The impact of diabetes nurse care managers in outlying medical offices on quality of care: An empirical investigation

Edward Alan Hess

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THE IMPACT OF DIABETES NURSE CARE MANAGERS IN OUTLYING MEDICAL OFFICES ON QUALITY OF CARE: AN EMPIRICAL INVESTIGATION

A Project
Presented to the
Faculty of
California State University,
San Bernardino

In Partial Fulfillment
of the Requirements for the Degree
Master of Business Administration

by
Edward Alan Hess, M.D.
December 2001
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ABSTRACT

The objective of this study is to evaluate the impact of the Diabetes Nurse Care Manager on an at-risk diabetic population using a Primary Care Group Visit Model in Outlying Medical Offices within the Kaiser-Permanente Health Care System upon the process and outcome of care in this population.

This study was performed in the Primary Care Clinics of a large group-model Health Maintenance Organization (HMO) in Southern California. Poorly controlled diabetic members > 30 years of age were selected for a nurse management intervention based upon elevated Hemoglobin Alc (HbAlc) values of 8.9% and higher. These patients attended least one nurse managed group visit appointment in their Local Medical Office with their Primary Care Physician acting as a figure of authority. The Care Management nurse subsequently followed each individual patient by phone in order to improve patient adherence to Clinical Practice Recommendations.

In a three and six month analysis, the intervention group had significantly improved its Outcome Parameters for Quality of Care. HbAlc, which is a clinical marker for diabetes control, improved by 23.9% in three months.
and improved by 27.8% in six months. Surrogate Parameters for long-term Quality Measures such as Urinary Microalbumin, LDL-Cholesterol, and Retinal Screening Examinations also improved.

A Primary Care Group Visit Model that utilized a Diabetes Nurse Care Manager in a shared-practice situation with the Primary Care Doctor in the Outlying Medical Offices has demonstrated improved Quality of Care delivered to at-risk diabetic patients.
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CHAPTER ONE

PROPOSAL

Introduction

Diabetes is a chronic, sometimes debilitating, disease. Based upon research reported in the Diabetes Control and Complications Trial [DCCT] (1993) as well as the UK Prospective Diabetes Study [UKPDS] (1998), improved diabetic control of blood sugars has helped decrease the incidence of certain long-term complications. The monitoring of yearly retinal screening examinations, Hemoglobin Alc (HbAlc), Urinary Microalbumin (MA), and Low-Density-Lipoprotein (LDL) Cholesterol all contribute to improved clinical outcomes. Greenfield, Rogers, Mangotich, Carney, and Tarlov (1995), McCullough, Price, Hindmarsh and Wagner (1998), and many others, have shown that any method that improves compliance with routine monitoring and treatment will translate into improved health status for the patient.

Recently, Martin, Selby, and Zhang (1995) and Ho, Marger, Beart, Yip, and Shekelle (1998) have shown that most health-care organizations approach the challenges of monitoring and screening for diabetes complications in a
haphazard manner. The implementation of computerized databases used to manage large numbers of people with chronic conditions is still in its infancy. According to Frame (1995) there are no set standards for their usage. The point is well made by Ornstein, Garr, Jenkins, Musham, Hamadeh, and Lancaster, (1995) that the majority of these Computerized Decision Support Systems (CDSS) are compartmentalized in large, centralized Diabetes Care Specialty Clinics. Paradoxically, it is the Primary Care Practitioner that requires this data tool to help manage the relatively well-controlled diabetic patient before he/she becomes a high-risk diabetic patient.

Wagner (1998) concluded that the role of Diabetes Nurse Educators and Diabetes Nurse Care Managers is a field in evolution. The Nursing Scope of Practice (2000), which allows a Registered Nurse the capacity to monitor and modify treatment regimens on an individual basis, has undergone a great metamorphosis in recent years. These highly trained professionals must constantly use their skills for assessing compliance, determining the degree of diabetes control, and changing treatment parameters in the course of managing those patients under their care.
The research of Aubert et al. (1998) and others has demonstrated that Diabetes Nurse Care Managers have proven to be the best resources for following diabetic patients through the use of large computerized databases. Their skills include Case Finding the optimal population to be followed, contacting the Primary Care Physician (PCP) and diabetic patient in order to initiate Case Management, and performing the actual psychoeducational and management interventions during the course of treatment.

The presence of computerized Clinical Patient Registries such as those evaluated in the study by Shea, Du Mouchel, and Bahamonde (1996), in addition to detailed Clinical Practice Guidelines (CPG), and precise Policies and Procedures (P&P) for delivering diabetes care have provided the ideal manner for improving the quality of diabetic care in the managed-care environment. The combination of these tools together with Computerized Decision Support Systems and a functioning Electronic Health Record (EHR) as documented by Baker, Lafata, Ward, Whitehouse, and Divine, (2001) have vastly improved our proactive approach to diabetes care. Batalden et al., (1997) have demonstrated that the data generated from
these electronic databases should form the basis of a Continual Quality Improvement approach to managing a large group of diabetic patients. The national organizations responsible for monitoring the quality of care within large healthcare systems, such as the National Committee for Quality Assurance (NCQA), have begun to require the measurement of such data and the creation of systems for maintaining and improving the quality of care being delivered.

Statement of the Problem

As Physicians become more and more overworked, their time spent per patient goes down. Physicians are unable to fully-educate their diabetic patients, and therefore have delegated this duty to the Diabetes Nurse Educator. The Diabetes Educator, as described in the work of Peters, Davidson, and Ossorio (1995), has become a Physician Extender in the sense of monitoring laboratory results and ordering routine lab testing for the specialty clinics supporting the work of the Primary Care Provider. However, the full use of Diabetes Nurse Educators in the Outlying Medical Offices was never realized in the past due to resource and staffing
limitations within the Fontana Diabetes Care Clinic. Primary Care Physicians are now becoming even more interested in improving care and outcomes in their diabetic populations. The British studies by Pringle, Ward, and Chilvers (1993), Farmer and Coulter (1990), and Koperski (1992) show that the development of the "mini-clinic" is a movement toward providing much more than routine care in Outlying Medical Offices.

In following the Clinical Practice Recommendations (2001) of the American Diabetes Association (ADA), we find that routine care for persons with diabetes should consist of yearly monitoring of Hemoglobin Alc, Urinary Microalbumin, Low-Density-Lipoprotein Cholesterol, and Retinal Screening Examinations. In addition, there should be feedback of pertinent information to the patient in order to initiate any necessary changes in diabetes treatment. This is usually followed up with an assessment of the patient's response to the new treatment and the need for further treatment. However, the work of Khoury, Churgin, and Strawn, (1998) demonstrates that Physician compliance with the many Clinical Practice Guidelines (CPG) that they are required to be familiar with has been diminishing due to lack of available time and the
proliferation of multiple new guidelines. Physicians are increasingly unable to provide this care on their own and within a reasonable amount of time.

Diabetes Nurse Care Managers are individuals that have, in the past, provided basic educational interventions, individual consultations, and formalized medication management in a highly structured and centralized hospital clinic environment. Their role is changing as the population of people with diabetes within any given healthcare organization becomes better defined. Wagner, Austin, and Von Korff, (1996) again has shown that the higher-risk patients need more direct care. Those patients in most need of care are often those who do not keep their appointments in a standard clinic setting. Therefore, changing the venue in which the care is delivered back to the Primary Physician’s office has become a useful adjunctive treatment to routine diabetes care. However, no one has determined the impact of this intervention on the overall quality of care delivered to a higher-risk diabetic population.
Need for the Study

This study has been designed to assess the effectiveness and impact of allocating Diabetes Nurse Care Managers to Outlying Medical Offices of the Kaiser-Permanente Health Plan in the Fontana Service Area. This study has helped to determine whether the allocation of Clinical Nurse Educator resources to the outlying clinics improves the parameters associated with good quality diabetes care. There is still a need for subsequent research upon potential savings, benefits, limitations, and trade-offs associated with this change in resource allocation. In addition, this model of care must directly or indirectly benefit the Physicians in the medical offices in which the care is delivered. Furthermore, in order to continue this model of care, there must be an assessment of satisfaction of the patients, since profound patient dissatisfaction would hinder long-term compliance with the requirements mandated for quality patient care.

Regulatory agencies such as the National Committee for Quality Assurance have begun to require studies of impact and quality of care when assessing the effectiveness of large managed healthcare agencies with
defined patient populations. This study helps meet the needs of these agencies as well as the needs of the Department of Preventive Medicine in which these Diabetes Nurse Care Managers function. Additionally, this information has permitted the Department of Preventive Medicine to demonstrate value to the Medical Group Administrative Team in Fontana.

Scope and Limitations

This study has been conducted entirely with members of the Kaiser Health Plan that are managed by the Southern California Permanente Medical Group (SCPMG). There are over 3 million lives covered by the Kaiser-Permanente Health Care System in Southern California. In the Fontana Medical Service Area there are approximately 371,000 active members. Of this number there are 15,482 individuals (4.2 percent) identified as having Diabetes Mellitus. A nonrandomized longitudinal study was conducted on a subset of this population being followed in the Outlying Medical Offices of Colton and Victorville in the Fontana Medical Service Area. All participants were over 18 years of age and had been
Kaiser Health Plan members continuously for the one year preceding enrollment in this study.

The patients being studied had been chosen only for those Physicians that wished to participate in a shared-practice group visit model of care in which a Diabetes Nurse Care Manager helped that Physician manage a higher-risk subset of his/her diabetic patients. There is insufficient evidence to note whether cooperative physicians have better or worse outcomes with their diabetic patients. Therefore, this population must be considered to be a nonrandomized sample.

In addition, the choice of selecting a range of Hemoglobin A1c from 9.0 and above to represent a higher-risk group was arbitrarily based upon the Health Plan Employer Data and Information Set (HEDIS, 2000) measures demonstrating poor vs. acceptable control for diabetic Health Plan members whose Hemoglobin A1c was at-risk of exceeding the threshold value of 9.5%.

The patients that participated in this shared-practice model had agreed to come to one physician visit during which the Diabetes Nurse Care Manager explained his/her role and limitations. He/she also discussed general Diabetes Care Guidelines with the
participating members. This could lead to some degree of bias towards ambulatory patients or patients with available transportation. The work of Wagner et al., (2001) at the Group Health Cooperative of Puget Sound demonstrated that patients with good family or community resources tend to do better in their diabetes care than do those patients who do not have these resources.

In the course of this dissertation, the issues of patient compliance, general authority figures as well as time and place utility have been discussed in the context of the study layout. Discussion of group dynamics and educational interventions also plays a significant part in describing the full impact of this study. The importance of Provider - Patient communication and timely feedback of results also plays an important role in the final discussion.

Sampling Plan

The population for this study was defined through a Care Management tool (POINT) developed by Pharmacy Analytic Systems within Kaiser-Permanente. This database system allowed queries to be undertaken on the Southern California Region-wide Diabetes Registry. The Medical
Center's and the individual Physician's diabetes panel was easily identified using this tool. A list of those patients with a Hemoglobin Alc greater than 8.9% were presented to their Primary Care Physician for approval. If approved, these patients were then contacted by phone and/or letter asking them to participate in a two-hour doctor's visit in which several individuals would address their diabetes management. It is at this point that some individuals were excluded by refusal, educational barrier, or language barrier. These individuals were then offered one-to-one counseling and management by a culturally appropriate Physician or Nurse Educator.

When the group of selected members met with the Diabetes Nurse Care Manager and their Primary Physician, they received an educational intervention followed by a review of their medical treatment and pertinent laboratory testing. Those patients that needed any changes in medication got those changes made on the spot. Pertinent laboratory tests were ordered and performed the same day. The Diabetes Nurse Care Manager was responsible for informing his/her patients of the results of their tests and maintaining phone and letter contact with his/her patient population for at least one-year.
However, for the purpose of this study, each patient population was studied for six months prior to their intervention as well as six months after their intervention.

The data collected on each patient by each nurse at every intervention was recorded in a clinical diabetes database that served as an Electronic Health Record (EHR). Further data for this study were available on legacy mainframe computers that compiled administrative data, as well as demographic, laboratory, pharmacy, and hospitalization data for the members of the Kaiser Health Plan.

Methods and Procedures

The population already discussed had been followed for improvement in their surrogate care parameters (Frequency of performing HbA1c, MA, and LDL-Cholesterol) as a measure of their quality of care. During the course of the study any changes in these parameters have been attributed to the Nurse Care Manager intervention as these patients were receiving routine care prior to their intervention. In addition, all participants had been continuously enrolled in the Kaiser Health Plan for the
one-year preceding this study thus allowing direct comparisons to take place within each group.

In order to demonstrate statistically significant changes in Hemoglobin A1c frequency, Urinary Microalbumin frequency, LDL-Cholesterol frequency, as well as changes in HbA1c values; an Average Frequency, Analysis of Variance (ANOVA), and/or t-test has been calculated for each parameter. To control for the patient's expected likelihood of receiving the routine care and screening tests, these patients have been compared to their own previous lab values prior to the Care Management intervention.

Additional data was collected on the frequency of performing yearly Diabetic Retinal Screening Examinations. This data was compared to regional averages within the Kaiser-Permanente Health Care system as well as to national averages for other health care plans. That data is available through the National Committee for Quality Assurance (HEDIS, 2000).

Data on the presence of abnormal urinary Microalbumin and abnormal LDL-Cholesterol were obtained through the POINT Care Management tool. This data tool also provided information on whether each patient had
received pharmaceutical treatment for his or her clinical laboratory abnormality. That data was also compared with National and Regional averaged data.

Brief Summary
This study was designed to help answer the question on whether allocating Diabetes Nurse Care Managers to outlying Medical Offices is effective in improving care to diabetic members of Kaiser Permanente by evaluating the frequency of testing Hemoglobin A1c, Urinary Microalbumin, and LDL-Cholesterol for a six month period before and a six month period after initiation of Diabetes Care Management in outlying Medical Offices. The Hemoglobin A1c value has also been used to help assess the degree of improvement in diabetes control during the course of this study. This study also helps determine whether Diabetes Nurse Educator resources shall continue to be allocated to Outlying Medical Offices and whether this model of care should be expanded in the future. The business case for expansion will be presented to the administrative team at the Fontana Kaiser-Permanente Medical Center.
CHAPTER TWO
REVIEW OF THE LITERATURE

Historical Background

Since this study is based upon the evaluation or a new method of care delivery within the Department of Preventive Medicine at the Kaiser Permanente Medical Center in Fontana, California, it is obligatory to look at what has come before in order to fully understand the impact of the ongoing process of change.

In the past, Preventive Medicine has been the department that provided health education and training to people with identified disease processes and disease risks in order to modify behavior toward a more healthful lifestyle. This function was provided by Health Educators, nurses, dieticians, and behavioral specialists who used commonly available educational tools, such as classroom instruction, individual instruction, books, pamphlets, and handouts. These goals were defined by getting the greatest number of identified people to classes. The greatest problem that arose with the traditional educational function of Preventive Medicine was that there were no measurable clinical outcomes (just
educational outcomes), and that the people with the most need for any intervention were almost always the ones who never came to the classes. Over time, other health plans scaled back their Preventive Medicine Departments to reflect a subordinate role in the health care system. In discussion with others, I have learned that Preventive Medicine Departments frequently consisted of a single person who coordinated classes and mailings. The lack of a consistent business case hurt the development and growth of Preventive Medicine in the past. The lack of defined populations of people with a disease or disease risk posed another great obstacle to the development of modern Preventive Medicine. It was the growing use of Information Technology that helped bring the science of Preventive Medicine to the forefront of medical science.

Dr Eric Ngo began the Preventive Medicine Department at the Kaiser Permanente Medical Center in Fontana, California in 1976. He had the support of Kaiser Health Plan as well as the Medical Group Administration to place the multiple functions of Preventive Medicine beneath one roof. This served to coordinate and integrate the delivery of Preventive care as well as allow innovation in the design of preventive care programs. Dr Ngo hired
nurses and educators with good clinical backgrounds since they would have an existing store of knowledge to share with our at-risk patient population. These core individuals became the innovators of new models of preventive care delivery.

The nurses and physicians in Preventive Medicine forever changed the diabetes program. In 1979, Marli Crane RN, MFT had attended a lecture by Dr. Mayer Davidson describing a concept of using Registered Nurses to advise patients on how to use their diabetic medications properly. This involved changing insulin dosages based upon an algorithm prescribed by a treating physician. This Model of Care, which Davidson et al., (1998) described in subsequent papers, placed more responsibility upon the nurse and actively included nurse educators in the treatment portion of care. Over time, these nurses developed the skills involved for using most of the medications needed in diabetes management. Algorithms on standing orders enabled a much greater participation by the Nurse Educator in the practical care of our diabetic patients.

The traditional concept of Preventive Medicine was extended to its logical limits within the next eight
years. In 1987, a comprehensive treatment team was formed to treat diabetes and its many complications. An MD Endocrinologist was hired to improve the health of all diabetic Kaiser Health Plan members. This meant that the role of Preventive Medicine would have to be extended to outreach to all people affected by diabetes. A means of identifying those people affected by diabetes had yet to be developed. However, planning was begun to convert a system of paper charting to an electronic record of all diabetic members. This would at least create a list of people identified with diabetes who have been referred to the Preventive Medicine Department. This would form the core of what would become a complete registry of all Kaiser Health Plan members with diabetes in the Fontana Service Area.

The Fontana Diabetes Team in 1987 consisted of one (1) MD Endocrinologist, five (5) Diabetes Nurse Specialists that obtained Certified Diabetes Educator (CDE) credentials, one (1) Registered Dietitian (RD) who obtained CDE certification, and the staff of Preventive Medicine for program support (one (1) MD Chief of Department, one (1) Department Administrator (DA), three (3) PHD Doctors of Health Science, three (3) Registered
Dietitians, three (3) Certified Health Educators, and their clerical support). During this period of time, diabetes care was expanded into perinatal care, which includes gestational and pre-gestational diabetes care. The team became capable of handling complex cases, including people on insulin pumps. However, the major change was focus on diabetic complications rather than glucose numbers and glucose control. This shift in emphasis meant that more resources would be needed to identify at-risk individuals and target specific treatments. In 1989, Dr Gary Wong became a member of the Department of Preventive Medicine. His background with a Masters in Public Health gave the department the skills needed to actually create a patient tracking system for diabetes. The greatest difficulty in creating such a system was to create the database structure to store the information needed to identify and follow this patient population. Meetings between Dr Wong and the Endocrinologist, Dr. Edward Hess, resulted in a clinically useful tool for managing an identified diabetic population. The missing step was to identify diabetic members who had not been referred to the Preventive Medicine Department. This relational database
had many features that allowed improved patient identification and tracking. Laboratory data was downloaded into the database to allow tracking of critical valves for diabetes management. Communication between the patient and the department improved with the use of a letter generation function.

Between 1993 and 1995, a similar system was created on a region-wide scale. A Diabetes Registry was generated from laboratory, pharmacy, hospital, and emergency department data. This was to be used to provide compliance data for national quality standards data collection. That system has evolved into a regional repository of diabetes data that allows a comparison within a Medical Service Area as well as between Medical Service Areas, as well as between various Health Plans. From 1995 onward, other Medical Centers within the Southern California Permanente Medical Group had developed patient tracking systems. Most of these systems also had means of tracking changes in laboratory values and clinical complications. The major differences were in the manner in which this data was used to improve patient care, and the allocation of resources required to provide that care within each Medical Service Area.
From 1995 to 2000, the role of the Diabetes Nurse Specialist had shifted slowly toward becoming a Care Manager. The nurse had become a vital partner in the ongoing care of people with chronic conditions. The algorithms for changing insulin dosages had expanded to full Policies and Procedures that helped identify people at-risk for stroke, heart attacks, or renal failure. Assisting people in obtaining proper treatment for diabetic complications permitted earlier diagnosis and treatment. This treatment is essential in preventing progression of serious complications. The focus on Population Care Management (PCM) required that nurses become aware of other co-morbid states that occur more frequently in the diabetic population. That stage was begun in the year 2000, as changes were initiated in the Department of Preventive Medicine to help coordinate simultaneous care in multiple disease states.

In that year, efforts were made to coordinate the Care Management areas of Diabetes Mellitus (DM), Coronary Artery Disease (CAD), Congestive Heart Failure (CHF), and Asthma (as well as Elder Care, End Stage Renal Disease [ESRD], and Perinatal Care). These efforts resulted in greater understanding and greater cooperation among these
Care Management areas. Ultimately the nurses involved in care managing Diabetes Mellitus, Coronary Artery Disease, Congestive Heart Failure, and Asthma have all joined the Department of Preventive Medicine in tracking, preventing, and managing the progression of chronic diseases. An important component of the care management model of care is Continuous Quality Improvement (CQI) and feedback of results. That has formed the basis of the present goals and objectives of the Preventive Medicine Department in Fontana.

Finally, by 2001, the expertise in care management was beginning to produce results in developing a new model of diabetes care. Diabetes Nurse Specialists were cross-training in cholesterol management and had begun to interact with other care managers in other departments. A Registered Nurse Practitioner (RNP) was hired to address more complex cardiac cases. All the nurses and Clinical Health Educators were trained in computerized outreach toward defined disease populations. The staff of Preventive Medicine was always included in the development of this new model of care. Eventually, the lingering problem of reaching the at-risk individual was addressed by this present study. "How does one reach the
person with difficult to control diabetes when transportation or time constraint hinders care?

Implementation of Preventive Services

Since Preventive Medicine had evolved from a purely Public Health perspective and educational perspective, it is important define the arena in which Preventive Medicine operates. The definition of Preventive Medicine as it appears in Stedman’s Medical Dictionary (1972) is “a medical specialty primarily concerned with prevention or disease and the promotion and preservation of health in the individual”, has given way to a more comprehensive and outreaching definition used by the Accrediting Council for Graduate Medical Education (Green Book) 2000. “The primary foci of Preventive Medicine are the study of disease processes as they occur in communities and defined population groups, and the stimulation of practices with respect to the community and the individual that will advance health by promoting health enhancing environments and behaviors, so preventing disease and injury, making possible early diagnosis and treatment, and fostering habilitation and rehabilitation of persons with disabilities.”
The major changes in definition center around the study of defined population groups, the involvement of entire disease processes, and the outreach involved in promoting health within these populations. This has formed the basis for developing goals and objectives for the Department of Preventive Medicine in Fontana. First and foremost, we must strive to improve the health of all our diabetic members. This population numbers approximately 15,482 people using data derived from our diabetes population registry. Second, we must provide comprehensive diabetes education and training in addition to all other activities. Third, we must continue to supply over 2000 individual appointments per year and over 3000 class and group appointments. Fourth, we will continue to receive over 2200 new referrals per year that add to our population. Fifth, we will start over 500 people on insulin this year and follow up on their education and management. Sixth, Care Management initiatives have now included the ability to outreach to groups we have missed in the past. We will also have greater effect on outcomes of the various diabetic complications that are impacted by Population Care Management. Seventh, Clinical Information Systems (CIS)
provide the means for following our defined diabetic population from cradle to grave (only after a long productive life). Eighth, We have developed a focus on measurable outcomes; this is a crucial point upon which a Continuous Quality Improvement (CQI) program will assist care providers with the tools for improving care and changing the processes by which care is provided. As noted in the work of Peters and Davidson (1998), information technology (IT) has become an indispensable tool in the provision of Preventive Medicine to a growing population. Besides registering and tracking a population, a computerized database allows complex searches for common attributes among at-risk individuals and provides an ideal outreach tool. The ability to track a subpopulation permits individualization to a single department, a single medical office building, or a single practicing physician. Resources can be directed to assist individuals or outlying medical offices that have a high number of significantly at-risk patients. This concept has permitted the Department of Preventive Medicine to direct more care to people who have not benefited from traditional, centralized care. We are finally able to develop outreach programs that extend our sphere of
influence to the furthest reaches of our Medical Service Area. That satisfies the requirement that Preventive Medicine go out into the wider community to promote health and prevent disease.

Diabetes Outcomes

Diabetes Mellitus (DM) is a serious, chronic disease that affects over 15.7 million people (5.9% of the population) in the United States. According to the American Diabetes Association’s Diabetes: 1996 Vital Statistics (1996), approximately 800,000 people are diagnosed every year and that number is considered to be an epidemic in The United States. Many people are not aware that they have diabetes until they develop a life-threatening complication. Diabetes is the seventh leading cause of death in The United States of America. Diabetes contributed to 198,140 deaths in 1996 according to death certificate data. For the purpose of determining diabetes outcomes, we must look at the incidence of complications. Cholesterol abnormalities associated with diabetes contribute to a two to four times greater risk or a stroke or heart attack in the person with diabetes.
Heart disease is present in seventy five percent (75%) of all diabetes-related deaths in the United States.

The American Diabetes Association's web site (Accessed October 16, 2001) cites diabetes as the leading cause of End Stage Renal Disease (ESRD) in this country. Over 51% of all people on dialysis are receiving treatments due to diabetic complications. Diabetes is also the number one cause of new cases of blindness in The United States among people ages 20-74. Between 12,000 and 24,000 people lose their sight because of diabetes every year. Additionally, a person with diabetes has a 15-40 times greater risk of amputation compared to a person without diabetes. There are more than 56,000 amputations performed each year among people with diabetes.

Much attention is paid to the economic impact of Diabetes Mellitus. One in seven health care dollars are expended on diabetes-related disease in The United States. According to the American Diabetes Association’s publication on diabetes costs (1996), the direct and indirect costs of diabetes now exceed $100 billion per year. It is one of the most costly health problems of our times.
Improving diabetes outcomes has been the aim of many scientific studies. Despite the fact that improved glucose control would appear the most obvious way of improving outcomes, it was not until the DCCT (Diabetes Control and Complications Trial) of 1993 that the dramatic degree of improvement in the outcome of Type 1 Diabetes could be fully demonstrated. This was followed by the UKPDS (United Kingdom Prospective Diabetes Study) in 1998, which demonstrated that people with Type 2 Diabetes had significant improvement in outcomes associated with improved glucose control. The outcomes studied included Retinopathy (Ocular Disease), Nephropathy (Renal Disease), Neuropathy (Neuronal Disease), and Cardiovascular (Heart) disease.

The measurement of glucose control in every study has been the determination of Hemoglobin A1c (HbA1c) as well as Self-Monitoring of Blood Glucose (SMBG) values recorded on home blood glucose monitors. Hemoglobin A1c is an objective laboratory study that integrates three months of glucose concentration in the blood. Whereas, SMBG gives isolated values spread over a short period of time. This is useful for day-to-day management of blood glucose, but lacks the ability to give an average
measurement of glucose concentration. The HbA1c is used as the sole measurement of glucose control in this study.

Diabetes outcome studies, such as Greenfield et al. (1995), use surrogate markers to evaluate intermediate steps toward improving the health of a defined population. As previously mentioned, the Hemoglobin A1c test represents the integration of average blood sugar values over a 90-120 day period. This is most commonly used as a marker for clinical improvement over a two to three-month period of time. That data if further extrapolated to clinical outcomes.

The frequency of performing a Retinal Screening Examination in a diabetic population is a surrogate for care performed at appropriate intervals in that population. As we have learned from McCullough et al., (1998), the ability to coordinate care for a large group is modeled by performing a yearly retinal exam on this defined population. The yearly retinal examination also translates to an improved quality of life, since each case of early Diabetic Retinopathy detected by screening lessens the chances of permanent blindness in the population group being evaluated.
Urinary Microalbumin (MA) testing is a surrogate marker for prevention of End Stage Renal Disease (ESRD). As we have learned from McCullough et al., (1998), yearly urinary Microalbumin screening improves the chances of early detection and treatment of Diabetic Nephropathy, which eventually leads to Chronic Renal Failure (CRF). The earliest stages of this process are reversible, and initiation of proper treatment may delay progression in later stages. This is also a marker for improved quality of life, since the outcome of poor control is death or dialysis treatment.

The performance of LDL-Cholesterol as we have learned from McCullough et al., (1998), is directly related to initiation of treatment with behavioral modification as well as with pharmacological treatment. The higher the LDL value, the greater the risk for a Myocardial Infarction (MI) or a Cerebral Vascular Accident (CVA). Lowering the LDL value has the benefit of improving overall health and improving quality of life. This test also has the benefit of motivating individual patients toward making the lifestyle changes necessary for achieving better health. In order to further improve the individual health outcomes, a pharmaceutical agent is
often added as an adjunct to the behavioral changes. The appropriate attention to total health outcomes is a critical factor in reducing the risk factors for serious diabetic complications.

Clinical Practice Guidelines

Clinical Practice Guidelines (CPG) are evidence-based recommendations that are agreed upon by a panel of experts that direct a specific course of action within medical decision making. These guidelines are clinically useful in the determination of appropriateness of ongoing medical care. Every medical field has Clinical Practice Recommendations (CPR) specific to that field. Wagner, Austin, and Von Korff (1996) is a proponent of Clinical Practice Guidelines as a means for dealing with chronic illness.

Diabetes guidelines, such as the Clinical Practice Recommendations (2001) of the American Diabetes Association, govern the type and frequency of specific testing procedures. The goal is to always improve clinical outcomes with respect to resource utilization. The frequency of performing a diabetic Retinal Screening Examination is set at one-year intervals. This period of
time was chosen due to the slow progression of sub-clinical Diabetic Retinal disease. Intervals over one year generally demonstrate a decrease in the quality of care delivered.

Hemoglobin A1c testing is done at intervals that would influence or change the care of an individual patient. This interval could be from one to eight times per year.

However, the minimum interval is set appropriately at once per year. This gives much leeway toward approaching the upper end of the interval, but dropping below once a year would hinder proper care. For the purpose of this study, we have evaluated Kaiser Health Plan members who have had HbA1c values in the past 12 months and we have used this value to stratify our population for the purposes of determining the course of their care.

HbA1c values indicate the degree of glucose control during the prior three months. American Diabetes Association publications such as Medical Management of Type 2 Diabetes (1998) quote that "Excellent control" is generally cited as less than 7%, "Good control" up to 8%, "Fair control" up to 9%, and "Poor control" greater than
or equal to 9%. The ADA Clinical Practice Recommendation is to improve HbA1c as much as possible, and to address HbA1c values of 9% or greater as a priority group requiring greater attention and treatment.

Urinary Microalbumin (MA) is measured at yearly intervals in the early stages of Diabetic Retinal disease. The clinical goal is to maintain the MA value at less than 30 mcg/mg creatinine. This value is associated with less risk of progressive Diabetic Nephropathy and is associated with reversible changes within the renal parenchyma. Treatment may consist of improved glucose control and/or pharmaceutical intervention.

The frequency for measurement of Low-Density Lipoprotein (LDL) Cholesterol is cited in the ADA Clinical Practice Recommendations (2001) as at least once per year. Elevation of LDL-Cholesterol is directly related to the risk of Cerebral Vascular Accident (CVA) or Myocardial Infarction (MI). Clinical Practice Guidelines suggest that LDL-Cholesterol be maintained at less than 130 mg/dl. Many specialists now prefer to keep this value at less than 100 mg/dl. The Fontana Diabetes Clinic uses this value for the initiation of treatment of elevated LDL-Cholesterol. The percentage of the
population in good control of Cholesterol is an important marker of potential Atherosclerotic Heart Disease within a population. Cholesterol treatment helps to significantly lower coronary heart disease risk. The percentage of the population at-risk for elevated LDL-Cholesterol that receives treatment is an important measure of active medical treatment plans aimed at lowering the incidence of coronary artery disease within a defined population.

Dissemination and promotion of Clinical Practice Guidelines are essential in improving the health of all care-managed populations. The closer the population approaches the ideal standard, the better the health status of the individuals comprising the population. That is why many Continuous Quality Improvement programs concentrate on bringing their populations closer to the ideal standard promulgated by Clinical Practice Guidelines.

Diabetes Quality of Care Measures

At first, Quality of Care (QC) in any medical context may be an elusive concept to quantify. How do you measure the caring of the physician or the skills of the
nurse? Therefore, measurable outcomes in improvement of clinical health status become the measurable quantities. The areas of diabetes care most often cited as Quality of Care Measures (QCM) by national standards organizations (HEDIS 2000) are: Frequency of Retinal Screening Examinations, frequency of HbA1c measurements, frequency of urinary Microalbumin monitoring, and frequency of LDL-Cholesterol measurements. Secondarily, the improvement in HbA1c is used to assess the outcome of any diabetes intervention. In addition, treatment of abnormal values of urinary Microalbumin and elevated values of LDL-Cholesterol are measures of the efficacy of the process of delivering care. Used together, these Quality of Care Measures are powerful tools in assessing the impact of any clinical intervention.

A diabetic Retinal Screening Examination is defined as a dilated eye exam performed by a licensed professional within their Scope of Practice that includes evaluation or interpretation of Diabetic Retinal changes. A non-dilated photographic study may be used if it is evaluated or assessed for Diabetic Retinal changes by a Licensed professional trained in the evaluation or interpretation of Diabetic Retinal Photographs. The
standard of care by national standards organizations (HEDIS 2000) for performing this test is a yearly examination in all diabetics, except those people having Type 2 Diabetes for less than 5 years. The interpretation of this Quality of Care Measure is that any qualifying exam performed within a 12-month period is indicative of a higher quality of care, and any examination not performed within a 12-month period is indicative of a lower quality of care.

Urinary Microalbumin monitoring defined as a urinary assay for the protein albumin, which is capable of quantitative measurement within the range of 30-300 mcg/mg creatinine. The measurement may be performed on a first morning sample, a random sample, or a timed urinary sample. The value must then be recorded in a medical record in order to be interpreted. The standard of care by national standards organizations (HEDIS 2000) for performing this test is a yearly examination. The interpretation of this Quality of Care Measure is that any qualifying exam performed within a 12-month period is indicative of a higher quality of care. And any examination not performed within a 12-month period is indicative of a lower quality of care.
Low Density Lipoprotein (LDL) measurement is defined as a quantitative assay of serum LDL that has been performed at a facility that meets CLIA (Clinical Laboratory Improvement Amendments) standards. This may be performed as part of a fasting lipid test or a non-fasting test. The value for LDL may be calculated or direct. The standard of care by national standards organizations (HEDIS 2000) for performing this test is a yearly examination. The interpretation of this Quality of Care Measure is that any qualifying exam performed within a 12-month period is indicative of a higher quality of care. Any examination not performed within a 12-month period is indicative of a lower quality of care.

The frequency of HbA1c measurements is dependent upon the type and severity of diabetes. Type 1 Diabetics are insulin-dependent and ketosis prone. The frequency of performing HbA1c in this population is cited by the American Diabetes Association Clinical Practice Recommendations (2001) as at least twice a year. More frequent tests are done when trying to optimize glucose control. Type 2 Diabetics are non-insulin dependent and non-ketosis prone. Their standard for performing the HbA1c measurement by national standards organizations
(HEDIS 2000) is cited as at least once per year. The interpretation of this Quality of Care Measure used by this study is that any qualifying exam performed within a 12-month period is indicative of a higher quality of care. Any examination not performed within a 12-month period is indicative of a lower quality of care.

The improvement in HbA1c can be demonstrated in two ways. First, separating the HbA1c values into quartiles allows one to demonstrate changes over time among the quartiles for, "Excellent", "Good", "Fair", and "Poor" glucose control. The values for these quartiles are: HbA1c less than 7.0% is "Excellent control", HbA1c greater than or equal to 7.0% and less than 8.0% is "Good control", HbA1c greater than or equal to 8.0% and less than 9.0% is "Fair control", HbA1c greater than or equal to 9.0% is "Poor control". Percentage changes between quartiles are evidence for clinical changes in the study population.

The second method of demonstrating improvement in HbA1c is by direct measurement of HbA1c before the intercession and after the intercession. This may have two phases: an early HbA1c change as well as a later HbA1c change. The improvement or worsening of values can
be evaluated for degree of change by a standard statistical analysis.

Finally, the outcomes of a treatment intervention may be measured by the number of abnormal laboratory values that receive appropriate treatment. This would include treatment of elevated urinary Microalbumin values with an Angiotensin Converting Enzyme (ACE) inhibitor or other equivalent treatment, or treatment of elevated LDL-Cholesterol with a "statin" lipid lowering drug or other equivalent treatment. The quality of care standard is to treat the abnormal value. The interpretation of this Quality of Care Measure is that any prescription for an appropriate drug within a 12-month period is indicative of a higher quality of care, and the absence of any prescription for an appropriate drug within a 12-month period is indicative of a lower quality of care.

Diabetes Models of Care

The models of care that are used for providing medical attention to a diabetic individual or to a defined diabetic population vary widely. According to the study by Hayes and Harries (1984), they may include doing nothing (a minimalist approach) or providing one-to-one
physician contact on a daily basis (the private hired physician approach). The approach used to monitor or manage a large population must include appropriate resource allocation as well as information management. Physician extenders become mandatory with larger populations.

The role of the Diabetes Nurse Educator has grown over the past ten years as described by Wagner (1998) in the Annals of Internal Medicine. Initially, a Registered Nurse was member of the health care team whose role was to follow specific physician orders to administer medications, provide palliative care, and basic personal hygiene, as well as educate and console. Very little deviation was allowed from this traditional model of care in nursing.

However, over time, the Outpatient Clinical Nurse Educator was given protocols that gave this individual the ability to act on the doctor's behalf as an interpreter of clinical protocols for one individual patient. At this stage, the Registered Nurse could assist a diabetic patient in increasing his/her insulin dosage by a small amount only by referring to a specific written instruction written by a physician for this patient. From
this early beginning, the more complex protocols of today developed.

As other medications became available for the treatment of diabetes, the existing nursing protocols became more complex. Policies and Procedures that permitted changes in classes of drugs as well as permitted adding new drugs to an existing regimen all the while being closely mentored by a physician who remained responsible for prescribing the individual medications.

The more complex medical regimens lead to more sophisticated monitoring of drug reactions. The nurses were given additional Policies and Procedures that permitted them to stop medications, order appropriate blood tests, then restart the same medication if the testing was negative.

This expanded role of the clinical diabetes practitioner has lead to the development of the Certified Diabetes Educator (CDE) certification. Skill in assessing difficult situations as well as recognizing clinical scenario became a foundation of the job of Clinical Diabetes Nurse Educator. These nurses assess compliance, determine the degree of diabetes control, change treatment parameters, and follow up on complications and
problems that fall within their clinical nursing Scope of Practice.

The present model of care for our diabetic members at the Kaiser Permanente Medical Center in Fontana had evolved to the point that Registered Nurses and Registered Dietitians teach all of the diabetes classes in our clinic. The Nurse Care Manager triages phone calls and manages medication changes by phone with approval of the Physician mentor. The Nurse Care Manager reviews abnormal laboratory values and discusses medication changes with the Diabetes Specialist. The Clinical Diabetes Nurses interact individually with their patients and teach the most effective ways of maintaining excellent glucose control. They also start new diabetes medications based upon strict diabetes management protocols.

Primary Care Physicians have indicated that they would prefer to have the Fontana Diabetes Clinic (together with Dr. Hess, the Endocrinologist) manage their diabetic patients. The clinic has been able to order appropriate laboratory tests on active patients and monitor the results of those tests. Abnormal values are communicated back to the primary physician for treatment.
or further study. Diabetes medications are optimized and glucose control improved under strict protocols. Follow-up appointments are made at the Fontana Medical Center in order to maximize the use of the nurses’ time.

Eventually, it became evident that the Kaiser Health Plan members that did not improve over time were the members who did not show up for appointments and did not respond to phone calls and letters. Many of these members were assigned to physicians in the outlying medical offices as far away as Pomona and Victorville, California. There had to be a way to place a highly trained Diabetes Nurse Educator in the outlying medical offices such that the quality of care issue brought to light by having poorly controlled diabetic members could be addressed in an effective manner. This study describes one such model of care and attempts to define the characteristics that make this model of care so effective.

Care Management

Care Management has been described by the SCPMG Diabetes Outcome Report (2000) as “Improving the health of a population one member at a time.” It applies the
knowledge and science of Public Health to a chronic disease arena. The critical steps as stated in the article by Gurnee and Da Silva (1997) for applying Care Management to a large population include 1) Identifying the at-risk population, 2) Stratifying the population by acuity, 3) Tracking and monitoring interventions upon the population, 4) Developing and implementing Clinical Practice Guidelines, 5) Creating new, proactive interventions (both outreach and inreach), 6) Coordinating care among various individuals, 7) Measuring outcomes, and 8) Continuously improving the quality of care.

Defining an at-risk population is one of the first steps in Care Management. For diabetes, this is accomplished by the Southern California Permanent Diabetes Registry Database. Fontana patients are a subset of that database, and all efforts are measured through that database. National quality standards for diabetes care, such as HEDIS (2000) are tracked through this database as well as through others.

Risk Stratification is a method by which the sickest patients or the most at-risk patients are identified and categorized by their likelihood of developing significant
illness or requiring significant intervention. This is most often performed by examining the medical record and developing an algorithm for ranking individual clinical characteristics, such as laboratory results, frequency of hospitalization, and concurrent illnesses. A value is then applied to this ranking, thus allowing comparison among the members of the at-risk populations.

Tracking interventions that are subsequently performed upon the population then becomes the focus of the Care Manager. This requires access to quantifiable clinical data that impacts the overall health of the study population. The goal is to improve the overall health and move as many people as possible from high risk to lower risk categories.

Clinical practice guidelines (CPG) are the tools for moving a large clinical population from higher to lower risk. The Physicians and Care Managers both try to deliver the highest quality care to those people they serve. Having a standard by which to measure that care is critical to day-to-day treatment, as well as to improving future treatment.

Outreach is an important component of care management. This requires identification of people at
need for extra care. Outreach may take the form of a letter or phone call. Newsletters and flyers are used to address large numbers of at-risk individuals. Whatever the means of communication, the goal is to provide better diabetes care and, therefore, improve clinical outcomes. Computers, as proposed by Peters and Davidson (1998), have improved outreach programs significantly. Targeting a population identified in the outreach process allows intervention with the people at highest risk. The method or encounter may be done one-to-one, small group, large group, or classroom. Contact by phone, E-mail, or fax may be sufficient in some cases.

Inreach involves the same technique applied to at-risk individuals already, involved in an intervention program. Some of their needs may be already met by their medical care system; but there are always gaps in care that must be identified, addressed, and treated.

Following the initial Care Manager contact, there must be a way to identify the patient receiving care management in order to affect long-term survival, such as in the study by Verlato, Muggeo, Bonora, Corbellini, Bressan, and de Marco, (1996). This assists the follow up and patient tracking process. This also makes information
available to other care managers in order to avoid duplication of effort. This ability to track a patient makes possible the evaluation of the care managing process and coordinate care among various providers.

Care Managers use tools to remind patients to perform required laboratory testing. These tools improve the delivery of care and facilitate compliance with national healthcare standards such as HEDIS (2000). The Clinical Information Systems (CIS) makes it possible to access many forms of data simultaneously, including pharmacy data, laboratory data, demographic data, and hospitalization data. This information set ultimately becomes part of the reporting set to employer groups and the National Committee for Quality Assurance.

Finally, the techniques of Continuous Quality Improvement (CQI) have crucial bearing upon the field of medical care. The work of Dalzell (1998) shows that feedback of data to care providers becomes essential. Giving providers a yardstick against which they may measure their own efforts provides a means for striving to improve the standards of care. Those who exceed the standard should be recognized and rewarded for their efforts. Those who under-perform the standard have the
opportunity of learning from their peers. Over time, as observed by MacKinnon, (1990), the health of the population will improve to an optimum point possible with existing resources. Study of the population also promises to demonstrate how to best utilize those resources. The best measure of quality improvement is a healthy patient.

Clinical Information Systems

Clinical Information Systems (CIS) serve several purposes. First, they must access legacy systems that store individual demographic data, clinical medical data, laboratory data, hospitalization data, and intervention data. Second, they must link the databases served by the legacy systems in order to permit "data mining" for clinical purposes. Third, these linked systems permit the formation of data registries that hold the key to identifying at-risk populations. Fourth, the at-risk population may be stratified through the use of clinical data, and this data used as an outreach, as well as inreach, information tool. Fifth, patient tracking and monitoring involves a separate tool that has been brought down to the provider level. Sixth, a measurement and communication tool has to be developed in order to
disseminate Clinical Quality Information to the appropriate medical provider.

Legacy systems, such as those described by Shea, Du Mouchel, and Bahamonde (1996), often share the attributes of incompatibility and lack of data standardization. Assuring that the data obtained from these systems matches the needs of the clinical care provider is a difficult undertaking. This is due to the fact that one is extracting data not initially intended for this ultimate purpose. For example, hospitalization data has traditionally been collected for use by the hospital. Obtaining this data often requires a thorough understand of five to ten separate data formats and programming languages.

Linking incompatible databases often requires setting up yet another database that stores merged data. This requires frequent updating of information and may introduce a source of error. This requires that data be analyzed before releasing it for use by the care provider.

Data registries, such as those of Baker et al. (2001) at the Mayo Clinic, are the result of analyzing clinical date on an identified population. The population
can be categorized by the presence or absence of a clinical condition, such as diabetes. This is done through the use of identifiable characteristics, such as blood glucose values. These clinical data registries form the basis of all monitoring, tracking, and interventions. This data is frequently used by National Quality of Care organizations, purchaser groups, as well as by the providers in the medical organization.

Risk stratification identifies the characteristics of group members at-risk for significant mobility or mortality. This helps to provide a continuum over which the entire population may be placed. These data form the basis of outreach and inreach initiatives. This also allows for the placement of scarce resources where they will have the most impact on the population.

Care providers will see only a portion of the overall data as it applies to their individual patient population. The ability to track the improvements in health of any individual holds the potential to raise the standard of health of the entire population. Each provider can monitor normal and abnormal laboratory values on his/her patients and subsequently provide an intervention that will move their patient closer to
optimum health status. Using a patient tracking system acts as a behavior modifier for the provider and as a motivator to continuously improve care.

Finally, the outcomes of this clinical intervention must be collected, analyzed, and reported. The provider must be able to see the result of his/her work. The Care Managers, such as those in the Weinberger et al., (1995) study must be able to assess the efficiency of their interventions with the populations. The clinical quality managers must be able to spot trends that would detract from care and that would improve care in used more widely. Patients should witness their own health improvements, and the purchasers of health care should see that their health care premiums are well spent. The national quality standards organizations also hope to identify best practices among health care organizations for the purpose of disseminating the most useful health care practice models.

Tracking Care Improvement

Quantifiable outcomes are necessary for evaluating any medical intervention. These outcomes may be measured by frequency of hospitalization or mortality. However,
these are considered to be very long-term outcomes. Intermediate outcomes need to be developed in order to assess progress towards long-term outcomes. That is why surrogate outcomes are used to model the health status of an at-risk population group.

Hemoglobin Alc is a measure of glucose control over a three months period of time. However, it is used to model the health of a diabetic population since it is directly correlated to the incidence of chronic diabetic complications. In the DCCT trial of 1993, the incidence of new Diabetic Retinopathy was reduced by 76%. The incidence of new Diabetic Nephropathy was reached by 50%, and new Diabetic Neuropathy was reduced by 60% in a population composed of Type 1 Diabetics. The UKPDS study of 1998 showed that improved glucose control reduced the risk of requiring Retinal Photocoagulation by 25%, and the risk of Myocardial Infarction (MI) by 16% in a Type 2 Diabetic population. This has significant clinical impact upon the entire diabetic population and is often cited as a reason to promote Diabetes Care Management.

Performing the Diabetic Retinal Screening Examination at regular intervals permits the detection of treatable stages of Diabetic Retinopathy. Early treatment
will generally delay the progression to blindness that results from this disease. Therefore, it is used to assess the degree of care in a diabetic population. In addition to lessening the risk of permanent blindness, the documented Retinal Screening Exam permits outside reviewers, such as NCQA, an assessment tool in documenting the care processes of a health care organization.

Urinary Microalbumin is a critical tool for assessing the presence of Diabetic Nephropathy in a diabetic population. It also tracks the progression of this disease over time. Once proper treatment is initiated for Diabetic Nephropathy, the urinary Microalbumin is used to assess the efficacy of the treatment intervention. Lack of monitoring of this marker for chronic complications demonstrates poor surveillance techniques for an at-risk population. Producing a list of untested individuals permits a Primary Care Physician (PCP) or Care Manager (CM) the means for scheduling and performing the proper testing. This list also forms the basis of one arm of the outreach program by identifying under-served individuals in the population.
Monitoring LDL-Cholesterol is a much more global marker for overall health outcomes since over 75% of people with diabetes ultimately expire from atherosclerotic disease complications. Improvement in LDL-Cholesterol values tracks the improvement in cardiovascular risk. The use of pharmaceutical interventions in this population promises to significantly impact the mortality figures for Coronary Artery Disease in this population. Following up on treatment is one method by which the care manager impacts the overall health of the population that is being followed. The importance of tracking care improvement is essential to the mission of a preventive care organization.

Compliance/Adherence

Adherence to any medical regimen is important in determining the outcome of treatment. In Gurnee and Da Silva’s 1997 article on constructing disease management programs, the regimen that is adhered to the best will have the greatest effect on the health of the population under study. Several factors that determine adherence are: simplicity, clarity, relevance,
accessibility, and reinforcement. Other factors include: age, maturity, and educational level. However, these factors are less modifiable than those previously mentioned.

Education is necessary to elicit compliance when the tasks involved are either complex or do not show obvious connection to readily perceptible consequences. Diabetes self-care is not particularly complex, as Peters and Davidson discuss in their 1995 article. However, the general population of the United States of America continues to move further away from good health principles in its diet and activity regimen. We are becoming grossly overweight and in poor physical condition. Efforts must be undertaken to prevent this decline in our community health. Studies published by the American Diabetes Association, referred to in Diabetes Mellitus (1999) have shown the connection between poor eating habits, increasing weight, decreasing activity, and the onset of chronic conditions such as Diabetes Mellitus. Many people with this diagnosis are in denial of the seriousness of their disease. This is evidenced by the increased profitability of herbal remedies that purport to improve, and even cure hypertension, diabetes,
and heart disease. However, the failure of alternative treatment eventually leads to complications and even death. This is an inescapable truth that needs repeating.

The explanation of simple concepts is important but time-consuming. Many Physicians lack the time needed to adequately address the issues and educational needs of their diabetic patients. That is why diabetes educators, such as in the study by Weinberger et al. (1995), are a necessary part of the diabetes treatment team. Patients tend to comply with what they understand best. The simplest explanation is often considered the best. Bringing the message down to the proper grade level often makes it more accessible to the listener. Language is another barrier to learning that must be overcome by a skilled instructor. That is a compelling reason to have a diverse staff working in the Department of Preventive Medicine.

Making this topic relevant is an important tool in achieving adherence to a self-care regimen. Everyone has a unique background and comes from a unique environment. The ability to address a group of people and individualize the experience for each person is a considerable task. Diabetes educators are trained to
facilitate learning by finding common experiences in a group of individuals and extracting relevant information that assists the learning process for the entire group. The location at which the care is provided should be convenient to the individuals being treated. The further away the facilities of care the more likely that members of the target population will be missed by the planned intervention. The clinic where the member has a Primary Care Physician and where the member obtains the majority of his/her care is the ideal location for a highly successful intervention.

Repetition aids learning and provides positive reinforcement. Patients appreciate the concern demonstrated by a return phone call. This simple intervention permits the care manager to keep closer tabs on the individuals that are followed and address any concerns that could have otherwise hindered appropriate care.

Authority Figures in Medical Studies

Studies completed in the 1960’s by Stanley Milgram (Obedience to Authority, 1974) demonstrate that people are prone to obey those in authority even under extreme
circumstances. This is evident when one experiences the "white coat mystique" upon entering the doctor's offices. Physicians have long been considered authority figures by the public and by those that work alongside them. The public is much more likely to obey a medical recommendation if it is reinforced by a "Doctor" than if it were recommended by another ancillary medical personnel. This effect is perceptible even when actors portray physicians on television commercials.

The use of a Physician in emphasizing the need for a lifestyle change can make the difference between adherence and non-adherence. This effect is amplified if the Physician is the same Primary Care Provider who has already established a relationship with this patient.

The Physician as authority figure also provides a source for enforcing logical consequences with the patient. Many people will cooperate with a treatment plan so that they do not disappoint their family doctor. The physical presence of this Physician in the examination room emphasizes the importance of the issues addressed by the treating Clinical Nurse Educator. People perceive a greater value in an appointment in which their own Doctor has made an appearance.
The presence of a Physician in a group setting makes the patient more confident that the information being given is medically correct. There is now a central figure that can take responsibility for the care being provided to the members of the group. The Physician is seen as the coordinator and ultimate provider of any intervention made during this appointment, even if the intervention was made at the recommendation of the Clinical Nurse Educator.

Time and Place Utility

As was previously stated, the location for delivering care may be determining factor between adherence and non-adherence. Any study of care delivery and models of care must look at the most appropriate location for that care, as was reported by Hayes in 1984. If traditional care was held in a centralized location, then non-traditional care must look elsewhere if access to care is a critical factor. The location may be within a few miles of the home itself. House calls may be done in person, over the phone, or over the World Wide Web. There does not seem to be any means of communication that
is considered to be too convenient. Both time and place must be considered in planning an intervention.

In a population that may be hampered by transportation-related issues, both time and place utility come up as critical factors in providing appropriate care. If the initial appointment was successful in obtaining the cooperation of the patient in his/her own care, then the follow-up contact has to be equally as appropriate in time and place. This is the obvious scenario for phone contact. The patient has already encountered the Clinical Nurse Educator in the clinic setting with their Primary Care Doctor as the initiator. A relationship of trust has been developed between the patient and the nurse. Now, reinforcement of the educational objectives may be accomplished at one’s leisure by phone, and the nurse is free to suggest other changes to follow the successful changes made previously. This is the ultimate goal of the Care Manager, that the patient be the main focus of the care management program and that the process of Care Management be the transfer of information by means of telecommunications. This allows the Care Manager sufficient time to assist many individuals in a single workday.
Group Dynamics

The manner in which care is delivered is as important as the location of its delivery. The Group Medication Model is successful not only due to its ability to reach more people, but due to its ability to facilitate interpersonal interaction. People are social beings. This concept was explored by Ho et al., (1997) when examining the model of care delivery at the centralized diabetes clinic. Their behavior is changed when they go out in public. Opinions are often formed by group norms. The use of a group for the purposes of teaching lifestyle changes goes back to prior to recorded history. The dynamics of group interaction plays a pivotal role in shaping human behavior.

People frequently assume well-defined roles when interacting as a group. One or more individuals are seen as leading the group. Others are seen as active participants, others as passive participants. If the leader has sufficient skills then most other participants should see themselves as active group members. Well-run groups participate fully in the educational process by asking questions and assisting others in the group to understand the responses. Ideally a diverse group will
have answers to Frequently Asked Questions among the participants. People are naturally curious as to the insights of other group members. This allows those members who ask the questions to see that others likely share their opinions. When some individuals in a group show enthusiasm for the message being taught, the passive participants tend to show consensus with the group norm. People that would otherwise be slow in accepting a message may quickly accept the message in order to be perceived as part of a group. Therefore, group messages tend to be effective if the majority of the group members embrace the message.

Group appointments also tend to discourage disruptive behavior. Disruptive group members can always be invited to an individual appointment or be asked to discuss their concerns after the session has ended. The group facilitator must be well versed in group teaching skills. That is why sufficient time must be given to the facilitator of the group for developing rapport with the multiple group members.
CHAPTER THREE

REPORTING OF FINDINGS

Restatement of the Problem

For many years, Primary Care Physicians have had little time to spend instructing their own patients on the correct manner for taking care of one's diabetes. This shortened period of time meant that some of the complex needs of patients with diabetes were not being met in brief problem-oriented office visits. This led to the creation of specialized diabetes clinics, such as those described by Ho et al., (1997) that brought together the personnel and resources needed to meet the needs of those diabetic patients. This exact model for a centralized diabetes care clinic exists presently in the Fontana Service Area of the Kaiser Permanente Health Care System.

However, this trend raised concerns among Primary Care Practitioners in Britain, with the publication of studies by Farmer (1990), Koperski (1992), and Pringle Ward, and Chilvers (1993), where a Primary Care Model exists within a socialized medical structure. There was sufficient impetus to create a series of chronic disease
“mini clinics” that attempted to incorporate the teaching and specialized care of the centralized diabetes clinic model into the realm and domain of the Primary Care Provider.

These “mini clinics” were comprised of patients all with a specific disease entity into a specially designed visit with a team approach to care. These clinics met at regular intervals and were shown to improve glycemic control and reduce hospitalizations.

The present study incorporates yet another care design that was not feasible 15 years ago. The Diabetes Nurse Care Manager has been trained to evaluate and assess the physical, social, and medical needs of individual patients as well as at-risk diabetic populations. Through the use of computerized case-finding tools and electronic database management techniques, the Diabetes Nurse Care Manager identifies, and then follows, an at-risk population for trends in each individual’s care. This job entails scheduling office visits, laboratory testing, ophthalmology visits, and monitoring changes in glucose control, in much the same way as the study nurses acted in Wagner’s study published April of this year. The nurse intervenes with letters, office
visits, phone calls. The Diabetes Nurse follows a strict protocol for changing medication dosages as well as for adding or starting new diabetic medications. The frequency of this intervention depends upon the severity of the illness. The recording of clinical data, as well as the analysis of that data is an important part of the role of the Care Manager. This Quality of Care (QC) data allows each Diabetes Nurse Care Manager to determine the impact he/she had on the diabetes population being followed. This study is the report of the first two (2) Diabetes Primary Care Group Visit Model clinics held in Colton, California and Victorville, California during the year 2001.

Scope and Limitations

This study is being conducted entirely with members of the Kaiser Health Plan that are managed by the Southern California Permanente Medical Group (SCPMG). Founded in 1945, Kaiser Permanente is the nation’s largest nonprofit health plan serving 8.2 million members. There are over 3 million lives (3,052,644) covered by the Kaiser-Permanente Health Care System in Southern California as stated on the Kaiser-Permanente
Intranet site (accessed September 27, 2001). In the Fontana Medical Service Area there are approximately 371,000 active members. Of this number there are 15,482 individuals (4.2 percent) identified as having Diabetes Mellitus. A nonrandomized longitudinal study was conducted on a subset of this population being followed in the Outlying Medical Offices of Colton and Victorville in the Fontana Medical Service Area.

All participants are over 18 years of age and have been Kaiser Health Plan members continuously for one year preceding enrollment in this study. The patients being studied had been chosen through the use of a computerized relational database tool (POINT) that derives diabetes data from Laboratory, Pharmacy, Hospital, Emergency Department, Outpatient Department, and Demographic Administrative databases to form an automated Diabetes Registry. The principle criterion for inclusion in this study was an HbA1c value of 8.9 and greater. Lists of the at-risk diabetic population were created for each participating physician in the Outlying Medical Offices listed above. The nurses created lists only for those physicians that wished to participate in a shared-practice group visit model of care in which a
Diabetes Nurse Care Manager helped that Physician manage a higher-risk subset of his/her diabetic population. There is insufficient evidence to note whether cooperative physicians have better or worse outcomes with their diabetic patients. Therefore, this population must be considered to be a nonrandomized sample.

The patients that participated in this shared-practice model had agreed to come to at least one physician visit during which the Diabetes Nurse Care Manager explained his/her role and limitations. He/she would also discuss general Diabetes Care Guidelines with the participating members. This would lead to some degree of bias towards ambulatory patients or patients with available transportation. Patients with good family or community resources tend to do better in their diabetes care than do those patients who do not have these resources.

The model of care described in this study is in addition to the presently available centralized model of care utilized in the Fontana Medical Center Diabetes Care Program. There are two (2) Physicians, seven (7) Registered Nurse Diabetes Educators, one (1) Registered Nurse Practitioner, six (6) Registered Dietician Health
Educators, four (4) Health Education Specialists, two (2) Ph.D. Public Health (Doctors of Health Science, one pending dissertation), and one Department Administrator Ph.D. Public Health currently full or part time. All Kaiser Health Plan members may access the Diabetes Care Clinic by self-referral or provider referral. The combination of classes, groups, and individual appointments provided at the Fontana Medical Center would be the alternate care provided to those who chose not to participate in the study. All nonstudy participants are derived from the diabetic population at large in the Fontana Service Area.

Finally, the choice of selecting a range of Hemoglobin A1c from 8.9 and above to represent a higher-risk group was arbitrarily based upon HEDIS 2000 measures demonstrating poor vs. acceptable control for diabetic Health Plan members whose Hemoglobin A1c was at-risk for exceeding 9.5%.

Sampling Plan

A Care Management tool (POINT) developed by Pharmacy Operations within Kaiser-Permanente was used to develop the Intervention Population that was followed by the
Diabetes Nurse Care Manager. This database system allows queries to be undertaken on a Southern California Region-wide Diabetes Registry. The Medical Center’s and the individual Physician’s diabetes panel were easily identified using this tool. A list of those patients > 18 years of age with a Hemoglobin A1c > 8.9% were presented to their Primary Care Physician for approval. Each Physician was given the opportunity to exclude patients due to unsuitability to a group format. If approved, these patients were contacted by phone and/or letter asking them to participate in a two-hour doctor’s visit in which several individuals will address their diabetes questions. It is at this point that some individuals were excluded by refusal, educational barrier, or language barrier. Approximately 45% of all invited patients never attended a single clinic session. These individuals were offered one-to-one counseling and management by a culturally appropriate Physician or Nurse Educator.

The number of participants attending a group visit appointment was often 8-12 patients. When the group of selected members met with the Diabetes Nurse Care Manager and their Primary Physician, they received a psychoeducational intervention followed by a review of
their medical treatment and pertinent laboratory testing. Those patients that needed any changes in medication got those changes made on the spot. Pertinent laboratory tests were ordered and performed the same day. The Diabetes Nurse Care Manager was responsible for informing his/her patients of the results of their tests and maintaining phone and letter contact with his/her patient population for at least one-year. However, for the purpose of this study, each patient population was studied for six months prior to their intervention as well as six months after their intervention.

The data collected on each patient by each nurse at every intervention was recorded in a clinical diabetes database that served as an Electronic Health Record (EHR). Further data for this study were available on legacy mainframe computers that compile administrative data, as well as demographic, laboratory, pharmacy, and hospitalization data for the members of the Kaiser Health Plan.

This has been an ongoing project of the Preventive Medicine Department in Fontana even before the initiation of the present study. This study was a nonrandomized, longitudinal, statistical monitoring study that falls
into the category of causal-comparative research design. Therefore the intervention group was not subject to investigator bias because this investigator had no input into patient selection.

Methods and Procedures

The population already discussed has been followed for improvement in their Surrogate Care Parameters (Frequency of performing HbA1c, MA, and LDL-Cholesterol) as a measure of quality of care. During the course of the study any changes in these parameters have been attributed to the Nurse Care Manager intervention as these patients were receiving routine care prior to their intervention. In addition, all participants have been continuously enrolled in the Kaiser Health Plan for the one-year preceding this study thus allowing direct comparisons to take place from within as well as from without this study population.

This data has been extracted from the Electronic Health Record (FileMaker Pro 4.0) used by the Diabetes Nurse Care Manager for recording all routine interventions in the Preventive Medicine Department including those interventions performed on the study
population. The study group used a specific code for the purpose of separate identification. However, no Care Manager was instructed to give either better or worse care to this group. The Standard of Care was to be the same degree of excellence given all our patients. This also allowed direct comparisons to take place from within as well as from without this study population.

Other sources of data include the POINT Care Management System, the legacy demographic and laboratory databases, as well as the Diabetes Outcome Reports from the Southern California Permanente Medical Group. The data was analyzed with Excel functions and analysis tools as well as with Statistical Package for the Social Sciences (SPSS). These also formed the basis for the charts and graphs used within this study.

Data Analysis

In order to demonstrate statistically significant changes at baseline in Hemoglobin A1c frequency, Urinary Microalbumin frequency, LDL-Cholesterol frequency, as well as changes in HbA1c values; we report simple means or proportions with P-values from an unadjusted mixed model analysis to compare the control and intervention
groups. To control for the patient’s expected likelihood of receiving the routine care and screening tests, these patients are being compared to their own previous lab values prior to the Care Management intervention.

Additional data was collected on the frequency of performing yearly Diabetic Retinal Screening Examinations. This data was compared to regional averages within the Kaiser-Permanente Health Care system as well as to national averages for other health care plans. That data is available through the National Committee for Quality Assurance website (HEDIS, 2000).

Data on the presence of abnormal urinary Microalbumin and abnormal LDL-Cholesterol were obtained through the POINT Care Management tool. This data tool also provided information on whether each patient had received pharmaceutical treatment for his or her clinical laboratory abnormality. That data was also compared with other Kaiser regions outside of Southern California by the use of the same statistical methods.

Results

There were a total of 91 participants in the study that attended the two-hour session with the Diabetes
Nurse Care Manager and their Primary Care Physician. This population consisted of 46 males and 45 females. There were 55 participants from the High Desert Medical Office in Victorville and 36 participants from the Colton Medical Offices. Their average age was 56.2 ± 11.2 years. The range was from 33 to 84 years of age. No participants were lost due to mortality. When examined for the co-morbidities of Congestive Heart Failure, Renal Disease, or Coronary Artery Disease; there were fourteen (14) participants with one co-morbidity, three (3) participants with two co-morbidities, and one (1) participant with three co-morbidities.

Table 1 shows the outcomes of the care intervention at three and six months. The average Hemoglobin A1c at baseline was 10.34 ± 1.33%. This illustrates the poor control of the target population. The average Hemoglobin A1c at three months post intervention was 8.34 ± 1.61%. This illustrates an improvement from the baseline value in the short term. The average Hemoglobin A1c at six months post intervention was 8.09 ± 1.52%. This value illustrates improvement from the baseline in the longer term.
For illustrating compliance/adherence the frequency of performing a Hemoglobin Alc during the study period was evaluated. This value was 86.81% compared with a Southern California Regional average of 81.25% during a similar period. Similar data from the National Committee for Quality Assurance (HEDIS 2000) shows that Health Plans from across the United States averaged 75.07 + 11.50%. Although this figure appears better than the regional comparison figure, no statement can be made about significance in the above cases.

The frequency of Retinal Screening Examinations, Urinary Microalbumin measurements, and LDL-Cholesterol measurements illustrates the surrogate measures of Quality of Care for this population. These are the same measures used by national Quality Assurance organizations for ranking Managed Care Organizations. The frequency of Retinal Screening Examinations within a one-year period was 81.32% for the study group. The national data from the HEDIS data set of NCQA gives a value of 45.30 + 15.00%. The frequency of Urinary Microalbumin screening was 93.41% for the study group and 36.08 + 14.38% for the HEDIS data set of NCQA. The frequency of LDL-Cholesterol
Screening was 96.70% for the study group and 69.09 + 11.15% for the HEDIS data set of NCQA.

Table 2 illustrates the changes in glucose control of the study group during the three and six month follow-up periods in this intervention. The bar graphs are skewed to the left (corresponding to poor control) in the baseline (pre-intervention) chart due to the nature of the study model that pre-selected for poorly controlled at-risk diabetics with a HbA1c of 8.9% and above in order to qualify for this study. The subsequent three-month and six-month post intervention bar graphs illustrate the profound change between the statistical quartiles for Poor, Fair, Good, and Excellent glucose control occurring over time.

Tables 3, 4, and 5 focus upon the intent to treat section of the study. There were 85 study participants that performed a Urinary Microalbumin within a one-year period around the study dates. Of this number, there were 44 confirmed positive Microalbumin measurements and 41 confirmed negative measurements. 88.63% of the positive group received appropriate treatment for their Microalbumin. Southern California Regional values for
Microalbumin treatment are 77.35 + 2.78% in an unselected diabetic population.

There were 88 study participants that performed an LDL-Cholesterol measurement within a one-year period around the study dates. Of this number, 62 were confirmed positive for abnormal LDL-Cholesterol using the Regional Guideline of > 130 mg/dl. 72.58% of the positive group received appropriate treatment for their Cholesterol abnormality. This compares with 77.59 + 8.39% in an unselected diabetic population in the Southern California Region.

There were 74 study participants that performed a Screening Retinal Examination within a one-year period around the study dates. These studies were reviewed by an Ophthalmologist to determine the course of treatment. 81.32% of the study population received this evaluation. National statistics from the HEDIS data set of NCQA gives a comparison of 45.30 + 15.00% in an unselected national diabetic population.

The above data appears to support the hypothesis that the introduction of the Diabetes Nurse Care Managers into the Outlying Medical Offices has had a positive effect on the care delivered to an at-risk diabetic
population selected for poor glucose control. These finding will impact the decision to continue and to increase the use of this model of care within our healthcare system.
Conclusions

Analyses of effective models of care for diabetes and other chronic diseases suggest that the design of practice plays an important role in their success. The design of the practice refers to the delegation of roles within the practice team, the involvement of other disciplines, the organization of visits and follow-up, and the integration of psychoeducational interventions. Efforts to redesign primary care to improve outcomes in diabetes have varied widely in approach. The interventions include increased involvement of nonphysician providers (usually nurses or nurse practitioners), or changing the design of visits or the handling of follow-up. An early approach was the establishment of a periodic mini-clinic in primary care as described in the British Studies.

We chose to test the effectiveness of chronic care clinics (mini-clinics) with relatively unselected primary care practices and diabetic patients in an HMO, as opposed to limiting the intervention to volunteer
practices and highly motivated patients, in an attempt to assess its practicality and effectiveness as a system change strategy. Because potential study patients were selected at random, not by virtue of their interest in participating, we had to make compromises in the completeness of the baseline data to assure high rates of participation.

The intention-to-treat analysis findings suggest that participation in Diabetes Nurse Care Manager clinics resulted in improved processes of care and somewhat better health. All measures of the process of diabetes care were better in the intervention group than in the control group, and many reached statistical significance.

Whereas chronic care clinics, as described by Wagner, Austin, and Von Korff (1996), relied on existing clinic personnel to deliver services, Diabetes Care Management nurse played an important role in the present study that must be considered when estimating the full cost of the intervention. A Diabetes Care Management nurse handled most of the Group Appointment clinic organizational tasks, i.e., scheduling time, space, and patients; organizing patient assessments and treatment planning; and planning the group session. Our initial
plan was to have the study staff gradually turn most of these responsibilities over to practice staff, but this training takes time and resources that were unavailable at that time. Ultimately, several practices took on these responsibilities. We suspect that the impact of mini-clinics on clinical and health outcomes would have been much greater if practice nurses had sufficient time and training to provide clinical case management as described in the work of the British Physicians. This may explain the modest effects of chronic care clinics on HbAlc and other health status indicators.

This study provides evidence that relatively unselected primary care practices can be reorganized to provide better care for patients with chronic illnesses in a system with other enhancements, such as registries and guidelines. A related model, the cooperative health care clinic (31), has been shown to improve outcomes in diabetic patients (32). The diabetes cooperative health care clinics differed from the chronic care clinics in that they were led by a diabetes nurse educator, they did not involve the primary care team, and they conducted most of their assessment, education, and other activities in a group setting (32). Bringing groups of chronically
ill patients into special primary care sessions designed to meet their clinical, educational, and psychosocial needs appears to be a feasible and effective way of improving their care.
Table 1. Outcomes of Care Intervention at Baseline, 3 Months, and 6 Months

<p>| | |</p>
<table>
<thead>
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<tr>
<td>Average Age (years)</td>
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<td>3</td>
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<td>Ave. HbA1c (Pre-Intervention)</td>
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<tr>
<td>Ave. HbA1c (3 Months)</td>
<td>8.34 ± 1.61</td>
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<td>Ave. HbA1c (6 Months)</td>
<td>8.09 ± 1.52</td>
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<td># Having at least 1 HbA1c</td>
<td>79 (86.81%)</td>
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<td># Having at least 2 HbA1c</td>
<td>27 (27.67%)</td>
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<tr>
<td># With Eye Exam W/l 1 Year</td>
<td>74 (81.31%)</td>
</tr>
<tr>
<td># With Urine MA W/l 1 Year</td>
<td>85 (93.41%)</td>
</tr>
<tr>
<td># With LDL-Chol W/l 1 Year</td>
<td>88 (96.70%)</td>
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</table>
Table 2. Change in Glucose Control During the Study Period.

**Pre-Intervention**

- Poor: 82
- Fair: 9
- Good: 0
- Excellent: 0

**Glucose Control**

**3 Months Intervention**

- Poor: 24
- Fair: 20
- Good: 16
- Excellent: 14

**Glucose Control**

**6 Months Intervention**

- Poor: 9
- Fair: 12
- Good: 7
- Excellent: 7

**Glucose Control**
Table 3. Treatment of Abnormal Microalbumin

N = 85 Having Urinary MA Performed within 1 Year

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<tr>
<th>Study Group</th>
<th>Control Group</th>
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<td>77.35 ± 2.78% Southern California Region</td>
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<td>44 Measured Not Treated</td>
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Table 4. Treatment of Abnormal LDL-Cholesterol.

N = 88 Having LDL-Cholesterol Performed within 1 Year.

77 + If using LDL Cutoff > 100 mg/dl
62 + If using LDL Cutoff > 130 mg/dl

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<thead>
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<tr>
<td>Study Group</td>
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<td>45 Treated (72.58%) and (27.42%)</td>
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<td>62 Measured Not Treated</td>
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Table 5. Frequency of Retinal Eye Examination and Evaluation.

N = 74 Having Eye Screening and Evaluation within one Year.

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<th>Study Group</th>
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<td>44.1 + 7.48% Southern California Region</td>
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<td>91 Population Not Treated</td>
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Article 2. Scope of Regulation
2725. Legislative Declaration; Practice of Nursing; Functions

(a) In amending this section at the 1973-1974 session, the Legislature recognizes that nursing is a dynamic field, the practice of which is continually evolving to include more sophisticated patient care activities. It is the intent of the Legislature in amending this section at the 1973-1974 session to provide clear legal authority for functions and procedures that have common acceptance and usage. It is the legislative intent also to recognize the existence of overlapping functions between physicians and registered nurses and to permit additional sharing of functions within organized health care systems that provide for collaboration between physicians and registered nurses. These organized health care systems include, but are not limited to, health facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, clinics, home health agencies, physicians' offices, and public or community health services.

(b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

1. Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.
2. Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.
3. The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.
4. Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures.

(c) "Standardized procedures," as used in this section, means either of the following:

1. Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses.
(2)—Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code. The policies and protocols shall be subject to any guidelines for standardized procedures that the Division of Licensing of the Medical Board of California and the Board of Registered Nursing may jointly promulgate. If promulgated, the guidelines shall be administered by the Board of Registered Nursing.

(d)—Nothing in this section shall be construed to require approval of standardized procedures by the Division of Licensing of the Medical Board of California, or by the Board of Registered Nursing.

(Amended by Stats. 1995, c. 279 (AB 1471), § 15; Stats. 1996, c. 124 (AB 3470), § 2.)

2725.1. Dispensing Drugs or Devices; Registered Nurses; Limitations
Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon when the nurse is functioning within a licensed clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of the Health and Safety Code.

No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 3.5 (commencing with Section 4063) of Chapter 9.

(Amended by Stats. 1999, c. 83 (SB 966), § 3; Stats. 1999, c. 914 (AB 1545), § 1.)

2725.3. Health Facility; Use of Unlicensed Personnel in Lieu of Registered Nurse; Authorized Acts
(a)—A health facility licensed pursuant to subdivision (a), (b), or (f), of Section 1250 of the Health and Safety Code shall not assign unlicensed personnel to perform nursing functions in lieu of a registered nurse and may not allow unlicensed personnel to perform functions under the direct clinical supervision of a registered nurse that require a substantial amount of scientific knowledge and technical skills, including, but not limited to, any of the following:

(1)—Administration of medication.
(2)—Venipuncture or intravenous therapy.
(3)—Parenteral or tube feedings.
(4)—Invasive procedures including inserting nasogastric tubes, inserting catheters, or tracheal suctioning.
(5)—Assessment of patient condition.
(6)--Educating patients and their families concerning the patient's health care problems, including postdischarge care.
(7)--Moderate complexity laboratory tests.
(b)--This section shall not preclude any person from performing any act or function that he or she is authorized to perform pursuant to Division 2 (commencing with Section 500) or pursuant to existing statute or regulation as of July 1, 1999.
(Added by Stats. 1999, c. 945 (AB 394), § 2.)
### Exhibit 2. Raw Data Prior to Analysis.

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Verlato, G., Muggeo, M., Bonora, E., Corbellini, M., Bressan, F., & de Marco, R. (1996). Attending the diabetes center is associated with increased 5-year survival probability of diabetic patients: the Verona Diabetes Study. Diabetes Care, 19, 211-213

