Design of a nurse-run, telephone-based intervention to improve lipids in diabetics

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A B S T R A C T
This randomized, controlled trial tested the effectiveness of a nurse-run, telephone-based intervention to improve lipid control in patients with diabetes. Our patient population is predominantly low-income and Latino. Using our diabetes registry, we randomly assigned 381 patients to continue with their usual care and 381 to participate in our nurse-run program. Three registered nurses learned algorithms for diabetes care. These algorithms address management of lipids, glycemic control, blood pressure, nephropathy, aspirin use, eye screening, pneumovax and influenza vaccines, obesity, and cigarette smoking. The nurses were also trained in motivational interviewing techniques and facilitation of patient self-management. The primary goal was to improve lipid control in our diabetic population. Secondary outcomes address blood pressure control, glycemic control, renal function, and medication adherence. In addition, a cost-effective analysis is being performed. This article summarizes the design of the intervention.

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1. Introduction

Diabetes is a disease growing in epidemic portions worldwide, especially in the United States. The U.S. Census Bureau estimates that approximately 14.5 million people by the year 2010, and 17.4 million by 2020 will be diagnosed with diabetes in the United States [1]. Diabetes is a major cause of microvascular and macrovascular complications which are responsible for over $90 billion of direct/indirect costs per year. Numerous prospective interventional studies have demonstrated that the complications associated with this disease can be retarded or even prevented [2,3].

In our institution, Denver Health Medical Center (DHMC), the majority of patients with diabetes are of Latino ethnicity (59%) and a substantial minority are African-American (21%). Most of the patients enrolled in our system either have no insurance coverage or have inadequate insurance coverage. Consistent with national trends, the majority of our diabetic patients do not meet American Diabetes Association (ADA) and National Cholesterol Education Program (NCEP) guidelines [4].

A major contributing factor to the suboptimal care in diabetic patients, especially in a disadvantaged population, is access to the primary care provider. Increasing productivity demands for providers have led to larger patient panels and an average of only 15–20 min per visit. This abbreviated time period makes it difficult to adequately address the guidelines recommended by the ADA, which serve as a template for the care of the diabetic patient [5]. Recent reviews of diabetes disease management programs point to growing evidence for the benefits of nurse-run case management and targeted interventions [6,7].

In recent years there have been models of non-physician phone care that have demonstrated success in improving cardiovascular risks but have focused mainly on patients with pre-existing coronary artery disease [8–10]. A retrospective, observational study showed significant improvement in low density lipid (LDL) cholesterol levels in patients with coronary...
artery disease through contact by clinical pharmacists [11].
There is a growing but insufficient study of phone care in
diabetes. Telephone-based case management interventions
of diabetics have targeted the veteran population as well
as elderly, ethnically diverse patients [12,13]. To date, how-
ever, no study has evaluated the utilization of a nurse-run,
telephone-based intervention to improve lipid control in a
diabetic population composed mainly of minorities with no or
inadequate insurance coverage. Thus the ultimate objective of
this study is to provide a cost-effective intervention that will
improve adherence to lipid targets and potentially improve
other parameters of diabetes care.

2. Methods

2.1. IRB approval

This study was approved by the Colorado Multiple
Institutional Review Board (COMIRB) prior to implementation.
Requirement of consent was waived because i) the control
group received usual care ii) there was minimal risk to patients
in the intervention group and iii) it would have been very
challenging to conduct this study if consent was required.

2.2. Study design

Using a randomized, controlled trial design, a nurse-run,
telephone-based intervention for patients with either type I
or type II diabetes was studied. The intervention continued
for 20 months ending May 31, 2007.

2.3. Study site

The study was conducted at one of our community health
centers, Westside Family Health Center (Westside Clinic),
where 81% of the patients are of Latino ethnicity, and almost
half lack health insurance.

2.4. Inclusion/exclusion criteria

Patients were identified through the diabetes registry
(Fig. 1). We included both Type I and Type II diabetics. We
included only adult patients (>17 years old) who were
actively utilizing Westside Clinic for their primary care (at
least two visits in the past year) and who speak either English
or Spanish. We sought to maximize the generalizability of the
study and therefore had only minimal exclusion criteria:
pregnant or lactating women, patients with end-stage renal
disease (creatinine > 3.0 mg/dL), and/or a co-morbid illness
with life expectancy less than 12 months, (e.g. terminal cancer
or Child’s Class C hepatic cirrhosis).

2.5. Randomization process

The study patients were selected from Westside Clinic’s
diabetes registry, which is made up of more than 1600 patients
(Fig. 1). After limiting the registry patients to those with age
>17 years old, creatinine < 3.0 mg/dL, English or Spanish as a
primary language, and at least two visits to Westside over the
past year, 954 patients remained eligible for the study. A manual
chart review was performed to confirm the diagnosis of
diabetes and to assess for exclusion criteria. This left 839
patients eligible for the study. From the 839 patients, 762 were
randomly selected and then randomized to either receive their
usual care, or nurse case management. This approximated a
panel size of 130 patients per nurse, a manageable number
based on previous chronic disease management experience at
Denver Health. The date of randomization and study entry for
all participants was September 28, 2005.

2.6. The intervention

The telephone outreach program was considered an adjunct
to usual care. The study nurse focused on optimizing lipids
utilizing published guidelines from the most current NCEP and
ADA recommendations. In response to recent clinical trials
including the Heart Protection Study [14] and PROVE-IT [15]
an update to the 2001 NCEP guidelines suggests as a therapeutic
option, or “reasonable clinical strategy,” the goal for secondary
prevention in diabetic patients with known cardiovascular
disease (CVD) of an LDL of less than 70 mg/dL. In addition, the
ADA now recommends a statin medication for diabetics over age
40 with total cholesterol more than 135 mg/dL with the goal of
achieving a 30–40% reduction in LDL, regardless of the baseline
LDL. The LDL goal for primary prevention in diabetics remains
less than 100 mg/dL [16]. The nurses followed lipid management
algorithms based on the ADA and NCEP guidelines. The nurses
independently checked labs and initiated and titrated lipid
lowering medications (see Figs. 2 and 3 for flow diagram and
titration algorithm). The nurses used pre-printed prescriptions
signed by a physician champion, a primary care provider at the
clinic who offered educational and management support.

The nurses were also trained in algorithms addressing other
aspects of diabetes care, including management of blood
pressure, glycemic control, nephropathy, aspirin use, eye screen-
ing, pneumovax and influenza vaccines, obesity, and cigarette
smoking. The nurses addressed these non-lipid algorithms based on time constraints; the patient’s readiness for change; and input from the patient’s primary care provider (PCP). In addition, the physician champion regularly evaluated the nurses’ progress at contacting patients and achieving lipid targets to help decide whether they should pursue non-lipid algorithms.

The nurses were also trained in motivational interviewing techniques and facilitation of patient self-management. This training was conducted by a certified Diabetes Nurse Educator who attended the “Kate Lorig Self-Management of Chronic Disease” training program. Accordingly, nurses encouraged patients to independently choose self-management goals. Patients with difficulty determining a self-management goal were given a list of choices including diet (such as beverage choices, snack foods, or healthier fast food options), exercise (such as walking or discounted recreation center activities), medication adherence, and appointment attendance. Patients were asked questions like “On a scale of 1–10, how important is it to you to make this change?” as well as “On a scale of 1–10, how confident are you that you can make this change?” Follow-up questions clarified barriers to change, such as “…So you believe this change is very important but your confidence level is only a 5? Tell me more about that?” The nurses worked with patients to overcome barriers. For instance, when patients indicated financial barriers to medication adherence and appointment attendance, nurses assisted patients by i) facilitating enrollment into discount programs to make medicines and appointments more affordable and ii) recommending to the PCP and patient a switch to lower priced medicines. Or, if a patient cited adverse weather as a barrier to exercise, the nurse provided a list of discounted recreational facilities.

The nurses were trained for 10 h in a group format over a 6-week period. Each of the three nurses dedicated 25% time to this program.

The nurses interfaced with both the physician champion as well as with the patient’s PCP. The nurses met with the physician champion twice monthly for 90 min over the first 6 months of the intervention and then once monthly for 90 min for the remainder of the intervention. A document of each patient phone contact (Fig. 4) was scanned into our medical record and a copy was provided to the patient’s PCP. PCPs were encouraged to discuss any concerns with the nurses. The nurses consulted PCPs on difficult to manage patients, or approached the physician champion if the PCP was unavailable.

We estimated that each study nurse would be able to effectively manage 130 patients based on estimates of time
1) Patient more than 40 years old with total cholesterol > 135 and not on statin
   a. If LDL is already at goal (see #2, #3, and #4 for target LDL level), then start atorvastatin at 10 mg
   b. If LDL is not at goal, see #2, #3, and #4 below for appropriate atorvastatin dose
   c. If LDL not at goal on recheck, see #3 and #4 for adjustment in atorvastatin dose
   d. If LDL is at goal on recheck, is it less than 70% of original LDL level?
      i. If LDL is greater than 70% of original LDL, double the atorvastatin until reach maximum dose of 80 mg; continue to recheck per Figure 2 until LDL is less than 70% of original LDL.

2) Does patient have cardiovascular disease? Check problem list for: coronary artery disease, myocardial infarction, cardiac ischemia, angina, cerebrovascular accident, peripheral vascular disease

3) Diabetes without known cardiovascular disease (goal LDL < 100)
   a. If patient is not on statin, start atorvastatin as follows:
      i. If LDL between 100 and 150, start atorvastatin 10 mg
      ii. If LDL between 150 and 200, start atorvastatin 20 mg
      iii. If LDL more than 200, start atorvastatin 40 mg
   b. If patient is on atorvastatin, and LDL not at goal, adjust dose as follows:
      i. Check med profile to ensure adherence; work with patient on adherence if this is an issue. Otherwise, adjust as follows.
      ii. If on 10 mg, increase dose to 20 mg
      iii. If on 20 mg, increase dose to 40 mg
      iv. If on 40 mg, increase dose to 80 mg
      v. If on 80 mg and LDL not controlled, discuss with PCP

4) Diabetes with known cardiovascular disease (goal LDL < 70)
   a. If patient is not on atorvastatin, start atorvastatin as follows:
      i. If LDL between 70 and 115, start atorvastatin 10 mg
      ii. If LDL between 115 and 140, start atorvastatin 20 mg
      iii. If LDL more than 140, start atorvastatin 40 mg
   b. If patient is on atorvastatin, and LDL not at goal, adjust dose as follows:
      i. Check med profile to ensure adherence; work with patient on adherence if this is an issue. Otherwise, adjust as follows.
      ii. If on 10 mg, increase dose to 20 mg
      iii. If on 20 mg, increase dose to 40 mg
      iv. If on 40 mg, increase dose to 80 mg
      v. If on 80 mg and LDL not controlled, discuss PCP

* Substitute equivalent statin doses if alternative statin on formulary for patient

Fig. 3. Statin medication initiation and titration algorithm.

Per phone call and from previous chronic disease management experience at Denver Health.

2.7. Usual care group

Patients in the usual care or control group were contacted at the beginning of the study only if they had not had an LDL level in the previous 12 months. A letter requesting their presentation for an LDL test was sent to their last known address along with a lab slip and a reminder to schedule an appointment with their PCP for follow-up of results. No additional contact was made with them by the study nurses.

2.8. Intervention group initial contact

Study nurses attempted to contact all intervention patients, regardless of their last cholesterol level, at their last known telephone number. If no working phone number was available a letter was sent to the patient’s last address. Those who were contacted were told that the nurse would be helping their provider manage their cholesterol level and diabetes. If they had no LDL level drawn in the past 12 months, they were asked to present for blood work. If their last LDL test was done more than 3 months from the time of contact and was > 100 mg/dL (>=70 mg/dL with CVD), they were asked to present for blood work. The nurses followed the following algorithm for initial contact:

Goal number of patient contacts per week: 8 patients per week for 2 weeks, then 10 patients per week for 2 weeks, then continue with 12 patients per week

a. Initial contact: attempt 2 phone calls per week for 3 weeks
   Attempt calls at different times of day. Mail letter if cannot contact by phone after 3 weeks. Reattempt these contacts in 6 weeks if initial attempts unsuccessful.
   b. During initial contact with a patient, explain the intervention and obtain the patient’s permission to continue contacting them.
   c. Check LDL level and date last checked for a given patient and follow appropriate algorithm.
   d. Address other areas of care as time allows in order of importance as listed on Telephone Encounter Access Report.

2.9. Data collection

2.9.1. Tracking of patients and data

The nurses collected data on a given patient in a Microsoft Access® database, and a printable version of the data was scanned into our electronic medical record (Fig. 4). The nurses
tracked patients using Microsoft Outlook®. A software interface with our registry data (Fig. 5) allowed us to prioritize patients for nurse contact according to lipid, blood pressure, or glycemic control. For instance, lists of patients were generated based on the number of days since a given lab test was performed (such as >365 days for LDL) or based on a cut-off value for that test (such as LDL>99).

3. Data sources

1. Diabetes Registry (electronic) and Encounter File (electronic)
   • Demographic data (including insurance status); laboratory data which include lipid profiles, hemoglobin A1c, serum creatinine, urinary protein/albumin/creatinine measurements, and liver function tests; blood pressure; weight; smoking status; all visits to Denver Health made by the patient which include primary care, urgent care, sub-specialty clinics, emergency department and inpatient admissions, with associated ICD-9 codes.

2. Pharmacy Database (electronic)
   • Co-pay amount for each prescription, amount and date of medications received by patient.

3. Electronic Medical Chart Review
   • Hospital admission records to adjudicate potential cardiovascular outcomes noted by ICD-9 codes.
   • Potential hospital admissions “outside” the Denver Health System.

4. Study Nurse Utilization
   • Five 1-week time studies were performed to monitor the study nurse’s actual time spent on patient care. These time studies covered the initial, middle, and end phases of the intervention. The cost analysis will report the actual hours nurses performed the intervention, which best reflects a purely clinical setting.
   • Time was divided into tasks dealing with patient care (direct phone call with patient, lab review, interaction with the provider, etc.) versus data collection responsibilities for the study.
Nurses recorded the date and length of phone calls with patients in a Microsoft Access® Database. Data will include the mean number and length (in minutes) of calls per patient, the variance, and the average intervals between calls. Nurses also documented patients that refused participation as well as those they were never able to contact.

3.1. Outcomes

The primary outcome of the trial is the proportion of patients (both with and without CVD) with an LDL less than 100 mg/dL, checked within the 12 months preceding the end of the study. In other words, if a patient’s last LDL was 65 mg/dL checked 14 months previously, they would not be at goal since it was not checked within the recommended time-frame.

Secondary outcomes include: 1) Proportion of patients with CVD with a LDL < 70 mg/dL per NCEP guidelines; 2) Absolute and percent change in LDL from baseline; 3) Percent of patients over age 40 with total cholesterol > 135 mg/dL on a statin medication per ADA guidelines; 4) Proportion of patients at blood pressure target defined as a blood pressure less than 130/80 mm Hg as recommended by the JNC-7/ADA; 5) Glycemic control through mean HgA1c and proportion with Hgb A1c < 7 mg/dL; 6) Utilization of the urgent care and the emergency department and 7) Hospitalizations; 8) Rate of adherence to medications and 9) Cardiovascular disease events.

Baseline laboratory data will be obtained from the diabetes registry preceding the date of randomization.

3.2. Power and sample size

We performed a conservative estimate assuming that the percentage of diabetic patients during the follow-up period reaching the target LDL of < 100 mg/dl will be 50% in the control (current rate) group and 70% in the intervention group. Utilizing an alpha = 0.05, power of 90%, we estimated that we needed 129 patients in each randomization group. However, to more accurately estimate the cost effectiveness of the intervention we included 381 patients for each group.

3.3. Analyses plan

For the outcome of LDL control we will initially compare success rates, or the percent of patients achieving primary
and secondary lipid goals as defined above under “Outcomes”, for patients in the usual care and intervention groups using a corrected Chi-square test. Next we will utilize logistic regression methods to assess the effects of the intervention on success rates, controlling for socio-demographic (e.g., age, race/ethnicity, gender, language concordance with provider) and clinical (e.g., baseline blood pressure, co-morbidity) covariates. Preliminary analyses of secondary outcomes will include examination of pre- and post-intervention means and rates (paired t-tests, Wilcoxon test, and McNemar test) overall and within race/ethnicity strata.

Direct medical costs will be estimated by identifying, measuring, and valuing all resource consumption attributable to the intervention and control groups from the perspective of DHMC. The utilization of health care resources (prescription drugs, labs, outpatient visits, procedures, urgent care visits, emergency room visits, and hospitalizations) will be tracked in the database for the study. The monetary cost to DHMC of each unit will be applied to the utilization data to estimate the direct medical cost per patient. A 3% discount rate will be used to ensure that all costs are expressed in 2008 $U.S., under the assumption that the cost analysis will be conducted in that year. To compare differences in per patient cost by treatment group, the Wilcoxon rank-sum test for differences in median cost will be used.

In addition, nurse time studies during the study period will be utilized to estimate the costs of performing the intervention. For example, the cost associated with allocating time and effort for an existing nurse to the intervention is estimated at his/her wage rate (salary+fringe benefits+overhead) in 2008 dollars, multiplied by the proportion of FTE allocated to the intervention. The intervention costs and primary outcome data will be used to calculate the cost per gain in lipid controlled patient.

4. Measures of a successful intervention

Our primary goal was to improve adherence to ADA lipid guidelines. It was felt to be feasible, and an indication of success, if we could increase the percentage of intervention patients with an LDL<100 mg/dL checked in the year prior to the end of the intervention from 50 (baseline rate) to 70%. This criteria is consistent with the Health Resources and Services Administration’s guidelines for Health Disparities Collaboratives [19]. An alternative measure of success looks only at those patients who had an LDL checked in the past year, and thereby excludes those patients lost to follow-up. This removes the impact of the phone outreach program on keeping patients engaged with our medical system (and checking labs, a process outcome). Using the latter methodology, our goal and measure of success was to increase the percent of patients at lipid goal from 66% (pre-study rate) to 80%.

5. Discussion

This randomized, controlled trial is important given the substantial morbidity, mortality, and health care costs linked to diabetes in the United States. Our institution served over 3700 diabetic patients in the past two years and our inpatients costs for diabetes related complications now exceeds $20 million per year. There is significant room for improvement in diabetes outcomes, both at our institution and nationwide [4]. Improving diabetes outcomes will in turn lead to better health outcomes and likely to less health care costs [2,3].

The reasons for suboptimal performance on diabetes outcomes are complex and involve the patient, the provider, the systems of health care delivery, the ability to track and assist patient populations, and societal level factors [17]. Potentially modifiable patient level factors include lack of diabetes education, resources, motivation, and the tracking of patients. At the provider level, increasing productivity demands shortens the time allotted per patient, both during and outside of the clinic visit. Time pressures often lead to inadequate assessment of patient level factors, including the patient’s understanding of their illness as well as their willingness and ability to change behaviors [18]. There is also potential for improving provider performance through ongoing education in optimal diabetes care and updated guidelines.

The purpose of this study was to determine the effectiveness of an intervention aimed at improving the system of delivery of care to our diabetic patients. Giving nurses dedicated time to help manage a panel of diabetic patients allows for more frequent contact with diabetic patients and frees up time for providers. We expect that more frequent contact with patients allows for quicker recognition of poor medication adherence and adverse effects of medicines. We believe that the use of motivational interviewing techniques and the facilitation of patient self-management helps identify and overcome barriers to care.

There are several important questions to be answered in the final analysis. Should this intervention have been more targeted, such as by only reaching out to patients not on statins with elevated cholesterol levels? This question is relevant since close to 50% of our study population meets ADA guidelines for lipid goals. A related question is whether inclusion of algorithms beyond lipid management expanded the efforts too broadly. And, is it preferable to have one nurse dedicated to phone outreach as opposed to splitting 0.75 full-time equivalents between 3 nurses?

We wrote algorithms for diabetes care which can be modified as guidelines change allowing for diabetes care based on expert panel recommendations. A key to the design of the intervention was the ability to use a software interface with the diabetic patient panel which allowed for prioritization based on lipid, glycemic, or blood pressure control. Tracking of patients and data was facilitated by Microsoft Access® as well as Microsoft Outlook®. The use of motivational interviewing techniques and the promotion of patient self-management were key components of this intervention. All of these tools are increasingly available to safety net health organizations as they participate in diabetes collaboratives. The results of this intervention will be relevant to other health centers that also serve primarily indigent populations.

Analysis of this intervention will be completed by September 2008.

References


