delivered relevant, peer-reviewed articles to further emphasize the relevance of EHRs and the correlation between patient quality care in those patients who have been diagnosed with type II diabetes mellitus. It is expected that this study will have strong, positive results and show that certified EHRs are important in managing patient care and follow-through with patient compliance.

Chapter 3

Methodology

An observational research method was used to perform a case study of a group of individuals with a common diagnosis of type II diabetes mellitus. Patient data was gathered from a certified EHR from a rural Tennessee, single provider family practice organization. The data was compiled in order to draw conclusions about patient compliance with follow up-appointments, physician-ordered blood work and medication treatment compliance. This study will also evaluate changes in patients with type II diabetes mellitus and their HbA1c lab results and changes in BMI as a measure of changes in overall patient health over a given period of time.

Patient Selection

Patients were selected from a single provider, Family Practice in Lawrenceburg, Tennessee. Patients were selected using the following criteria:

1. Diagnosed with type II diabetes mellitus (ICD-9 code 250.00) previous to 9/15/2013.
2. Ongoing therapy for type II diabetes mellitus (ICD-9 code 250.00) with Dr. Gregory Hines at Family Medical Center, PLC from 9/15/2013 through 9/15/2015.
3. Patients selected were between the ages of 25 through 80 at the time of the study.
4. Patients must have been able to make their own decisions about complying with doctor's appointments, medications and therapy; patients in nursing homes, home health situations, or jail were omitted as to not give an advantage or disadvantage to the study.

Selection Results

- Ninety-five (95) patients were initially pulled from the report generator of the certified electronic health record for Family Medical Center, PLC.

- Eleven patients (11) were automatically omitted from the study, as they did not meet the criteria above.
- Eighty-four (84) letters generated and approved by the IRB- 15-04015-XP were mailed out to the remaining patients and two letters were returned undeliverable.

  No further actions on those letters were taken.
- Out of 82 eligible study participants, 52 approval letters were returned with permission to use their patient data for research.

Research Design

The data collection process:

1. Identify the patient in the old EMR and document:
   a. Patient age and sex.
   b. Last date of service and document the patient's height, weight, and BMI.
   c. Calculate number of visits to the provider involving diagnosis code 250.00, representing a follow up for their type II DM between the dates of 9/14/13 through 9/15/14. Report them as 1-4 (with 4 visits being the maximum for the year).
   d. If the patient had bloodwork performed between the dates of 9/14/13 through 9/15/14, then patient was documented as compliant.
   e. Last HbA1c, random glucose, and LDL levels.
2. Identify the patient in the certified EHR, capable of meeting MU and document:
   a. Patient age.
   b. Last date of service and document the patient's height, weight, and BMI.

c. Calculate number of visits to the provider involving diagnosis code 250.00, representing a follow up for their type II DM between the dates of 9/14/14 through 9/15/15. Report them as 1-4 (with 4 visits being the maximum for the year).
d. If the patient had bloodwork performed between the dates of 9/14/14 through 9/15/15, the patient was documented as compliant.
e. Document the patient's last HbA1c, random glucose, and LDL levels.

Research Variables and Rationale

Medical Facility Demographics. Family Medical Center, PLC is a single-physician owned, family medical practice located in a medically underserved community. It is located in Lawrenceburg, TN; approximately 90 miles south of Nashville, Tennessee and 90 miles Northwest of Huntsville, Alabama. The rationale for selecting this medical facility was that Lawrence County has a population of approximately 11,000 individuals with local medical access to a 99-bed hospital with no locally housed endocrinologist office within a 40 mile radius. Where many specialty providers do visit the area, endocrinologists cannot be reached without considerable transportation problems for patients. When reviewing the progress of the CMS, it is important to include patient research performed in underserved areas as well as those living in larger communities. The rational to studying patients with one provider is to establish consistency with the treatment of the patients in the study group. Using one provider will eliminate the variable of physicians with differing methods and treatment schedules.

Family Medical Center, PLC has been serving patients of any age since 2003. This organization accepts all insurance types, including patients considered to be "self-paying." All patients diagnosed with type II DM (ICD-9 250.00) were selected before October 1, 2015 from a report generator using the organization's own certified EHR. While reviewing the total patient

population at Family Medical Center, PLC, 2.5% have been diagnosed with type II DM (ICD-9 250.00). The rationale for using the type II DM (ICD-9 250.00) patient demographic is because the disease occurs in individuals of all ages; however, the disease most likely occurs in the older population of patients.

Medical Record. Two medical record systems were used during this study. The first, (EMR A) was an older generation electronic medical record which was incapable of meeting CMS quality measures. There were no patient reminders, automatic reminders of scheduled events such as office visits or pending lab work. This documentation system was strictly an EMR as it was unable to share or communicate information with any other facility; its primary purpose was to document patient visits only. This EMR was used to gather data for the first year of the study (Year 1).

The second, (EHR B) is a certified electronic health record capable of performing and reporting all CMS criteria for meeting MU and PQRS quality measures. This EHR includes automatic patient reminders for upcoming appointments, appointment tickler reminders for upcoming procedures such as lab work and pharmaceutical needs. EHR B is also capable of a consistent method of communicating with the pharmacy to assure patient compliance with filling prescribed medications. Quality control measures also remind the healthcare provider of lab work, vaccinations, and/or other procedures not yet ordered or performed. The rationale for selecting this medical record type was that it offered the opportunity to study two different electronic medical/health recording systems in the same practice presented itself and the advantage was taken. By limiting the health care provider as a variable, focus on two entirely different systems were allowed to be studied. This EHR was used during the second year of the study (Year 2).

Patient Selection Rationale

All patients previously diagnosed with type II DM (ICD-9 250.00), between the ages of 25-80 and capable of making their own medical decisions were included. The study did not discriminate between sex or ethnicity, but did limit the participating patients between 25 through 80 years of age. A majority of patients with DM are older, but assurances were made that the participants were capable of managing their own health and freely make their own health care decisions.

Initially, the lower and upper age limits were set to isolate adults who were capable of making their own medical decisions about setting and meeting medical appointments, completing lab work orders and filling/taking prescribed medications without the aid of another individual. An initial search of including patients ages 18 to 99 was performed and revealed 3 patients who would have been eliminated due to the set standards of inclusion/exclusion. The IRB approved ages 25-80 which included all eligible patients in this organization. The specific ICD-9 diagnosis code (250.00) was selected to include all eligible patients treated by this physician before ICD-10 was implemented. An initial search for patients diagnosed with alternative ICD-9 250.XX codes did not produce any new possible participants to the list of eligible patients in this study so the ICD-9 code (250.00) proved effective to include all eligible patients.

Research Criteria Selected

Change in Patient Visits from Year 1 to Year 2

Compliance in Completion of Lab Work from Year 1 to Year 2

Low-Density Lipoprotein (LDL) Comparison from Year 1 to Year 2

Body Mass Index (BMI) Comparison from Year 1 to Year 2

Glycosylated Hemoglobin (HbA1c) Comparison from Year 1 to Year 2

Percent Change in LDL from Year 1 to Year 2

Percent Change in BMI from Year 1 to Year 2

Percent Change in HbA1c from Year 1 to Year 2

Omitted: After further evaluation of EMR A, it was determined that data for measuring patient medicine compliance would not be collected. It was impossible to assess medication compliance consistency between these two medical health record systems, so further data collection was cut off for this variable.

Data Collection Instrument

Research Electronic Data Capture, otherwise known as RedCap through the University of Tennessee Health Science Center was used as a web-based database. This program is capable of utilizing a user-designed interface to collect and store data to later be extracted for research purposes. Full-user capabilities of RedCap will perform some analyses on the data entered, however the data collected was imported into Microsoft Excel where further statistical analysis was performed. First, a request for a new project was made and approved. Data forms were designed, testing of data was performed, and final approval was given on 9/29/15 to enter real patient data into the database. As each patient was entered, a Record ID code was "created" for that patient. Once data for that particular patient was entered into the database and Record ID code

was created, the association between any personal health information of that patient and the study data was severed. Patient data was entered into RedCap as described below.

Data Collection Procedure

All data was collected from both a non-certified EMR and a certified EHR from a single-provider, family practice in rural Tennessee. The collection methods were consistently gathered for every patient to reduce variability in the samples. The timeline was set to one year previous to the implementation of a certified EHR through one year after implementation. The timeline was designed to share an equal amount of time between the two health care record systems to compare patient data results.

First Year Data: Patient data was retrieved from EMR A (not certified and incapable of meeting CMS Quality Control measures).

1. Create a patient Record ID to link the following data with the data previously collected.
2. Patient Age at time of study.
3. Patient Sex.
4. Date of last visit with the health care provider (between 9/15/13 through 9/14/14).
5. Document number of visits with the health care provider for the purpose of following up on type II diabetes mellitus (ICD-9 code 250.00) between 9/15/13 and 9/14/14. Label 1, 2, 3 or 4 visits.
6. Locate lab work performed between 9/15/3 and 9/14/14. If no lab work is present, then label patient as "non-compliant." If lab work is documented, label patient as "compliant."
7. Locate last LDL, BMI and HbA1c results if patient is labeled "compliant" for lab work performed between 9/15/13 and 9/14/14. Document values.

Second Year Data: Patient data was retrieved from EHR B (certified and capable of meeting CMS Quality Control measures).

1. Document the date of last visit with the health care provider (between 9/15/14 through 9/14/15).
2. Document number of visits with the health care provider for the purpose of following up on type II diabetes mellitus (ICD-9 code 250.00) between 9/15/14 and 9/14/15. Label 1, 2, 3 or 4 visits.
3. Locate lab work performed between 9/15/14 and 9/14/15. If no lab work is present, then label patient as "non-compliant." If lab work is documented, label patient as "compliant."
4. Locate last LDL, BMI and HbA1c results if patient is labeled "compliant" for lab work performed between 9/15/ 14and 9/14/15. Document values.

Data Analysis:

After data was collected and submitted to RedCap, it was exported into Microsoft Excel 2007 for evaluation. Individual tables were created comparing the percent change from year 1 to year 2, pertaining to patient visit compliance, lab work follow through compliance, and the lab values. While creating the bar graphs, it became obvious that the correlation between year 1 non-compliant, converting to a more compliant patient in both follow up visits as well as lab work. By separating the data from previously identified non-compliant to compliant patients, a scatter graph was created to isolate those patients and how their lab value results changed. A standard deviation and standard deviation of error will determine whether there was a significant change in lab work values, thus reinforcing the direction of change in quality of care.

The standard deviation was calculated for all the lab values as a whole, as well as data separated by initially non-compliant patients turned compliant in reference to patient follow-up visits from year 1 to year 2. Standard deviation is the preferred measure of variability and the dispersion of the data collected (Osborne, 2008, p.151). By calculating the standard error of the mean, "conclusions are based on the relationships of the standard deviation and the mean to the normal curve. The smaller the standard error, the closer to the sample mean is likely to be the population mean" (Osborne, 2008, p.152). The relevance of the data collected will determine the conclusions drawn based on those results.

Chapter 4

Results

Response Rate of Sample/Population

A total of 52 responses were received from the patients selected from Family Medical Center, PLC out of 84 total eligible patients diagnosed with type II, diabetes mellitus (ICD-9 250.00). Of the 84 letters of invitation to participate, 2 were returned as undeliverable, leaving 82 eligible participants in this study. The response rate of patients responding to the IRB informed consent documents to use patient data for the purpose of this study was 63.4%. Of the 52 patients, there were 25 female and 27 male participants, with an average age of 66 years.

Summary of Chapter

The 52 eligible patients volunteered to allow their patient data be used in this study. They were gave informed consent that no personal health information would be contained in the final report and made the informed decision to participate. Data was collected on the number follow-up visits each patient made to Family Medical Center, PLC using the last year of an older EMR system, and the first year using a new, certified EHR. Patient compliance on following through with laboratory orders was also measured for both systems. Numerical data was collected for three identifying lab work values to determine whether patient DM was to be considered under control by the patient. It was determined that 52 patients was a solid representation of the total patients studied in this practice.

Table 1

Change in Patient Visits from Year 1 to Year 2

Number of Patient Visits	Year 1	% Visits Year 1	Year 2	% Visits Year 2
Patients with 1 visit/year	14	26.9%	1	1.9%
Patients with 2 visits/year	9	17.3%	1	1.9%
Patients with 3-4 visits/year	29	55.8%	50	96.2%
Total	52	100%	52	100%

**note: Patients visiting their provider 3-4 times per year are considered compliant.*

Table 2

Compliance in Completion of Lab Work from Year 1 to Year 2

Lab Work Compliance	Year 1	% Compliance Year 1	Year 2	% Compliance Year 2
Patients with 1 visit/year	9	64.3%	1	100.0%
Patients with 2 visits/year	7	77.8%	1	100.0%
Patients with 3-4 visits/year	27	100.0%	47	94.0%
Total	43*	82.7%	49*	94.2%

** note: Year 1, 9 of the study patients were non-compliant for blood work orders filled. Year 2, 3 of the study patients were non-compliant for blood work orders filled. Compliance percentages represent these missing patients.*

Table 3

Low-Density Lipoprotein (LDL)

Body Mass Index (BMI) and

Glycosylated Hemoglobin (HbA1c) Comparison from Year 1 to Year 2

	Year 1 Average	Year 2 Average	Average % Decrease Lab Levels Year 2
LDL n=43	92 mg/dL	79 mg/dL	14.0%
BMI n=52	34 kg/m^2	33 kg/m^2	2.6%
HbA1c n=47	6.8%	6.8%	0.6%

Table 4

Percent Change in LDL (mg/dL) from Year 1 to Year 2:
Separating Patients Based on Year 1 Patient Visit Compliance

Non-compliant Patients from Year 1			**Compliant Patients from Year 1**	
Percent Change in LDL (mg/dL)			Percent Change in LDL (mg/dL)	
1	-50.0%		19	10.3%
2	2.0%		20	19.4%
3	-66.7%		21	1.1%
4	-26.3%		22	1.1%
5	7.1%		23	-15.2%
6	-34.1%		24	-25.4%
7	-35.2%		25	-23.7%
8	-17.0%		26	-15.7%
9	-48.8%		27	20.8%
10	-69.0%		28	-10.8%
11	-7.2%		29	7.2%
12	0.0%		30	-22.1%
13	-28.3%		31	-13.8%
14	-1.1%		32	47.1%
15	-24.4%		33	-5.9%
16	-19.8%		34	-3.8%
17	11.7%		35	-16.4%
18	-27.6%		36	-11.6%
			37	50.5%
n=18			38	-4.7%
NC Mean	-24.1%		39	-20.0%
Median	-25.4%		40	-16.3%
Std. Deviation	0.240		41	-14.3%
SD Error	0.0565		42	-13.6%
			43	0.8%
			n=25	
			Comp. Mean	-3.0%
			Median	-10.8%
			Std. Deviation	0.199
			SD Error	0.0399

Table 5

Percent Change in BMI (kg/m^2) from Year 1 to Year 2:
Separating Patients Based on Year 1 Patient Visit Compliance

Non-compliant Patients Year 1			**Compliant Patients Year 1**	
% Change in BMI (kg/m²)			% Change in BMI (kg/m²)	
1	1.1%		24	6.3%
2	-6.4%		25	-0.3%
3	1.4%		26	-9.3%
4	6.3%		27	-9.0%
5	0.0%		28	-9.0%
6	3.6%		29	-10.0%
7	-1.0%		30	-0.9%
8	-9.7%		31	1.6%
9	-1.5%		32	1.4%
10	1.8%		33	0.0%
11	0.9%		34	-3.4%
12	0.0%		35	-1.8%
13	1.7%		36	-2.2%
14	-2.1%		37	1.6%
15	-0.2%		38	1.3%
16	-5.2%		39	1.2%
17	-26.6%		40	0.5%
18	-9.5%		41	4.1%
19	-4.8%		42	4.1%
20	-1.9%		43	-21.9%
21	-5.6%		44	-8.0%
22	5.0%		45	4.6%
23	0.3%		46	-7.1%
			47	-6.9%
n=23			48	-9.0%
NC Mean	-2.3		49	1.2%
Median	-0.2%		50	-3.4%
Std Deviation	0.067		51	-6.0%
SD Error	0.0140		52	-3.9%
			n=29	
			Comp. Mean	-2.9%
			Median	-1.8%
			Std Deviation	0.059
			SD Error	0.0087

Table 6

Percent Change in HbA1c (%) from Year 1 to Year 2: Separating Patients Based on Year 1 Patient Visit Compliance

Non-compliant Patients Year 1			**Compliant Patients Year 1**	
% Change in HbA1c (%)			% Change in HbA1c (%)	
1	-28.9%		20	18.9%
2	3.9%		21	1.7%
3	6.2%		22	-2.4%
4	-3.2%		23	5.3%
5	9.7%		24	5.3%
6	-7.5%		25	-3.2%
7	-11.3%		26	9.4%
8	15.5%		27	-1.6%
9	-3.1%		28	-1.6%
10	-1.3%		29	6.0%
11	-3.0%		30	18.3%
12	-8.4%		31	5.7%
13	-5.5%		32	-5.9%
14	4.5%		33	1.6%
15	-14.6%		34	13.2%
16	-1.7%		35	-6.2%
17	-7.8%		36	4.8%
18	-1.7%		37	11.3%
19	8.3%		38	4.5%
			39	-4.1%
n=19			40	-14.7%
NC Mean	-2.6%		41	-1.4%
Median	-3.0%		42	-1.8%
Std Deviation	0.099		43	7.9%
SD Error	0.0228		44	-4.3%
			45	-8.4%
			46	10.0%
			47	8.8%
			n=28	
			NC Mean	2.8%
			Median	3.1%
			Std Deviation	0.080
			SD Error	0.0159

Chapter 5

Analysis and Discussion

Change in Patient Visits from Year 1 to Year 2

63.4% of the current type II diabetes mellitus (DM) population selected at Family Medical Center, PLC volunteered to participate in this study. According to the EMR records from year 1, only 38.5% were compliant with their regular, quarterly visits required by the health care provider. These patients were accepting the advice of the provider and followed-up to regular doctor's appointments.

17.3% of the DM population studied, met provider/patient requirements by visiting the health care provider three times in the first year of study. Where four visits is ideal for compliance standards in the DM patient, those only meeting three of those visits are still considered compliant as long as their condition was under control. Combining patients visiting their primary care physician 3-4 times per year at Family Medical Center, PLC, rated patients diagnosed with DM during year 1 at a 55.8% compliancy rate with routine office visits.

The correlation between patients who comply with their physician orders to visit 3-4 times in a 12 month period represents a population of patients diagnosed with type II DM, either already under control, or have been educated on the necessary measures needed to control their own disease process. These patients have chosen to take their health seriously and were expected to continue to benefit with the use of a certified EHR. As demonstrated in Table 1, by combining those patients with 3-4 visit over the first year of study, the overall difference between patient data representing those who were non-compliant with their follow-up patient visits in year 1 are corrected in the 2nd year's data. Figure 2 is a bar graph representing patients who were compared

from year 1 to year 2. All patients in year 1 experienced a significant increase in follow up visits during year 2.

Compliance in Completion of Lab Work from Years 1 to Year 2

Overall, patients showed a 12.5% increase in lab work compliance from year 1 to year 2. Those patients exhibiting compliance with 3-4 follow-up visits per year remained consistent from year 1 to year 2. Table 2 illustrates that patients who were non-compliant with 1-2 visits/the first year, became compliant with completing their lab work during the second year of this study. Note that this table demonstrates totals of 43 patients during year 1 and 49 patients measured for lab work compliance during year 2. The reason for the discrepancy between 52 total patients in the study and 43 patients measured is that 9 patients were non-compliant in completing their lab work during year 1. The same goes for year two; 49 of the 52 patients were compliant in completing lab work, leaving 3 patients remaining non-compliant. What this concludes is that 7 patients who were did not participate in lab work during year 1 with the older EMR, became compliant with the new EHR during year 2. Total percentages were calculated using 52 total patients so as to disregard the non-compliant individuals. Figure 2 offers a visual representation of the comparison between patient visit compliance and patient lab work compliance. Note how those patients who began their journey as non-compliant patients, increased their visits to 3-4 times per year as well as improved when it came to lab work compliance. This demonstrates the correlation between patient, face-to-face contact with their provider, the education that is being offered, and the compliance level of that patient in regard to keeping follow-up appointments and completing their lab work orders as instructed.

Change in Patient Low-Density Lipoprotein Levels from Year 1 to Year 2

Table 3 is a combination of the three variables compared in this study. On the far left, patient overall LDL values have reduced from 92mg/from year 1 to 79mg/dL in year 2. Looking at the data in Table 4, 43 patients were evaluated; some patients experienced dramatic reductions in their levels, where others either remained constant or even increased in their numbers. As a reminder, 9 patients were non-compliant during the year 1 EMR compilation of data, so the correlation of the 2nd year for those same patients was disregarded for this part of the study as a percent change from year 1 to year 2 could not be calculated. The overall reduction between the two years is 14.0%, where only 12 of the 43 patients exhibited an increase in LDL values from year 1 to year 2. The standard deviation for both year 1 and year 2 are reasonably low at 0.240 and 0.199 respectively. The standard error of the mean creates confidence that these are reliable statistics. Table 4 includes the patient data collected with the standard deviation and significance levels calculated. A scatter diagram in Figure 4, located in the appendices section of this report, visually demonstrates how there is an improvement in the percent change of LDL values among patients from Year 1 to Year 2 when compared to patient visit compliance.

Change in Patient Body Mass Index Values from Year 1 to Year 2

Total BMI values showed very little reduction between patients in year 1 and year 2. Fifty-two patients were evaluated; some patients experienced great losses (up to 26.6%), however the largest gain was only 6.0%. Table 5 contains all the data collected during the patient visit, which is why all 52 patients are represented. The scatter diagram in figure 5 demonstrates a population with little variation in their BMI values. The overall average is a loss for both previous non-compliant and compliant patients. The significance of this test is to demonstrate that patients diagnosed with type II diabetes mellitus should, and probably are educated on reducing carbohydrates in their

diets, thus turning out a population who is able to either maintain their weight or decrease weight appropriately. Patient BMI levels are as expected in a patient population with the established diagnosis of DM. Both populations from the non-compliant patients from year 1 to year 2 have low standard deviation figures at 0.067 for year 1 and 0.590 for year 2. Together with the standard error of the mean (0.0140 and 0.0087 respectively), indicating a low variation in the data collected. Figure 5 in the appendices confirms the consistency of the data collected and the patient expectations as they grow from non-compliant patients to a compliant status.

Change in HbA1c Values from Year 1 to Year 2

Table 6 includes the data collected from the patient base, minus a few patients who were unable to produce initial HbA1c values. There is almost no difference between the total patients from year 1 to year 2; however, dividing the patients from non-compliant follow-up visit patients from year 1, data showed a negative 2.6 decrease in HbA1c values to those patients who were compliant, demonstrated an increase of 2.8 percent from year 1 to year 2. Both standard deviation of the data collected for non-compliant follow-up visit patients in year 1 (0.099) and compliant follow-up visit patients from year 2 (0.080) are backed by the standard error of the mean for both of these data sets. Figure 6 depicts a scatter diagram representing the values collected from those patients. The diagram gives a clear picture of patient fluctuation no matter how long they have been diagnosed with DM. Those patients who are either newly diagnosed, or learning to take their diabetes more seriously, represented a decrease in HbA1c percent which could be related to the increase in patient visits, and becoming more aware of their lab values as they trended to a more compliant status.

Limitations and Recommendations

Not all patients started at the same point of their diagnosis and disease process on year 1. It is expected to see some fluctuation in lab value numbers and patient visits as the changes in the EHR arose. It is important to remember that all patients are different and there will be some outliers no matter how the study is conducted. However, even some of the non-compliant patients from year 1 could have been diagnosed for years, but just now received information to encourage them to exceed their original expectations. Some of these patients could be newly diagnosed and either in denial about their condition, or embraced the change completely. Without this information, it is impossible to start every patient off at the same point. However, the purpose of this study is to demonstrate improvement over a two year period, using an older EMR which was incapable of meeting MU, and a new, certified EHR designed to improve overall patient care by meeting the MU initiatives introduced by the CMS.

This study was conducted over a two year period. The first year evaluated patient compliance with patient follow-up visits, lab orders and lab values using an older EMR system which was not capable of meeting MU. This is significant because without benefit of patient reminders and follow-up controls for compliance, patients with DM were not tracked as well as they were with the certified EHR. The changes were evaluated after one year; this time period may not have been long enough produce significant results.

There was no way to collect medication compliance data from the EMR during the first year. The certified EHR supplies the health care professionals with information about where the patients fill their mediations and if those prescriptions were purchased; however, this is only available for patients with health insurance (patients who have been denied the right to health insurance cannot be tracked in the current system). Even with the data collected during the second

year, there is not a way to determine if the patients are compliant with actually taking their medications except through lab work results. There are too many variables to assure a reliable result.

This study was performed in a rurally populated county in middle Tennessee, in contrast to some of the larger studies performed in higher populated cities. This was done purposely to either demonstrate that there is a difference or similarity between these two populations of patients. A much more inclusive study with more practices in the same community, or even similar communities of the same type of population would present a larger picture of what is going on.

Chapter 6

Analysis and Discussion

Summary of Findings

Patients diagnosed with type II diabetes mellitus (DM) require education and reminders about their disease to stay on track of patient follow-up visits and provider lab work orders. Because their condition requires consistent monitoring of particular lab values as well as medication and diet control, research has shown that there is a correlation between compliance of patient follow-up visits to the progress with improvement of lab compliance and the values collected at that time. With the implementation of a certified electronic health record (EHR), the health care professionals at Family Medical Center, PLC were able to provide patients with automatic patient reminders of appointments and lab work orders. From year 1 (using the older EMR system) to year 2 (using the certified EHR), patients were able to improve from a 44.2% non-compliancy rate for patient follow-up visits to a 3.8% non-compliancy rate the following year.

Of the 43 patients initially studied for lab work compliance, 6 patients converted from a non-compliant status to compliant after the implementation of the certified EHR. The total lab order compliant patient population grew from an 82.7% to 94.2%. The data was further dissected to represent those patients who were non-compliant with follow-up visits and the correlation between patient visits and lab work compliance. The data showed a relationship between patients who visit their health care provider on a consistent basis to those who are compliant with lab work orders. There were 16 patients during the first year who were non-compliant with their follow-up visits, but were compliant with lab work orders. As follow-up order compliancy increased, the lab work order compliancy for this population hit 100% in year 2. There were 43 original compliant patients out of the original 52 for lab work orders. The second year with the certified EHR picked

up 7 additional patients for lab work compliancy, thus improving those patients' lives in just one year time.

The data compiled from patient test values such as low-density lipoprotein (LDL), body mass index (BMI), and glycosylated hemoglobin (HbA1c). Total patient LDL values dropped from year 1 to year 2 by 14%, thus showing significant improvement. The greatest change in overall LDL values was discovered after isolating those patients who were non-compliant with follow-up visits to the office. Those patients showed a 24.1% improvement in LDL levels than those who were compliant with their patient follow-up visits year 2. It is possible to assess that there is a correlation between patients who are compliant with their follow-up visits with their health care provider and lab values directly related to their condition.

Patient BMI values showed a decrease in 2.5% in the 52 patient population studied. When those values were separated by year 1, non-compliant/compliant patient follow-up visits the consistency between the years remained the same. This division illustrates how patients who were non-compliant with their follow-up visits with the health care provider, showed 0.6% less improvement than those patients who were compliant with both the EMR and certified EHR.

It wasn't until the HbA1c values were separated before again, a correlation between patients who established follow-up visit compliancy between year 1 and year 2 and those who were compliant for both years. The 19 patients who improved their compliancy status also improved in their overall HbA1c values by 2.6%. Those patients who were compliant with their follow-up visits with the EMR and certified EHR increased their percent average HbA1c by 3.0%. Otherwise, total change in HbA1c percent for all patients included in the study rests at a 0.6% increase.

Conclusions

The research questions asked in this study were:

- Is there a direct correlation between the benefits of a certified EHR and patient compliancy in following up for their appointments as scheduled?
- Is there a correlation between the benefits of a certified EHR and patient compliance with physician ordered lab work?
- Is there a correlation between the benefits of a certified EHR and changes in Low Density Lipoprotein Levels (LDL mg/dL)?
- Is there a correlation between the benefits of a certified EHR and changes in patient Body Mass Index (BMI kg/m^2) values?
- Is there a correlation between the benefits of a certified EHR and changes in patient Glycosylated Hemoglobin (HbA1c %) values?

The results in this study strongly suggest that those eligible participants who are invested in a certified EHR can offer the convenience of automatic reminders about patient follow-up visits and lab work compliance. The added communication between patients and their health care provider improves patient compliance. Even though there was only a year to study the lab work values and BMI changes in patients diagnosed with type II diabetes mellitus, the current trend correlates that increased patient/provider face-to-face meetings can offer patients the chance to improve the quality of their health care by attaining more educational materials and direction from their health care provider. Research indicates that an educated patient is a compliant patient. Patients compliant with their health care provider orders are capable of improving their health if they choose to adhere to the plan.

Implications of the Study

Health care professionals could benefit from this study by understanding the effects of selecting a certified EHR to better care for their patients. With automated appointment reminders for follow-up visits as well as follow through of patient orders, patients are given the opportunity to keep the line of communication open with their health care provider. Results have shown a correlation between patient follow-up visit and lab work compliance when a certified EHR is used. Changes in lab work values were positively influenced by the environment created by the health care professionals and the quality of care of the patients demonstrates improvement. Overall, patients in this health care setting demonstrated an increase in quality of care after just one year exposure with a certified EHR, capable of meeting MU initiatives.

Recommendations

Where changes in lab work values demonstrated improvement in patients who were affected by the implementation of a certified EHR in their health care professional's office, this study needs to be performed on a much larger scale, differentiating patients at various stages of their diabetic care. To truly witness a stronger correlation between the effects of the certified EHR and patient quality of care, more time to focus on the individual quality care measures and whether each patient maintained or increased their quality of care status based with regards to their stage of diabetic care treatment.

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Appendices

Figure 1

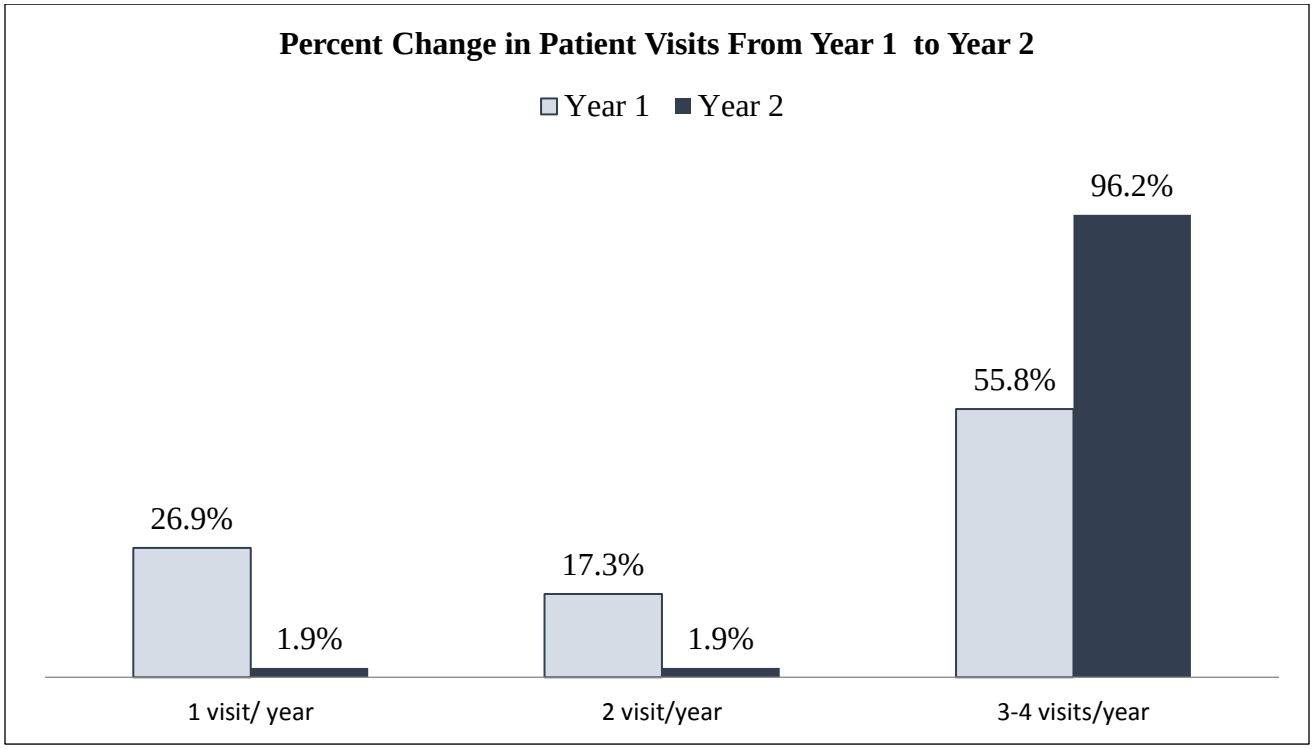

Figure 2

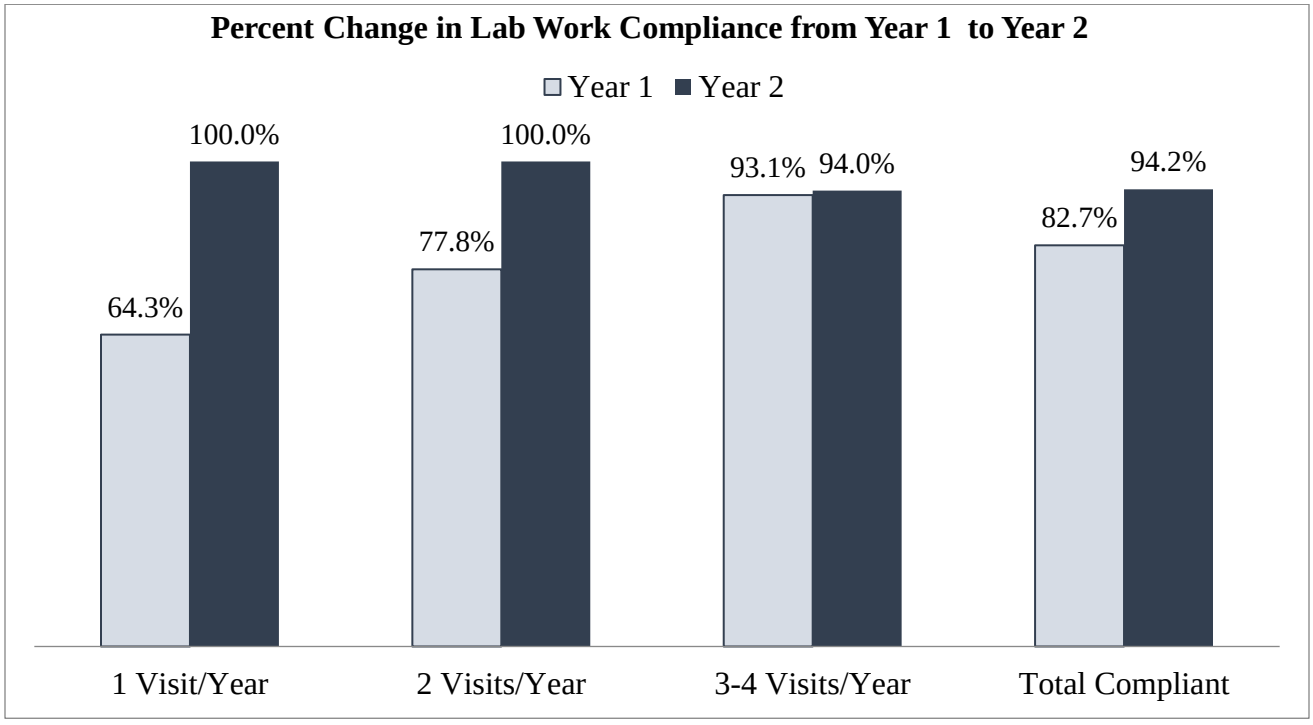

Figure 3

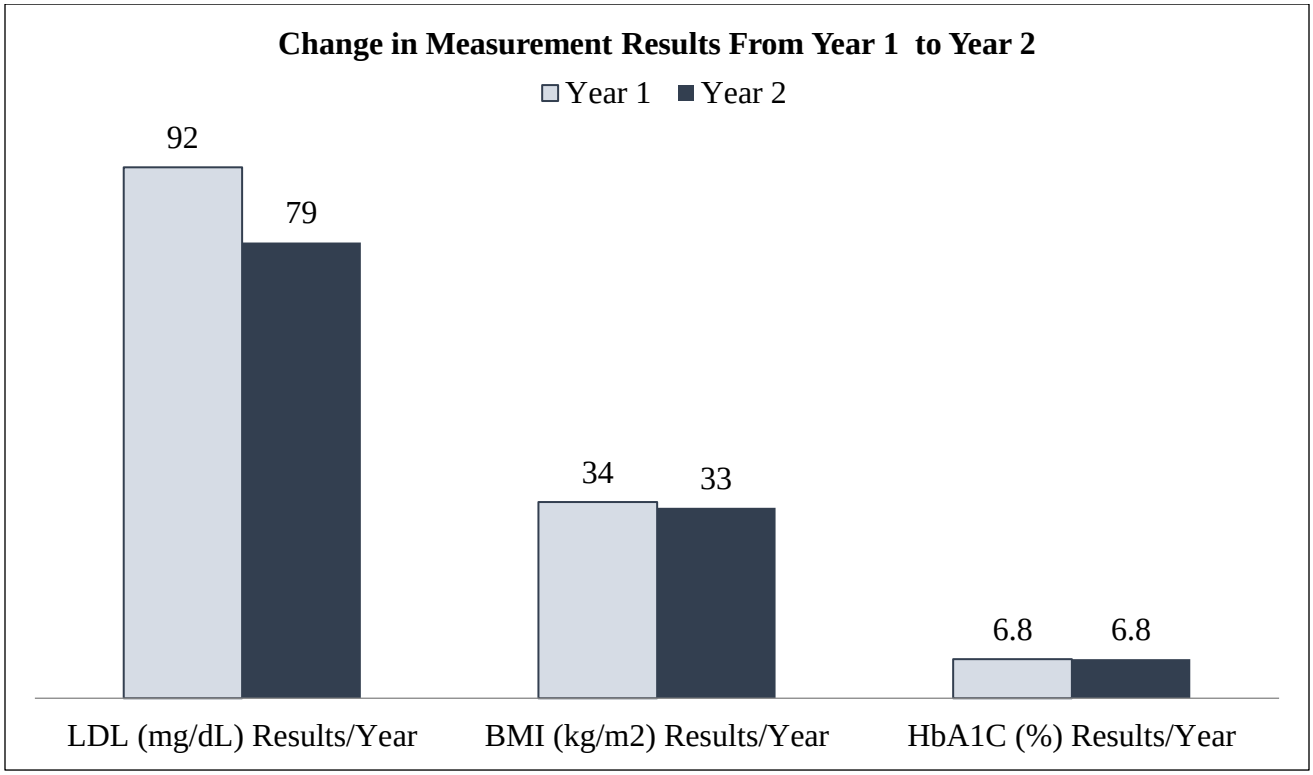

Figure 4

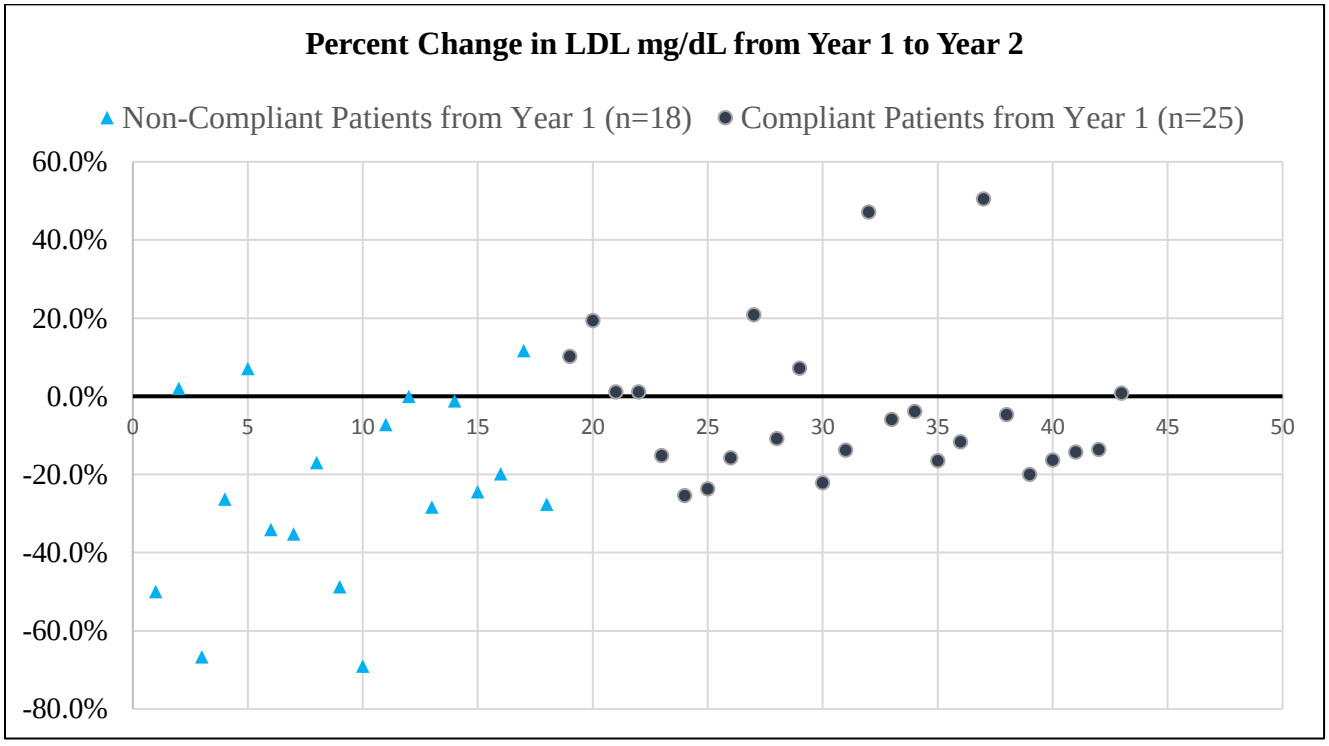

Figure 5

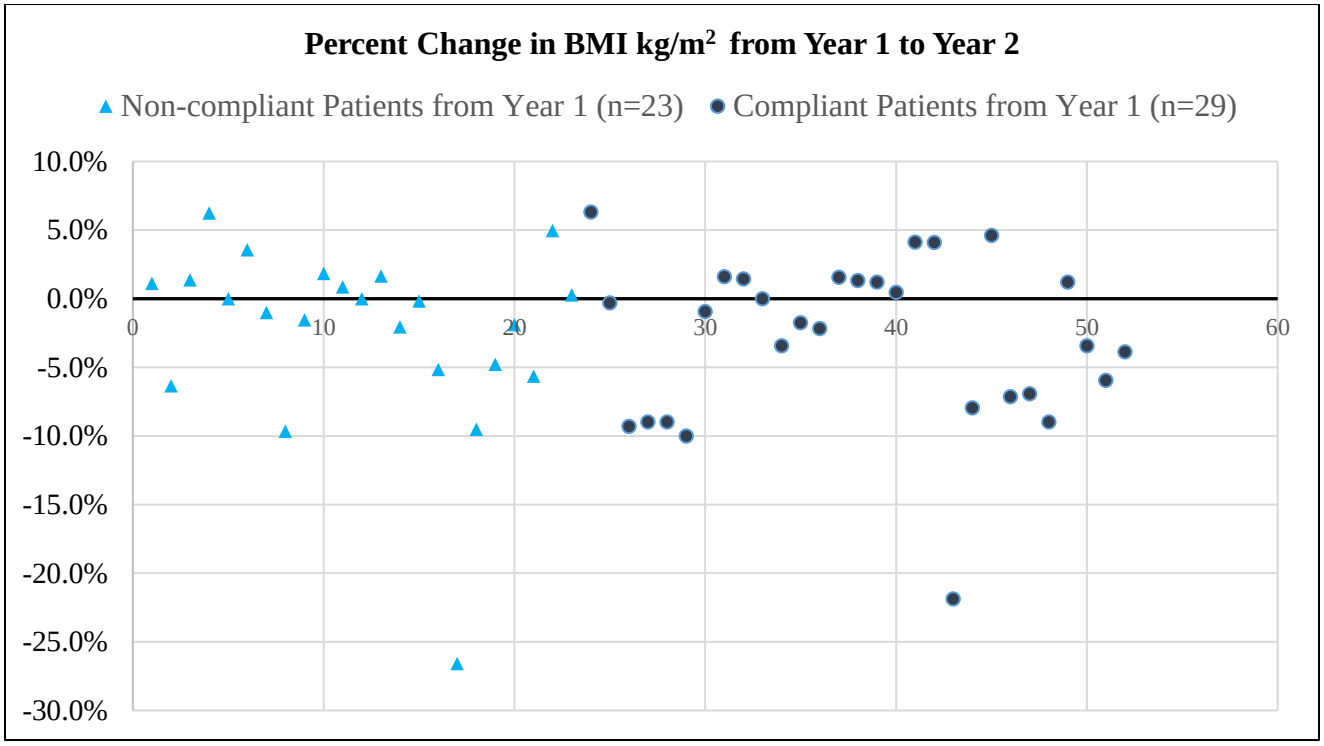

Figure 6